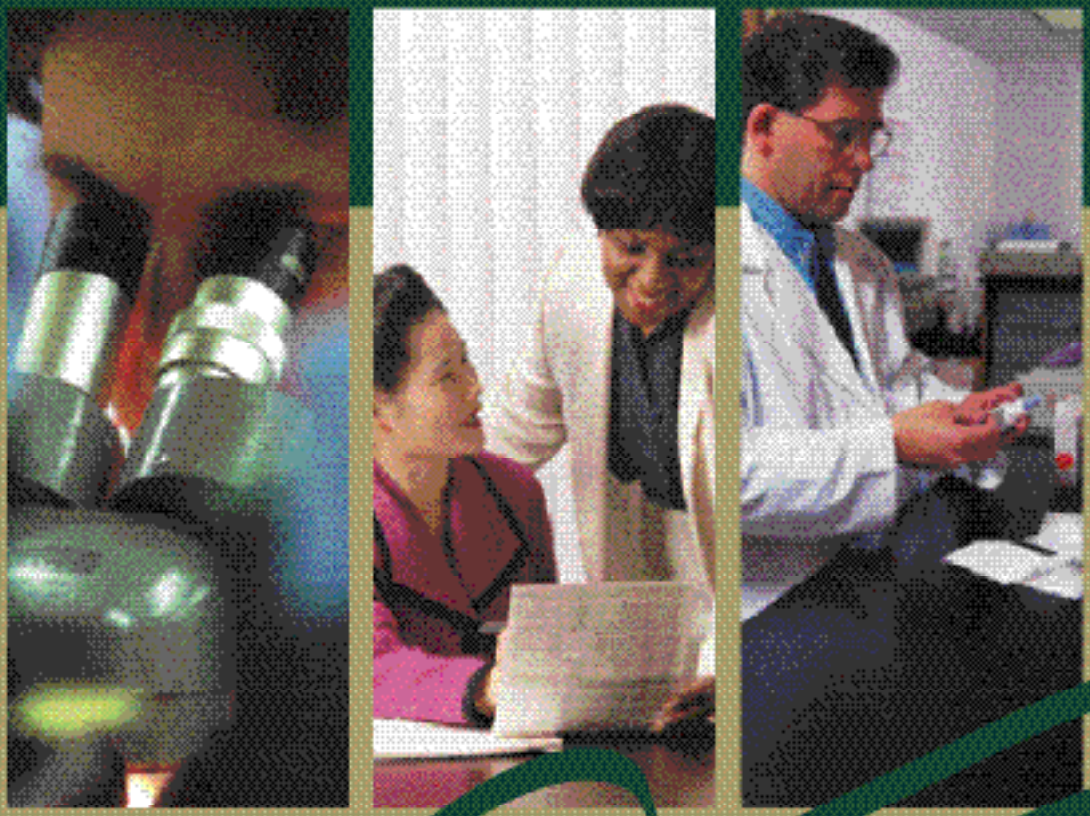
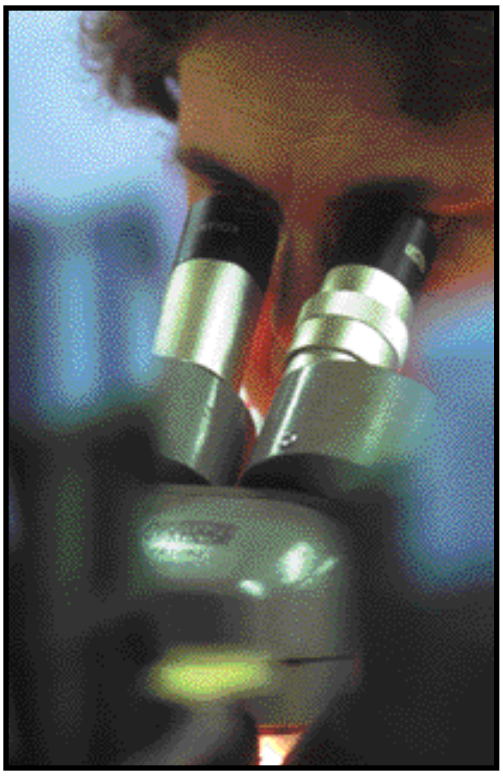
Chief Financial Officer's

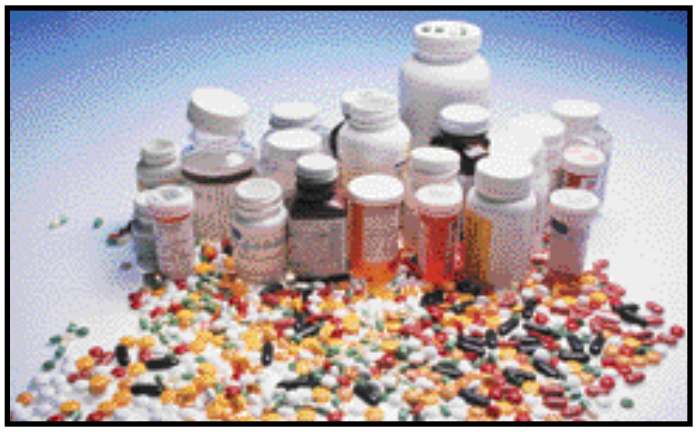


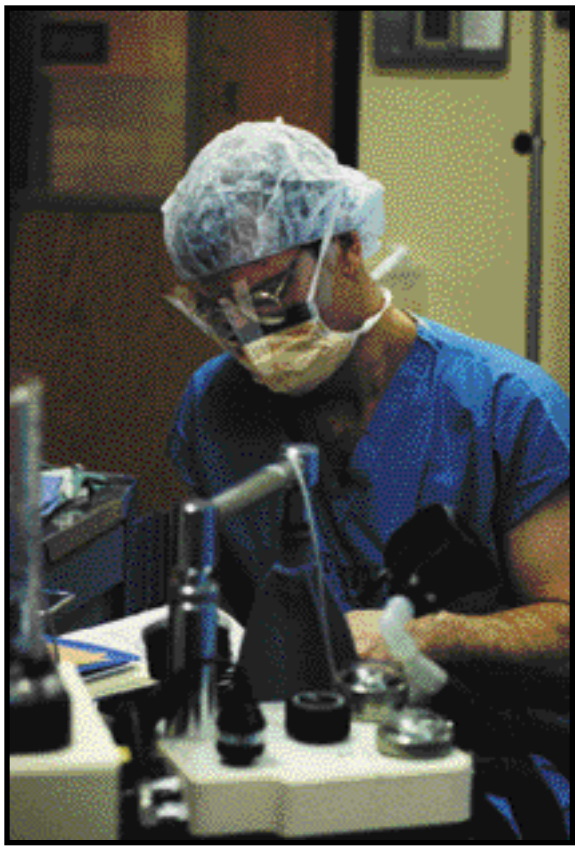
ANNUAL REPORT

FISCAL YEAR 2001

FDA
Food & Drug Administration



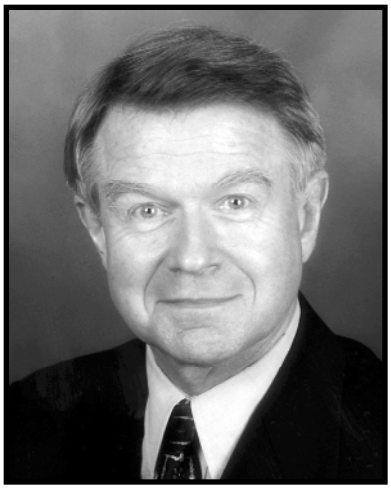




U.S. Department of Health and Human Services

Food and Drug Administration
Chief Financial Officer's Annual Report
Fiscal Year 2001

TABLE OF CONTENTS



ACTING PRINCIPAL DEPUTY COMMISSIONER'S STATEMENT

December 21, 2001

I present to you FDA's Chief Financial Officer's Annual Report for Fiscal Year 2001. I am pleased to report that the Agency has earned its fourth 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, taxpayers will realize that FDA is a good investment that yields valuable results.

Fiscal Year 2001 brought change to FDA. The DHHS Secretary, Tommy Thompson, announced a series of long-term initiatives to make the Department more efficient and effective. These initiatives support the President's Management Agenda announced during the middle of the year. The results should be an improved administrative infrastructure supporting a more responsive citizen-focused workforce.

FDA had another banner year of approving new and "breakthrough" products that will greatly benefit the American public. Gleevec, a treatment for certain types of leukemia, was approved in three months. Some other breakthrough products include a blood glucose monitor (Gluco Watch Biographer), which diabetes patients wear like a watch. Also approved was a novel device, "Camera Pill," which photographs the small intestine. A new type of mammography device was approved—digital mammography that can display high-resolution images on film or on a computer.

The most significant event for all of us occurred on September 11, 2001. Nothing could have prepared the Nation or FDA for the terrible events that happened that day and afterward. We commend the members of the Department who provided assistance to the rescuers, the victims, and their families at the World Trade Center and the Pentagon.

FDA has been taking part in the President's Initiative on Countering Bioterrorism. This initiative seeks to strengthen the infrastructure needed to address incidents of bioterrorism. This includes creating strategies for ensuring the safety of the Nation's food supply, developing new regulatory models for responding to attacks and creating a means for collaboration among Federal health agencies. By the end of the fiscal year, FDA was in the process of strengthening its crisis management and emergency preparedness capabilities.

The Reports Consolidation Act of 2000 requires that the Agency Head give an assertion on the information in this report. Thus, as acting Agency Head, I assert that the financial information in this report complete and reliable, based on data contained in FDA's financial information systems, reported in conformance with Generally Accepted Accounting Principles, and considered by the Department's Office of the Inspector General to "fairly represent" the financial condition and results of operation of the Agency.

Regarding program performance, the FY 2002 Performance Plans and Reports of HHS components will describe the means HHS programs use to verify and validate performance data and any related data issues. Where required, these reports discuss any actions planned or 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.

Bernard A. Schwetz, D.V.M., Ph.D.

BA Schwetz

MESSAGE FROM THE CHIEF FINANCIAL OFFICER

December 21, 2001

I am pleased to present to you the Food and Drug Administration's Chief Financial Officer's Annual Report for Fiscal Year (FY) 2001. The goal of this report is to inform you on our stewardship of resources and how we are achieving the Agency's mission.

This is the fourth consecutive year FDA has received an unqualified opinion on our financial statements. Moreover, this is also the fourth consecutive year that our auditors did not identify and report material weaknesses in FDA's internal controls. I look forward to the challenge of perpetuating and improving on the level of excellence exhibited by FDA in all aspects of financial management and reporting.

FDA is in the midst of change. The President announced his "Management Agenda" which is meant to transform the Executive Branch to become a more responsive and citizen-focused organization. To complement the agenda, the Department of Health and Human Services (DHHS) has embarked on several long term initiatives to more efficiently and effectively operate the department.

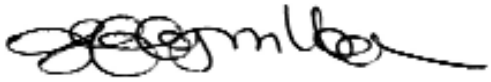
One of these initiatives, the Unified Financial Management System, is consistent with the concept of "one DHHS." The Department plans to develop two unified accounting systems at the DHHS level, rather than invest in the five existing operating division level accounting operations. FDA is making structural changes to its existing system to prepare for the implementation of the unified system beginning in FY 2003.

Working in partnership with FDA's program managers, I support the Acting Principal Deputy 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.

As a science based regulatory agency, FDA's mission affects the health and well-being of all Americans. The scope of the Agency's jurisdiction spans a regulated industry producing over $1 trillion worth of products. While the mission is daunting in peacetime, it takes a greater significance since the events of September 11. The war on terrorism has moved the Agency to a higher state of preparedness. FDA is strengthening its infra-structure and capabilities to prepare and respond to future terrorist attacks. We remain committed to protect the health of the American public through the products we regulated while striving to fulfill our expanded mission.

The FY 2001 financial statements have been prepared in accordance with all new accounting standards that were effective for FY 2001 by the Office of Management and Budget and the Federal Accounting Standards Advisory Board as evidenced by the unqualified audit opinion we received. We will continue working diligently in the future implementing all new accounting standards in a timely manner.

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 Chief Financial Officers Liaison Branch at Pkelchne@oc.fda.gov or 301-827-4792.



Jeffrey M. Weber

Management Discussion and Analysis

Introduction

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 Chief Financial Officer's Annual Report contains the management discussion and analysis, financial statements and notes, required supplementary information, and the Inspector General audit reports.

The 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 - Presents mission, strategies, organizational structure, governing laws, and resources. It highlights major events in FY 2001 and presents major challenges facing FDA in the future.

- Six FDA Programs - Provides mission description, significant accomplishments, and key performance goals and results. The six programs are: Foods, Human Drugs, Medical Devices and Radiological Health, Biologics, Animal Drugs and Feeds, and Toxicological Research.

- Financial Management and Analysis – Provides overview of FDA's Chief Financial Officer's organization; key performance measures and results; description of FDA's systems, controls and legal compliance; discussion and analysis of the principal financial statements and the state of FDA's financial condition.

The Chief Financial Officer's Annual Report for FY 2001 is available on the Office of Financial Management Web Page at:
www.fda.gov/oc/oms/ofm/accounting/ofmaccounting.htm. A "PDF" and a non-PDF version are provided.

For questions regarding the Chief Financial Officer's Annual Report for FY 2001, please contact:

Peter Kelchner
Chief, CFO Liaison Branch
Division of Accounting (HFA-120)
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Agency Overview

The FDA is a scientific regulatory agency whose mission affects the health and well-being of all Americans. FDA was established in 1927 and is responsible for overseeing a regulated industry that produces over $1 trillion of products:

- National food supply (except meat and poultry)
- Over-the-counter and prescription medications
- Blood products
- Vaccines
- Tissues for transplantation
- Medical equipment and implantable devices
- Devices that emit radiation
- Animal drugs and feeds
- Cosmetics

FDA-regulated products account for over 20 cents of every consumer dollar spent in the United States each year.

Since the events of September 11, 2001, a new role has emerged, Counter Terrorism. This will be more fully developed during FY 2002. FDA has a legislative 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. A combination of public health and law enforcement responsibilities requires agency involvement in a number of aspects of the preparedness for and response to a terrorist act. FDA's responsibilities encompass both the civilian and military sectors of the population, thus broadening the scope of the agency's antiterrorism activities.

The terrorist attacks of September 11 have resulted in an accelerated need for attention to activities related to counter terrorism. Efforts at the FDA have focused on (1) protection of regulated products (foods and animal feed, radiologic devices, blood supply, drugs, vaccines) from contamination, tampering or deleterious uses, and (2) availability of medical products (drugs, vaccines, and devices) necessary to public health preparedness for the intentional use of biological, chemical, or nuclear agents.

FDA’s activities include the development of strategies to build upon existing capacities of surveillance, investigation, and laboratory support for detection and management of cases of possible contamination, including interdiction of such products; provision of regulatory guidance to other government agencies responsible for stockpiling or developing medical products in the event of a public health emergency; and communication with manufacturers to address the issues of availability of preventive and therapeutic products that may be needed in the event of the release of a biological, chemical, or radiologic agent.

The Year In Review – Significant Events

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

FDA's Response to Counter Terrorism

As the Nation's primary overseer of medical products, services, and the national food supply, FDA is a key player in the Federal government's preparedness and response to a biological, chemical or nuclear attack. In FY 2001, FDA made noteworthy contributions to this effort, including:

Terrorist Attack on September 11, 2001

FDA issued two policy statements on the urgent collection, shipment and use of whole blood and blood components intended for transfusion to address the blood supply needs in response to the disaster situation in New York City and at the Pentagon. The first statement issued on September 11 provided flexibility to emergency personnel in the collection of blood and blood components. A revised statement was issued on September 14 to strengthen the quality assurance and system integrity for blood previously collected.

FDA's Human Drugs Program approved one "emergency" investigational new drug and expedited approvals of two manufacturing supplements to respond to needs resulting from the September 11 terror attacks. The drug products involved were topical antibiotics used to treat burns.

Individual FDA employees who are members of the Public Health Service's Commissioned Corps Readiness Force (CCRF) responded to the September 11 terrorist attacks. The CCRF provided:

- Primary and emergency medical care and mental health care to rescue workers in New York City;
- Specialized pharmacy support for the National Pharmaceutical Stockpile, commonly called "push packs";
- Data entry and forensic dentistry to help confirm identities of the dead in New York;
- Replacement medical care and pharmacy care at the National Naval Medical Center in Bethesda, Maryland; and
- Stand-by primary and emergency care for the Pentagon attack.

Terrorist Threats of Anthrax and Other Biological or Chemical Agents

The President's initiative on Countering Bioterrorism is comprised of a number of essential elements for which FDA played an integral role. One such element is the expeditious review and approval of products to diagnose, treat or prevent outbreaks from exposure to the pathogens that have been identified as bioterrorist agents.

Although the medical community's interest in these types of products increased dramatically after September 11, staff worked with organizations and vaccine manufacturers in FY 2001 to guide their products through the regulatory process, including the manufacturing process, pre-clinical testing, clinical trials, and the licensing and approval process.

Bovine Spongiform Encephalitis (BSE) Preventative Measures

BSE, commonly called "Mad Cow Disease" belongs to a group of progressive degenerative neurological diseases known as transmissible spongiform encephalopathies (TSE). TSE diseases are always fatal. There are six TSE diseases that affect humans. The exact origin of the disease is still unknown, but overwhelming evidence points to meat and bone meal containing tissues affected from infected animals as the means by which the disease is spread. If BSE was to enter the U.S., it could pose a serious health risk to humans, and be financially devastating to the United States beef industry.

The United Kingdom's 180,000 cases of BSE make up the vast majority of cases so far, and the United States did not see any cases of the disease in FY 2001. This is in large part due to the efforts of FDA. Many FDA regulated products contain bovine products, including food, animal feed, drugs, vaccines, tissues, dietary supplements, cosmetics, and medical devices. FDA and its state counterparts continued inspections of renderers, feed mills, ruminant feeders, dairy farms, protein blenders, feed haulers, and distributors in FY 2001 to ensure that BSE did not become a part of the food supply or medical products.

Human Subject Protection in Clinical Trials

FDA's efforts in the area of bioresearch monitoring of clinical trials have received greater scrutiny over the past two years as a result of several high profile cases. In FY 2000, FDA shut down clinical trials at the University of Pennsylvania after a gene therapy patient died. In FY 2001, FDA investigations brought attention to the death of a healthy research subject that died in an asthma study at Johns Hopkins University. FDA was instrumental in the DHHS decision to temporarily halt all clinical trials at Johns Hopkins in July 2001. During FY 2001, FDA improved the protection measures for patients in clinical trials by increasing inspections, publishing a regulation to bolster child protections in clinical trials, and issuing a guidance on conflict of interest for clinical investigators.

Antimicrobial Resistance

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. This antibiotic resistance, also known as antimicrobial resistance or drug resistance, is due largely to the increasing use of antibiotics in humans and/or animal feeds. In addition to working with the agriculture and medical communities in FY 2001, FDA produced or participated in the following activities:

- Published the "FDA Task Force Report on Antimicrobial Resistance" in December 2000;
- Published a risk assessment on the "Human Health Impact of Fluoroquinolone Resistant Campylobacter Associated with the Consumption of Chicken"; and
- Held a public meeting on January 22-24, 2001 – "Use of Antimicrobial Drugs in Food Animals and the Establishment of Regulatory Thresholds on Antimicrobial Resistance."

Major Developments in Drug, Biologics, Device and Radiological Products

FDA is involved in the full life cycle of human and animal drugs, medical devices, and biological and radiological products. The Agency expends significant resources on product reviews and approvals, but also must monitor the marketplace for those products that increase the risk of injury or death to patients. Significant events in FY 2001 in the premarket and postmarket review include:

- Approval of Gleevec, a drug for treatment of certain types of leukemia, in less than three months;
- Withdrawal of Baycol, a cholesterol lowering drug from the marketplace after FDA reports of adverse events;
- Approval of "The GlucoWatch Biographer," a glucose monitoring device that diabetes patients wear like a wrist watch;
- Removal of phenylpropanolamine from all drug products and requests that all drug companies discontinue marketing products containing phenylpropanolamine. This drug was widely used as a nasal decongestant (in over-the-counter and prescription drug products) and for weight control (in over-the-counter drug products); and

Developments in the Areas of Food Safety and Dietary Supplements

In FY 2001, the FDA continued to be actively involved in the protection of the food supply. The Agency prompted numerous warnings and recalls associated with potentially hazardous foods and dietary supplements. Additionally, FDA was involved in the following types of activities:

- Issued a health alert suggesting that pregnant women and women of childbearing age avoid four species of fish--swordfish, king mackerel, shark and tilefish--because of potential methylmercury contamination;
- Distributed a senior citizen food safety video and 25 publications as a package to 800 offices of the Administration on Aging; 10,000 senior day care centers; FDA field public affairs specialists; and all county and state Extension service offices;
- Approved five food additive petitions intended to decrease the incidence of foodborne illnesses through their antimicrobial actions against human pathogens that may be present in food;
- Collected 236 samples of foods made from corn products or corn meal and tested them for the presence of StarLink corn, a bioengineered ingredient. Six products were found to contain StarLink corn. All products remaining on the market with positive findings were recalled; and
- Published regulations on egg safety and juice safety.

Mission and Strategic Direction

Ninety-five years ago, the first Federal Food and Drug Act was passed in 1906, and FDA's predecessor organization, the Bureau of Chemistry in the Department of Agriculture, administered the Act -- protecting the public health by ensuring the safety of food and drug products.

The FDA mission of protecting the public health was expanded with the passage of the FDA Modernization Act (FDAMA) of 1997 to include health promotion and collaborative function. The Act emphasized the prompt review of clinical research and related regulated products, engaging FDA various stakeholders, and harmonizing regulatory requirements among global regulators. The extent of FDA's regulatory responsibilities is seen in Figure 1 on following page.

Figure 1

Extent of FDA's Regulatory Jurisdiction

- FDA's responsibilities are far reaching: It is FDA's job to see that the food we eat is safe and wholesome, that the cosmetics we use will not harm us, and that medicines, medical devices, and radiation-emitting consumer products such as microwave ovens are safe and effective.
- FDA monitors over 20 percent of the Nation's consumer expenditures: Authorized by Congress to enforce the Federal Food, Drug, and Cosmetic Act and several other public health laws, the Agency monitors the manufacture, import, transport, storage, and sale of $1 trillion worth of goods annually, at a cost to the Public of a penny per day per person.
- FDA judges the safety of an expanding scientific revolution: Public and private entities invest an estimated $50 billion in biomedical research and technology each year on products that the Agency regulates – and FDA is the gateway to ensuring that the fruits of that cutting-edge research and technology are safe when they reach the market.
- FDA helps assure the safety of the products it regulates by overseeing their manufacturing and processing. FDA is a 9,000 person agency, but is responsible for monitoring over 100,000 U.S. firms that manufacture or process products.
- FDA also watches the safety of imported products: FDA tracks over 7 million import shipments that enter this country each year, and prevent violative products from reaching the U.S. consumer.

To achieve the expanded mission, in FY 2000, Agency leadership established two strategic goals: (1) bringing new products to the market place and (2) reducing the risk of marketed products. These strategic goals were characterized as premarket and postmarket. Since FDA's Results Act Plan[1] is organized by its budget-line programs: Foods, Human Drugs, Biologics, Medical Devices and Radiological Health, Animal Drugs and Feeds, and Toxicological Research,[2] five of the six programs with the exception of Toxicological Research, created their own premarket and postmarket strategic goals with corresponding annual performance goals.

[1]The Statement of Net Cost found on Page II-2 is also organized by budget line programs.

[2]The Tobacco Program is still shown on the Statement of Net Cost because appropriated funding is still being expended. The Tobacco Program was terminated by the FDA after the U.S. Supreme Court declared in March 21, 2000 that FDA lacked the authority to issue and enforce tobacco regulations. For purposes of the FY 2001 CFO's Annual Report, FDA Centers which are responsible for the six programs submitted their key performance goals for inclusion into the CFO report. A complete description of the results may be obtained in the FY 2001 Performance Report.

In FY 2001, FDA leadership modified their strategic thinking by adopting a new paradigm. This model focused on the life cycle of regulated products and the public health outcomes that result from FDA work. This new approach allowed FDA programs to reach the fullest extent of the reforms envisioned by FDAMA. Under FDAMA, Congress envisioned a transparent regulatory process and a new collaborative role for FDA and the regulated industry.

FDA leadership identified outcomes (which are elaborated in the FY 2001 Revised Performance Plan[3]) that would improve the health and safety of the American public. Some of the benefits include:

- A safe food supply;
- Rapid and safe access to the latest medical technologies;
- Safe blood and tissue-based products;
- An industry that manufactures and markets products under "world class" standards;
- Reduced deaths and injuries resulting from errors in the prescribing and use of medical products; and
- Protection of individual volunteers from harm during clinical research studies.

These outcomes provide a safety net for the American public that span the life cycle of FDA's regulated products from initial research through ultimate consumption.

To ensure successful public health outcomes, FDA leadership continued to encourage FDA programs to engage their stakeholders in formulating ways to accomplish the Agency's mission. FDA programs have been involved in various collaborations and initiatives. Some of these, as described in the FY 2001 Performance Report, are provided below:

- Collaborative Institutes – FDA and University of Maryland established the Joint Institute for Food Safety and Nutrition;

- Risk Management Communication and Education – FDA partnered with the National Association of Chain Drugstores and 80 national organizations to distribute millions of copies of the brochure, "My Medicines," to women to educate themselves and their families about using medicines wisely;

- Targeted Collaboration on Critical Health Issues -- FDA along with the National Institutes of Health, Centers for Disease Control and Prevention (CDC), American Red Cross, American Association of Blood Banks, and state agencies participate in setting standards and developing health education;

[3]Source: The FY 2001 Revised Final Performance Plan is available on FDA's web-site at: www.fda.gov/ope/fy02plan/default.htm.

- Shared Surveillance Networks – FDA partnered with CDC and the U.S. Department of Agriculture to develop the National Antimicrobial Resistance Monitoring System. This system helps to detect whether foodborne pathogens are developing resistance to drug treatment;
- Cooperative International Standard Setting – FDA participated in the International Committee for Harmonization, International Standards Organization, Codex Alimentarius, and the World Health Organization to ensure that U.S. interests are upheld in establishing standards for products under the Agency's regulatory purview; and
- Third Party Review, Inspection, or Testing – FDA contracts with state agencies to per form the mammography facilities inspections.

Organizational Structure

FDA is organized into eight major components consisting of the Office of the Commissioner, the Office of Regulatory Affairs (which is responsible for the FDA field force), and the following six Centers as displayed in Figure 2 below:

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

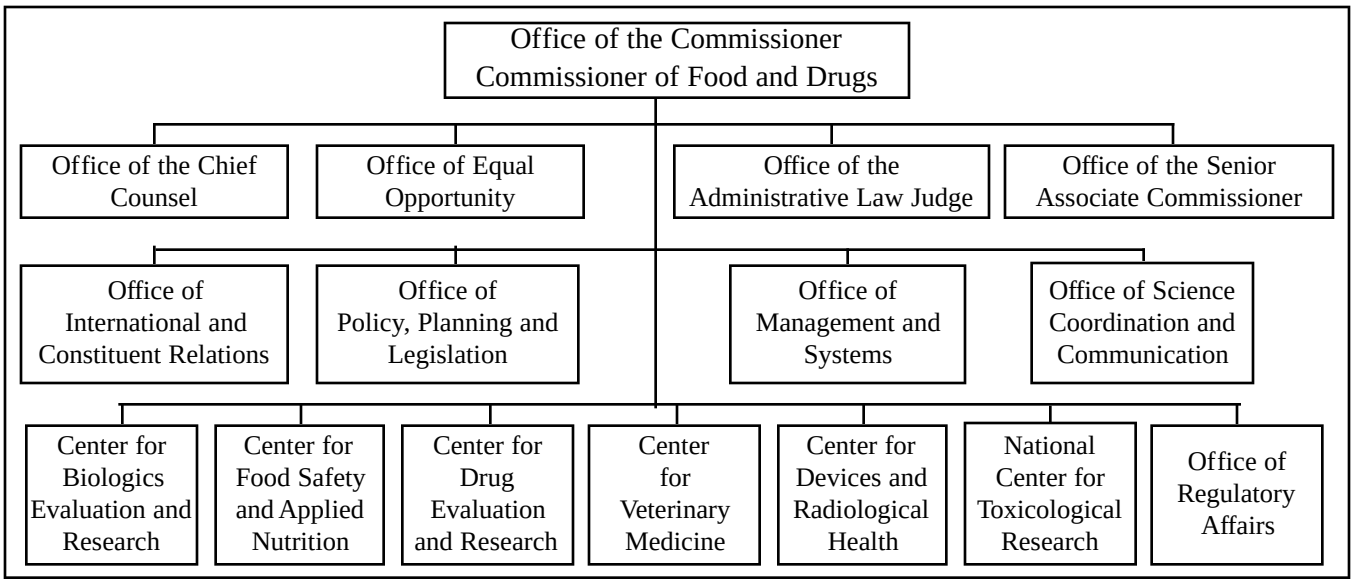


Figure 2

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.

During FY 2001, the Office of the Commissioner created the Office of Human Research Trials within the Office of Science Coordination and Communication to strengthen the oversight of the human subject protection. This office serves as the FDA focal point for overall management of FDA activities related to human subject protection and Good Clinical Practice priorities, resources, and leveraging activities.

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 in support of the product centers. With the exception of NCTR, located in Jefferson, Arkansas, the Office of the Commissioner, the Centers, and the Office of Regulatory Affairs (ORA) are headquartered within the Washington, DC metropolitan area.

The Centers administered the Programs that are described in six individual chapters contained in this CFO's Annual Report. Five of the six programs receive substantial support from the ORA's field organization.

The Office of Regulatory Affairs

This component is composed of a headquarters unit and a nationwide field force. ORA has approximately 3,150 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, 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
- Perform outreach to consumer groups, health professionals, states and industry to encourage compliance and safe use of FDA-regulated products.

ORA, through its field force provides a support role to the foods, human drugs, devices, biologics, animal drugs and feeds programs. In particular, the field supports the programs' premarket activities by conducting pre-approval inspections and laboratory method validations when requested by program managers responsible for premarket application decisions. These inspections, which can be either foreign or domestic establishments, include bioresearch monitoring inspections of clinical research that is part of premarket applications. Other premarket inspections are conducted in manufacturing facilities to determine if the facility is able to manufacture the product to the specifications stated in the application. Inspections are generally performed by consumer safety officers who may be accompanied by a laboratory analyst if review of manufacturing information in the application suggests that additional laboratory expertise is appropriate to assess the facility. Laboratory method validations are conducted to confirm that the methods described in the premarket application work as described in FDA laboratories.

Field investigators and laboratory analysts also conduct foreign inspections for both premarket approval and postmarket compliance purposes. Center managers select most establishments for inspection. Postmarket foreign inspections in drugs, biologic, animal drugs, and device 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. While Congress mandated that domestic manufacturers be inspected every two years, foreign manufacturers are not included in this requirement. Beginning in FY 1999, the Foods Program, which has historically supported fewer than 100 foreign inspections, began to expand foreign inspections. About 250 foods foreign inspections were planned for FY 2001.

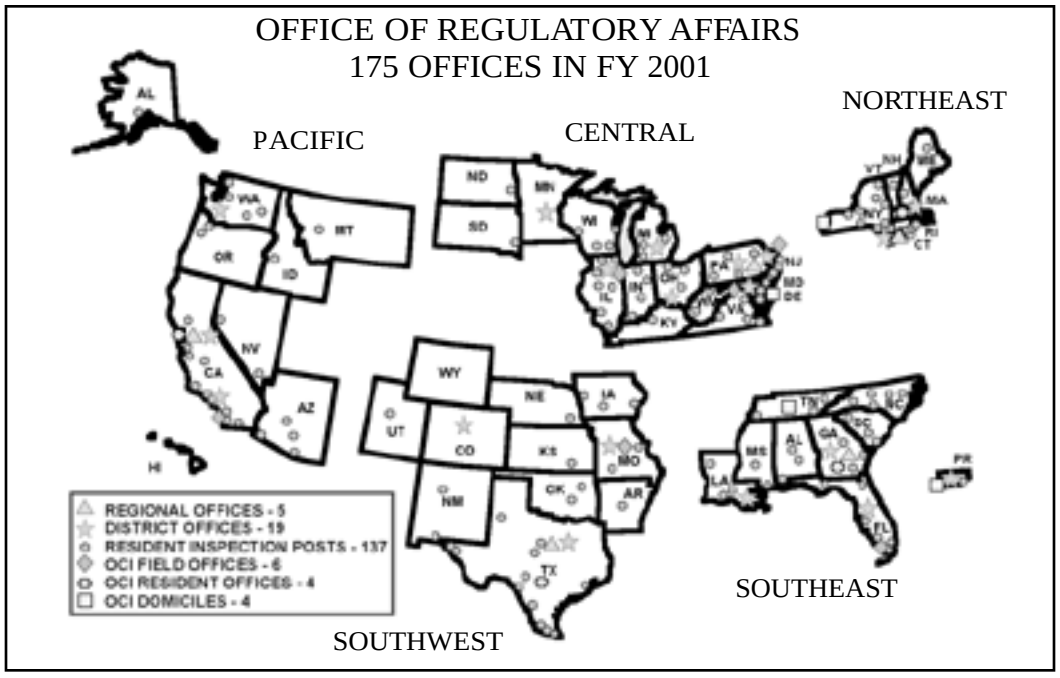
In addition to conducting regular surveillance over regulated products, the field workforce also serves a critical function when the Agency must respond to emergencies by immediately mobilizing to investigate reports of product problems including tampering incidents and those due to natural disasters such as hurricanes, floods, and earthquakes. The field workforce is also involved in informing businesses and consumers about FDA-related topics, and in working with state and local agencies to develop programs that make the best use of Federal, State, and local resources in protecting the public health.

Field facilities include Regional Offices, District Offices, laboratories, the Office of Criminal Investigations (OCI) field offices, and resident posts. The five Regional Offices are staff offices which coordinate FDA activities and also coordinate with state authorities. The 19 District Offices serve as offices for investigators and compliance action staff, and are the main control point for day-to-day operations in their assigned areas. The 13

laboratories provide FDA's basic field product testing capability. A number of these laboratories serve as specialized facilities for certain types of testing and new regulatory methods development.

FDA also maintains over 137 resident posts distributed widely across the country. These are smaller offices which serve primarily as a base for investigators. FDA can have investigative staff widely dispersed to respond to emergencies whenever they occur, as quickly as possible to minimize any potential harm. Together, FDA maintains offices and staff in 49 states, and in the District of Columbia and Puerto Rico. See Figure 3 for a map of ORA's field locations.

Figure 3



Governing Laws and Regulations [4]

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 (e.g., X-rays devices, lasers, microwave ovens, and televisions).

[4] 21 CFR Part 1 - 1299 interpret these and other laws and provides explanation on Agency's requirements.

- 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 total FDA resource level for FY 2001 was $1.466 billion.[5] This number includes: appropriations for salaries and expenses (S&E), building and facilities (B&F), user fees; offsetting collections (reimbursables); carry-over balances from prior years; and adjustments. For a complete analysis of FDA's resources in FY 2001, please read the Financial Analysis section in the Financial Management and Analysis Chapter on Page I-86.

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.

Biological, Chemical, and Nuclear 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 in October and November of 2001 demonstrated the need for the Nation to be better prepared in responding to similar events in the future. FDA managers and scientists must develop plans to expedite product reviews of this nature. Also, FDA's field staff is challenged by the task of defending the food supply against possible attacks.

The Safety of the Food Supply – FDA regulates 80 percent of all food consumed in the United States. FDA is responsible for ensuring the safety of the food supply, including imported foods and foods produced in the U.S. by minimizing contamination of food by pathogens, unlawful animal drug and pesticide residues and environmental contaminants. The task of ensuring safety has become more difficult because the nature of food and foodborne illness has changed significantly. In addition, the amount of food imported into the country has grown in exponentially in the last ten years. For example, foods are more technologically complex; the number of foodborne pathogens has increased five-fold in the last 50 years; consumers are eating more seafood, fresh produce, imported produce and other foods, and "convenience" ready-to-eat foods; and our vulnerable populations, including senior citizens, have increased.

[5] Source: The amount is from the FY 2001 Combined Statement of Budgetary Resources.

Prevent Outbreak of Bovine Spongiform Encephalopathy (BSE) -- FDA must assure full compliance with the BSE regulation through inspection and compliance actions. In addition, FDA must also consider areas not covered by the U.S. Department of Agriculture's ban such as: 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; 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 multiple 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 will have a dramatic effect on the economics of the food and agriculture community.

New Product Reviews -- Rigorous and punctual review of new product applications and post-market inspections, are the back-bone of FDA's system of public health protections. But FDA has been unable to completely fulfill its mandated responsibilities and public expectations in these two areas.

Human Subject Protections in Clinical Trials -- A large gap exists between FDA's current clinical research monitoring capability and the level of monitoring that is necessary to assure that volunteers in these studies are being protected.

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 into commerce. Public safety and confidence could be jeopardized by a failure to increase surveillance activities. Products may enter the U.S. through one of approximately 300 U.S. Customs ports located throughout the country. The growth of international trade has lead to a tripling of imports during past ten years. While the FDA continues to undertake activities to improve the safety of imported products, there is often no substitute for physically examining these products. FDA is monitoring regulated products in an environment that has become significantly more complex over the past several years.

The President's Management Plan -- In FY 2001, FDA developed its response to the President's Management Plan. Executing this plan is a long range, multi-year effort. This plan is aligned with the goals of making government more citizen-centered and results oriented. To reach these goals, FDA intends to: streamline the organization by consolidating common functions; respond more rapidly and comprehensively to citizens' needs; make greater use of the Internet; increase outsourced activities; and improve accountability for results. The Agency's actions will result in various degrees of challenge as these types of changes often produce resistance to change. In the end, FDA expects to increase efficiencies in delivering services to the American Public.

In addition to the response, FDA is also participating with other operating divisions of DHHS in the development of the Unified Financial Management System. When implemented, it will provide cost-based financial information to program and financial managers and facilitate the myriad of financial reporting requirements.

The Office of Inspector General's Top Management Challenges in DHHS -- At the end of FY 2001, the Office of Inspector General (OIG) identified two management challenges affecting FDA: bioterrorism and protection of critical infrastructure. OIG has assessed the security controls at laboratories of the FDA and other operating divisions. OIG also plans to work with FDA to improve security of the Nation's food supply. FDA is conducting security reviews of FDA laboratories and offices. Appropriate action will be taken when warranted.

The protection of critical infrastructure is in response to a Presidential Decision Directive 63 and to the Government Information Security Reform Act. The Federal Government is mandated to assess and report on the vulnerability of controls in place to protect assets critical to the Nation's well being. OIG has assessed the information systems controls as part of its evaluation on how well DHHS has implemented the directive and statute. OIG found information systems general controls weaknesses in entity-wide security, access control, service continuity, and segregation of duties. FDA is continuing its ongoing efforts to ensure the Agency has a reliable and secure information technology environment.

Discussion on 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 has a data verification and validation section by which they discussed how they

provide reasonable assurance that the performance data contained in their systems are relevant and reliable. For further information, please see the FY 2001 Performance Report.

Net Program Costs

For the FY 2001 CFO's Annual Report, we will continue to use net program costs displayed in a three year period. This information comes from the Statements of Net Cost found in the section on financial statements.

Net program costs are defined as the total expenses for a program, including the allocation of indirect expenses (i.e., administrative, field operations, rent, and other overhead), less exchange revenue.

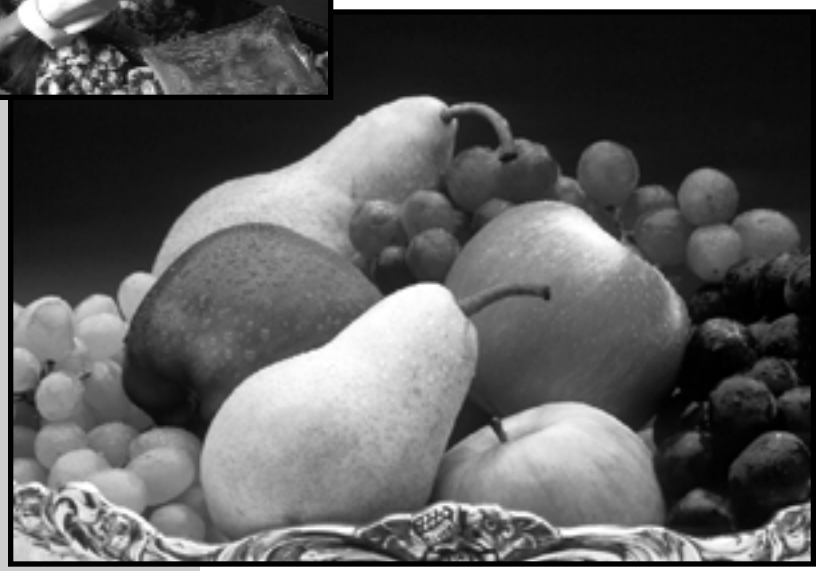
Under the Government Management Reform Act of 1994, Executive Branch agencies are required to determine the full cost of their operations. The Government Performance and Results Act directs Executive Branch agencies to define their mission and set strategic and annual performance goals. The aligning of full cost with performance objectives and results provides a clearer picture on the true cost of program performance. FDA wishes to take a first step in displaying net program costs in the context of a program's performance.

The Statements of Net Cost have been prepared in conformity with generally accepted accounting principles (GAAP) and the form and content for entity financial statements specified by the OMB. 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, 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.

FDA Programs

Foods Program



Foods Program

Background

The Foods Program, administered by the Center for Food Safety and Applied Nutrition (CFSAN) and supported by the Office of Regulatory Affairs[6] (ORA), is responsible for ensuring that the nation's food supply is safe, nutritious, wholesome, and honestly labeled and that cosmetics are safe and properly labeled.

The Foods Program accomplishes its mission by:

- setting standards and developing regulations for the food industry;
- taking timely and appropriate action on new food ingredients and dietary supplements before they go on the market to ensure their safety and effectiveness;
- conducting research to provide the necessary basis for its regulatory decisions;
- assuring the safety of foods, food ingredients, dietary supplements and cosmetics that are available on the market;
- identifying food-related health hazards; and
- taking corrective action to reduce human exposure to these hazards and the possibility of food-related illnesses and injuries; and expanding food safety education and training for consumers and industry.

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 [7]

Fiscal Year	Net Program Cost (000s)
2001	$390,085
2000	$364,914
1999	$320,432

The Foods Program has experienced a 6.9 percent increase in net costs since FY 2000.

[6] For a fuller discussion on the support provided by ORA to the Programs, see pages I-12 – I-14.

[7] Source: Statements of Net Costs for FYs 1999, 2000 and 2001. The source for the remaining programs' cost tables is the Statements of Net Costs for the three fiscal years.

This increase is attributed to the continued implementation of the Food Safety Initiative,

increases for dietary supplements, and the relocation of the CFSAN to College Park, Maryland. The net cost includes the total expenses for a program, including the allocation of overhead expenses (such as the Office of the Commissioner's costs [e.g., administrative and policy direction], ORA's field operations' costs, rent, and other overhead), less exchange of revenue.

Selected Initiatives, Goals, and Accomplishments

Food Allergens

As one of the program priorities for FY 2001, CFSAN worked to improve the regulatory guidance involving food allergens. Food allergens are substances in foods that may cause an allergic state or reaction. CFSAN partnered with ORA to perform various activities.

In April 2001, ORA published a Federal Register notice announcing the availability of the FDA's Compliance Policy Guide (CPG) on Allergens, entitled "Statement of Policy for Labeling and Preventing Cross-contact of Common Food Allergens." The Allergen CPG is available on the Internet at:
http://www.fda.gov/ora/compliance_ref/cpg/cpgfod/cpg555-250.htm.

CFSAN conducted in May 2001 food allergen training for field food regulators located at the Seattle, Philadelphia, and Cincinnati district offices.

The Center issued a field allergen inspection guide in August 2001 to assist field investigators in assessing conditions that can cause foods to contact allergens. A copy of this document is available at:
http://www.fda.gov/ora/inspect_ref/igs/Allergy_Inspection_Guide.htm.

Finally, CFSAN held a public meeting in August 2001. The meeting entitled, "Food Safety and Food Labeling: Presence and Labeling of Allergens," was held to discuss the labeling of foods containing allergens and the inadvertent addition of allergens to foods due to processing practices.

Egg Safety

On December 5, 2000, FDA published a final rule in the Federal Register (65 FR 76092) entitled, "Food Labeling, Safe Handling Statements, Labeling of Shell Eggs; Refrigeration of Shell Eggs Held for Retail Distribution." The final rule requires shell eggs to carry safe handling statements and refrigeration requirements for retail establishments such as grocery stores, nursing homes, and restaurants.

In July 2001, CFSAN issued a small entity compliance guide for industry entitled, "Food

Labeling: Safe Handling Statements, Labeling of Shell Eggs; Refrigeration of Shell Eggs Held for Retail Distribution." This guidance document restated in plain language the legal requirements set forth in the current regulations for the safe handling statement on labels of shell eggs and the refrigeration of shell eggs held at retail establishments.

Juice Hazard Analysis and Critical Control Point (HACCP)

FDA has taken substantial steps in the last two years toward improving the safety of fresh and processed fruit and vegetable juices by requiring domestic and foreign processors of packaged juices to equip their plants for prevention of microbiological, chemical, and physical contamination of their products. Specifically, the final rule entitled, "Hazard Analysis and Critical Control Point (HACCP); Procedures for the Safe and Sanitary Processing and Importing of Juice" requires juice processors must use HACCP principles to increase protection of consumers from illness-causing microbes and other hazards in juices. HACCP systems are already federally required for seafood, meat, and poultry processors.

It is estimated that each year, the rule will help prevent at least 6,000 juice-related food-borne illnesses, which have been on the rise in recent years. A 1996 E. coli 0157:H7 outbreak associated with apple juice products sickened 70 people, including a child who died as a result. A Salmonella Enteritidis outbreak in 2000 caused by unpasteurized orange juice sickened 88 persons, and a Salmonella Muenchen outbreak in 1999 caused by unpasteurized orange juice caused 423 illnesses and one death.

Foods Developed Through Biotechnology

During FY 2001, FDA issued a proposal rule (66 FR 4706; January 18, 2001) and a draft guidance document (66 FR 4839; January 18, 2001) concerning food developed through biotechnology.

The proposed rule would require food developers to notify FDA at least 120 days in advance of their intent to market a food or animal feed developed through biotechnology and to provide information to demonstrate that the product is as safe as its conventional counterpart. FDA is also proposing to increase the transparency of the Agency's review process for such foods. Currently, developers of food and feed developed through biotechnology participate in a voluntary consultation program with FDA. To date, all such food and feed marketed in the U.S. have gone through the consultation program before they have entered the market. Although this voluntary consultation process has worked well since its inception in 1994, a series of FDA-sponsored public meetings and subsequent written public comments indicated considerable public support for a mandatory pre-market consultation for bioengineered foods and feeds. This proposed rule can be accessed at: www.accessdata.fda.gov/scripts/oc/ohrms/index.cfm.

FDA also issued a draft guidance document, which if finalized, would provide direction to manufacturers who wish to label their food products as being made with or without ingredients developed through biotechnology. This guidance will aid manufacturers in ensuring that their labeling is truthful and not misleading. The FDA views the terms, "derived through biotechnology" and "bioengineered", as acceptable. Examples of terms that are not acceptable are "GM free", "GMO", and "modified."

Performance Plan Goals

The Foods Program's premarket performance goal is based on a cohort concept. A receipt cohort is defined as the group of applications received by the Agency during a particular fiscal year. For the FY 2000 receipt cohort, performance can be fully measured only 360 days after receipt of the last petition received during the fiscal year. Because of this time delay, we are reporting performance on the FY 2000 receipt cohort because the FY 2001 results are not yet available.

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 states how FDA would provide the U.S. public with quicker access to new food ingredients and dietary supplements and make timely decisions on new food and color additive petitions.

Performance Goal

Complete the first action on 40 percent of food and color additive petitions within 360 days of receipt.

Results

CFSAN reported it had met its goal for FY 2000. It had a rate of 91 percent for completing first action on those food and color additive petitions received during the period. A first action is defined as receipt of a request to withdraw a petition, or a review of all parts of a petition, followed by issuance of a "not approvable" letter or publication of a response in the Federal Register, if appropriate.

In further describing its performance, CFSAN divided its food additive petitions into two

classes: expedited and non-expedited. The Center has announced that it will expedite the review of petitions for food additives whose aim is to reduce the levels of food-borne pathogens. For the FY 2000 receipt cohorts, CFSAN achieved its goal for those petitions qualifying for expedited review and those that did not:

- Ten food additive petitions that qualified for expedited review were filed. CFSAN completed the safety evaluation in less than 360 days of filing for nine of the 10 petitions.
- Twenty-two food and color additive petitions that did not qualify for expedited review were filed. The safety evaluation was completed, or the petition was withdrawn, in less than 360 days of filing for 20 of the 22 petitions.

One of the factors affecting performance on review of food and color additive petitions was the implementation of the food contact substance notification program that was established by the FDA Modernization Act. The intent of the notification program is to provide an alternative to the traditional petition review process. Several of the petitions included in the receipt cohort of FY 2000 were withdrawn and converted to notifications, accounting in part for the performance far in excess of the goal for that year. In future years, it is envisioned that many of the simpler food additive petitions that could have been completed within 360 days will be filed under the notification program, thus decreasing the workload. With the remaining petitions likely being complex and taking more time in review, performance on the goal may decline initially. Once the notification review process becomes well established, CFSAN expects performance on this goal to increase substantially toward full performance.

During FY 2000, 109 notifications for food contact substances were received, including petitions for food contact substances that were converted to notifications. CFSAN completed review of all of the notifications within the statutory time frame of 120 days.

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.

High-risk domestic food establishments include those involved in the manufacture of low acid canned food (LACF) 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 [8]

Increase the percentage of high-risk domestic food establishments inspected once every year. The goal for FY 2000 is 90 – 100 percent once every one to two years.

Result

CFSAN reported that the performance measure was achieved in FY 2000. It had realized a rate of 91 percent of high-risk domestic food establishments inspected.

The existing Field Data Systems currently do not differentiate between low-, medium-, and high-risk domestic food establishments. The Agency has defined high-risk establishments as those producing foods with the greatest risk for microbial contamination and those foods requiring specific components for a safe and nutritious product. Foods following under this definition were infant formula, medical foods, scrombotoxic seafood, molluscan shellfish, low acid canned and acidified foods, ready to eat foods such as processed fresh fruits and vegetables, bakery goods (with filling), soft and soft ripened cheeses, cooked pasta dishes, prepared salads and heat and serve products. Based on this definition, the Agency estimates that there are approximately 7,000 such establishments in its establishment inventory.

[8] Because FY 2001 data is not currently available, we are using FY 2000 data.

Consumer Advisory, March 2001 from Center for Food Safety and Applied Nutrition, FDA

AN IMPORTANT MESSAGE FOR PREGNANT WOMEN AND WOMEN OF CHILDBEARING AGE WHO MAY BECOME PREGNANT ABOUT THE RISKS OF MERCURY IN FISH

Seafood can be an important part of a balanced diet for pregnant women. It is a good source of high quality protein and other nutrients and is low in fat.

However, some fish contain high levels of a form of mercury called methylmercury that can harm an unborn child's developing nervous system if eaten regularly. By being informed about methylmercury and knowing the kinds of fish that are safe to eat, you can prevent any harm to your unborn child and still enjoy the health benefits of eating seafood.

HOW DOES MERCURY GETS INTO FISH?

Mercury occurs naturally in the environment and it can also be released into the air through industrial pollution. Mercury falls from the air and can get into surface water, accumulating in streams and oceans. Bacteria in the water cause chemical changes that transform mercury into methylmercury that can be toxic. Fish absorb methylmercury from water as they feed on aquatic organisms.

HOW CAN I AVOID LEVELS OF MERCURY THAT COULD HARM MY UNBORN CHILD?

Nearly all fish contain trace amounts of methylmercury, which are not harmful to humans. However, long-lived, larger fish that feed on other fish accumulate the highest levels of methylmercury and pose the greatest risk to people who eat them regularly. You can protect your unborn child by not eating these large fish that can contain high levels of methylmercury:

- Shark
- Swordfish
- King mackerel
- Tilefish

While it is true that the primary danger from methylmercury in fish is to the developing nervous system of the unborn child, it is prudent for nursing mothers and young children not to eat these fish as well.

FDA Programs

Human Drugs

Human Drugs Program

Background

The Human Drugs Program, administered by the Center for Drug Evaluation and Research (CDER) and supported by ORA, is responsible for ensuring that all drug products used for the prevention, diagnosis, and treatment of human disease are safe and effective, and that information on proper use is available to all users. To achieve this mandate, premarket review, postmarket surveillance, education, research, and other strategies are employed and periodically assessed. The program's specific responsibilities include:

- regulating the testing of investigational new drugs (INDs);
- evaluating new drug applications (NDAs) and abbreviated new drug applications (ANDAs) for generic drugs;
- monitoring the quality of products manufactured in, or imported into, the U.S.;
- collecting and evaluating information on adverse effects experienced with marketed products;
- regulating the advertising and promotion of prescription drugs;
- establishing and monitoring standards for use, labeling, and composition of both prescription and over-the-counter drugs;
- disseminating timely and accurate product information to the medical community and the public;
- identifying drugs that have potential for abuse and making recommendations to the U.S. Department of Justice's Drug Enforcement Administration for drug classification and control;
- encouraging the development of new drugs; and
- enhancing DHHS' readiness against any terrorist act to assure public health safety.

Cost

Fiscal Year	Net Program Cost (000s)
2001	$255,316
2000	$251,243
1999	$223,855

The Human Drugs Program experienced a 1.6 percent increase in net costs in FY 2001. This increase may be attributed to funding for premarket review, for CDER's Office of Generic Drugs to reduce generic drug application review and improve approval times, for improvements to the Agency's current system of post-market surveillance to identify adverse events, and for enforcement of Internet drug sales. The net cost includes the total

expenses for a program, including the allocation of overhead expenses (such as the Office of the Commissioner's costs [e.g., administrative and policy direction], ORA's field operations' costs, rent, and other overhead), less exchange of revenue.

Selected Initiatives, Goals, and Accomplishments

Patient Safety Initiative

With the 1999 release of the Institute of Medicine (IOM) report on medical errors, much attention has been focused on what FDA can do to assess the magnitude of the contribution of pharmaceuticals, manage the risk from drugs, and minimize the potential for these products to result in patient injury. During FY 2001, CDER conducted various activities to support its patient safety initiative. Some of these examples include:

- CDER has participated in the Patient Safety Task Force that was established within the DHHS to integrate medical error data collection efforts, coordinate research and analysis efforts, and to develop strategies to implement patient safety programs.
- CDER proposed a new prescription drug labeling rule that will help reduce medical errors. The proposed new labeling is expected to reduce practitioners' time spent looking for information, decrease the number of preventable medical errors, and improve treatment effectiveness. The information will be easier to find, read, and use, and it should also enhance the safe and effective use of prescription drugs and reduce medical errors caused by inadequate communication.
- CDER, along with FDA's Office of Facilities, Acquisitions and Central Services, awarded three new three-year contracts that will permit access to drug utilization data from pediatric inpatient, general inpatient, and general longitudinal databases. These research resources are part of CDER's initiative to expand postmarketing drug surveillance. The ability of the Center to respond expeditiously to the increasing number of postmarketing issues is of paramount importance to the Agency and overall public safety. Access to these types of databases will increase the capabilities for pharmacoepidemiology surveillance and regulatory impact studies. The addition of these databases will also supplement and enhance the passive reporting systems currently in place.
- CDER developed a new subcommittee to the Advisory Committee for Pharmaceutical Science, the Drug Safety and Risk Management Subcommittee. It is intended to focus on issues involving drug safety, risk management, risk communication, medication errors, and patient safety. These issues play a significant role in CDER's overall evaluation of the risk/benefit of drugs, and are common topics of discussion at advisory committee meetings. This subcommittee will have the benefit of having its members work together as a group, learning the regulatory process and perspective,

and applying what has been learned at one meeting to the next.

- CDER also co-sponsored the nation's first certificate program with Temple University's School of Pharmacy and the Institute for Safe Medication Practices on medication safety as part of Temple's Doctor of Pharmacy program. The Temple Pharmacy 12-credit educational track will include coursework in pharmaco-epidemiology, risk management, medication error prevention, safe medical product design, and adverse drug reaction recognition, surveillance, and prevention.

- CDER created a Medication Errors Homepage on its Internet site (http://www.fda.gov/cder/drug/MedErrors/default.htm). It includes information on drug products associated with medication errors, medication error reports and articles, Federal regulations and guidances, how to report a medication error, and other resources. The Office of Postmarketing Drug Risk Assessment developed an agreement with Medical Economics to publish quarterly information on medication errors in their Drug Topics journal.

Pediatric Initiatives - Pediatric Exclusivity and the Pediatric Rule

Significant progress was made in pediatrics as a result of CDER's two major pediatric activities: FDAMA Section 111 and the final Pediatric Rule.

Section 111 authorizes FDA to grant six months of marketing exclusivity if a sponsor conducts and submits pediatric studies responsive to a Written Request. Under the exclusivity provision, 43 Written Requests were issued in FY 2001 and 19 Pediatric Exclusivity Determinations (see Figure 4 below) were made. Over 47,000 children have participated in clinical trials as of October 2001 as a result of the studies FDA requested under the exclusivity provision.

Figure 4

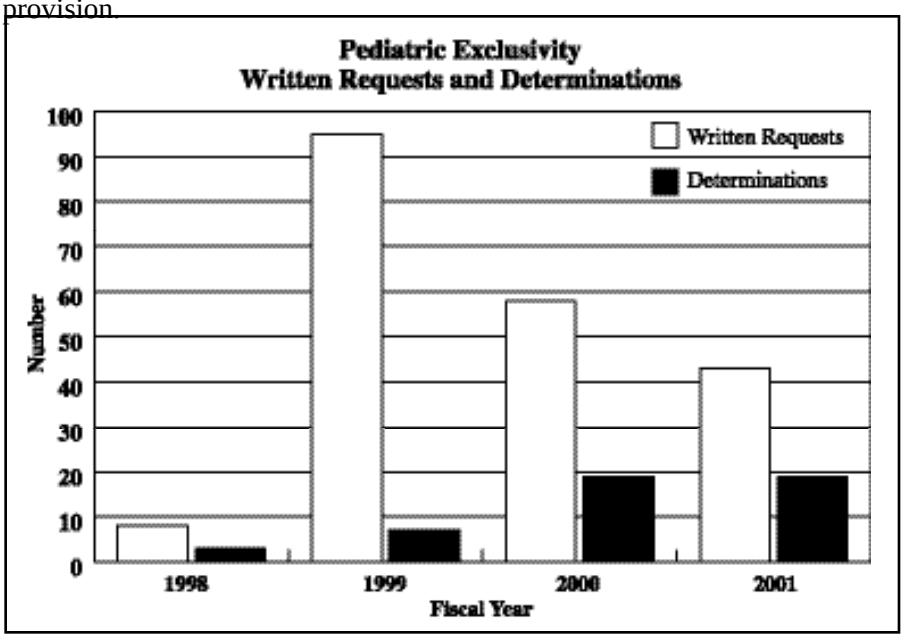
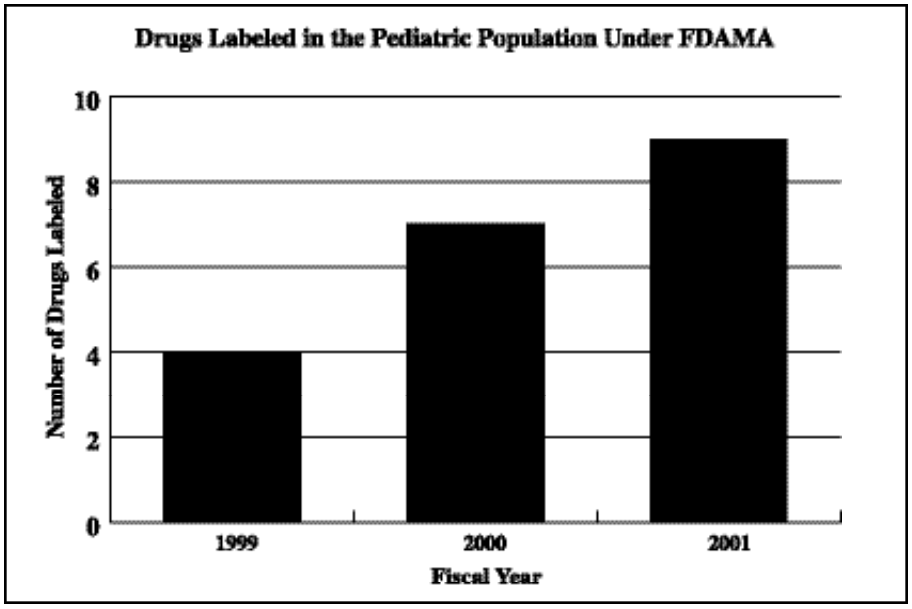


Figure 5



In FY 2001, nine drugs were approved and labeled for pediatric use (see Figure 5 above) based on studies conducted in response to Written Requests.

The Center contracted out the development of an inpatient pediatric database that will be used to accumulate information on the use of drugs in children in the inpatient care setting, e.g., children's hospitals, community hospitals, and chronic care facilities. The information is critical to the Agency as it determines the potential health benefit for drugs to be issued Written Requests or to comply with the Pediatric Rule.

Other activities that support the Pediatric Initiative include preparing a report to Congress, issuing a rule, and working with the National Institute for Mental Health:

- CDER prepared the mandated Report to Congress on Pediatric Exclusivity and forwarded it to Congress in January 2001. The Center updated the annual list of approved drugs for which pediatric information may produce health benefits in the pediatric population. It also maintained and updated a pediatric interactive web page at http://www.fda.gov/cder/pediatric that provides routine updates on pediatric statistics.

- CDER issued an interim rule on April 24, 2001, to provide additional safeguards for children enrolled in clinical trials. The Children's Health Act of 2000 mandates this action by adopting the principles described in Subpart D - Additional protections for Children Involved as Subjects in Research (45 CFR 46.401 - 46.409).

- The CDER Pediatric Team also participated in a working group that prepared the Report of the Surgeon General's Conference on Children's Mental Health: A National Action Agenda, which was released on January 3, 2001. FDA and the National Institute for Mental Health co-sponsored a research workshop on October 2-3, 2000.

The workshop, entitled "Psychopharmacology for Young Children: Clinical Needs and Research Opportunities," served as a forum to discuss the need for investigating psychotropic agents in young children, examine current obstacles to research, and identify possible solutions.

Counterterrorism Initiative

The Center is continually working to enhance DHHS' readiness against any terrorist act to assure public health safety.

CDER developed a draft guidance regarding the safe and effective use of potassium iodide as an adjunct to other public health protective measures in the event that radioactive iodine is accidentally released into the environment. This guidance updates FDA's 1982 recommendations for the use of potassium iodide (KI) to reduce the risk of thyroid cancer in radiation emergencies involving the release of radioactive iodine. These recommendations address KI dosage and the projected radiation exposure at which the drug should be used. This guidance neither prognosticates on the probability of an accident occurring nor on the type or severity of an accident if one were to occur.

CDER prepared for a bioterrorist attack involving biological concerns such as smallpox, anthrax, and plague. The Center collaborated with NIH to develop antiviral agents for the treatment of smallpox. CDER also worked with various government agencies to define appropriate animal models for developing drugs to treat smallpox.

Two approved cream prescription burn treatments received expedited review and approval of their chemistry supplements in response to medical needs resulting from the September 11, 2001, attacks. In addition, CDER had an active IND for their use on large burns. The Center facilitated submission of a protocol for the cream to be used on an emergency basis at the judgement of physicians. This allows more rapid utilization of the product and enrollment of patients.

The National Pharmaceutical Stockpile group of the CDC submitted a "streamlined IND" to FDA after much consultation and guidance from CDER. This IND will permit investigational use of gentamicin, an antibiotic with an established history, if a mass casualty situation occurs during the ensuing development stages. Also, in coordination with the CDC at Ft. Collins, Colorado, CDER obtained and reviewed all available data on patients with pneumonic plague in the U.S. from 1957 through 1999. The Center worked with the CDC and the U.S. Army to determine what additional data, such as animal data or other clinical data, are necessary to support the labeling of gentamicin for plague.

The Center also continues to enhance its drug registration and listing databases to have current information on the location of manufacturing facilities of important life saving drugs.

E-Government Initiative

CDER has received NDA case report forms and case report tabulations in electronic format in place of paper since November 1997. In February 1999, the Center began receiving archival copies of entire NDAs in electronic format in place of paper. The number of NDA electronic submissions has steadily increased. Approximately 75 percent of original NDAs received in CDER now include sections that conform to the electronic submission guidance. Over a third are completely electronic. CDER averaged approximately 100 electronic submissions per month, including full NDAs, supplemental NDAs, and amendments. Since the program began, the Center has seen over a 50 percent reduction in the average number of paper volumes for NDAs. The Electronic Document Room was expanded to manage receipt and handling of full electronic NDAs.

CDER also accepted postmarketing expedited safety reports in electronic format in place of paper and a number of sponsors successfully sent reports electronically that were directly transferred to a database. The Center began preparing regulations to require all adverse event reports from industry to be submitted electronically.

CDER published the draft guidance "Providing Regulatory Submissions in Electronic Format - Prescription Drug Advertising Material and Promotional Labeling" for providing advertising and promotional material in electronic format and had a pilot program to receive these submissions electronically. The Center also had a pilot program for receiving ANDAs in electronic format. In continued support of the generic drugs electronic submissions initiative, the Center enhanced its information technology infrastructure to support the electronic review process, promoted electronic submissions directly to industry and trade groups, and held training sessions for industry.

Performance Plan Goals[9]

Premarket Review: New Drugs

The first strategic goal of the Human Drugs Program is to reduce human suffering and enhance public health by facilitating access to important, lifesaving drugs, and assuring availability of safe and effective drugs. CDER achieved this goal through continued efforts to meet mandated review times for NDAs and ANDAs. This was accomplished through continued communication and collaboration with industry, academia, professional societies, and health care organizations.

The timely performance of high-quality drug reviews in recent years reflects the importance of CDER managerial reforms and additional resources provided to the Center under the Prescription Drug User Fee Act (PDUFA). The law, first enacted in 1992, was renewed for an additional five years in the 1997 FDA Modernization Act. Under the law,

[9] The Human Drugs Program reports on a premarket performance goal that has a time delay in reporting performance results due to the design of the performance measure. DHHS requires its operating divisions (e.g., FDA) to report only final data results and no partial data are allowed. Because of the time delay and DHHS policy, we are using FY 2000 performance data since the FY 2001 results are not available.

the drug industry pays user fees for NDAs, efficacy supplements, and some other activities. User fees helped CDER hire additional scientists to perform reviews.

PDUFA has resulted in increasing numbers of applications being filed, higher quality applications, and quicker approvals for products with the requisite data. CDER's goals become more challenging each year. Nonetheless, application filings and quality remain high by historic standards and approval times continue to drop. Additionally, American patients are receiving the benefits of important new drugs before they are available to citizens of other countries.

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.

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 six months.

Results

CDER met its FY 2000 performance goal (see Table 1 below).

Table 1
Fiscal Year 2000 Cohort (as of 9/30/01)

Submissions 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.	88	96%
		50% in 10 mo.	73	79%

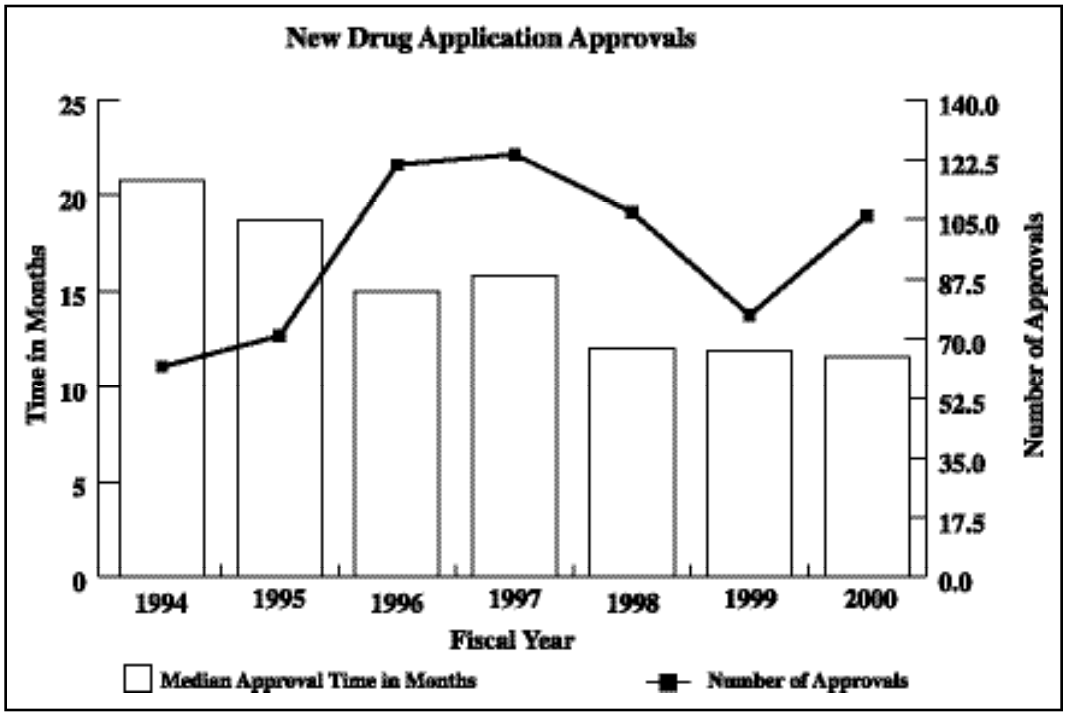
Several important new drugs were also approved by CDER in FY 2001 (see Table 2 on next page).

Table 2
Significant NDAs Approved in FY 2001

Drug	Purpose
Combination of Xeloda (capectitabine) and Taxotere (docetaxel)	Treatment of metastatic breast cancer that has progressed after treatment with anthracycline cancer therapy (such as Adriamycin and doxorubicin)
Natrecor® (nesiritide) Injection	Treatment of acute congestive heart failure (CHF).
Gleevec (imstinib mesylate, also known as STI-571)	Treatment of chronic myeloid leukemia – a rare life-threatening form of cancer
Cancidas (caspofungin acetate) Intravenous Infusion	New anti-fungal medication for patients who are unresponsive to or cannot tolerate standard therapies for the invasive form of aspergillosis
Femara (letrozole)	First-line treatment for postmenopausal women with hormone receptor positive or hormone receptor unknown, advanced or metastatic breast cancer

The median total approval time for new drugs acted on in FY 2000 was 11.6 months, lower than the 11.9 months in FY 1999 (see Figure 6 below). Approval time represents the total review time at the Agency plus industry response time to the Agency's requests for additional information.

Figure 6



Premarket Review: Generic Drugs

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. A generic drug product is one that is comparable to the reference listed drug product in dosage form, strength, route of administration, quality, performance characteristics, and intended use. Generic drug applications are termed "abbreviated" in that they generally do not require preclinical (animal) and clinical (human) data to establish safety and effectiveness. These parameters were established upon the approval of the innovator drug product.

Performance Goal

Review and act upon 45 percent of fileable original generic drug applications within six months after submission date.

Results

FDA met its goal for FY 2000 acting on 55.6 percent of original applications within six months after the submission date. This is an increase of more than 27 percent over FY 1999.

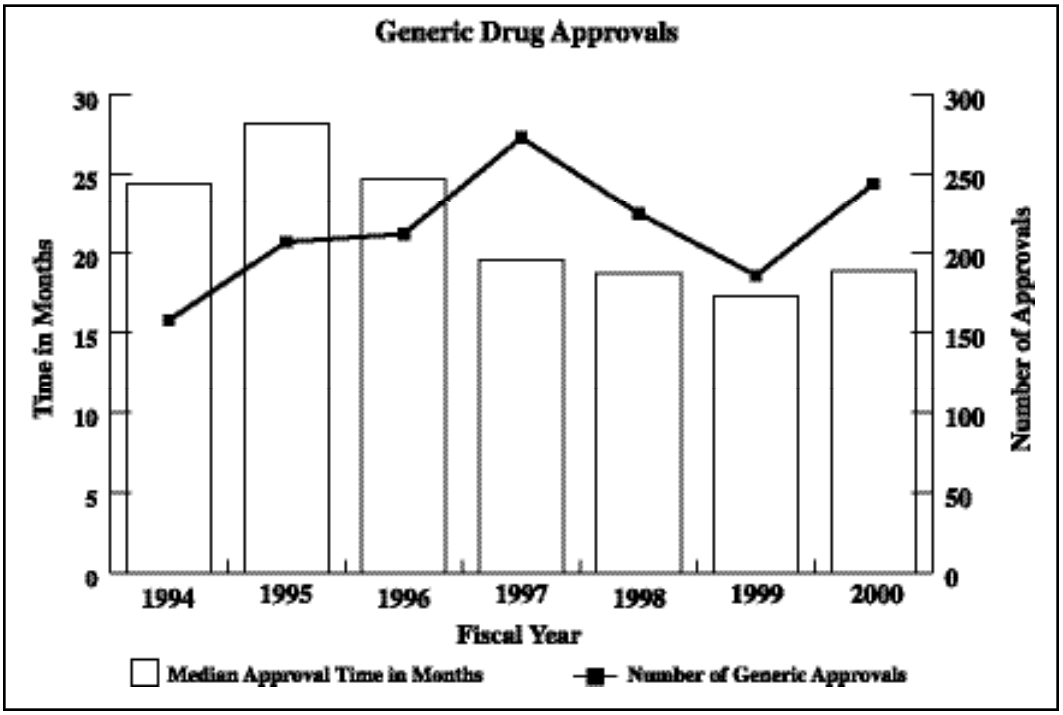
Of these, several represent the first time a generic was approved for a product. Examples of important first time approvals are listed in Table 3 below.

Table 3
Notable First Time Generic Approvals

Drug	Purpose
Buspirone Hydrochloride	Management of anxiety disorders or short-term relief of symptoms of anxiety (generic for Buspar by Bristol Myers Squibb)
Famotidine	Prevention and treatment of heartburn (generic for Pepcid AC by Merck)
Fluoxetine	Treatment of depression (generic for Prozac by Lilly)
Butorphanol Tartrate	Management of pain (generic for Stadol NS by Mead Johnson)
Levocarnitine	Treatment of primary systemic carnitine deficiency (generic for Carnitor by Sigma Tau)

The FY 2000 18.9-month median approval time compares to 17.3-months in FY 1999 and 18.7-months in FY 1998 (see Figure 7 below).

Figure 7



CDER used a $1.2 million dollar increase in FY 2001 to fully annualize the positions added in FY 2000 and to hire several additional FTE. Several of these staffers are already on-board, fully trained, and demonstrating high levels of productivity. With this additional increase, all chemistry reviewer vacancies are currently filled. This in itself will hopefully improve performance, as chemistry reviews were a source of delay.

The Office of Generic Drugs (OGD) continues to refine the review process to increase efficiency with the $1.2 million increase and increases in past years. It is also evaluating ways to increase resources devoted to information technology. As the backlog of applications is addressed, it is hoped OGD can close the gap between actions so that the first action is taken within the statutory time frame. There are certain factors outside the control of OGD that may prevent complete adherence to the 180-day time frame. These factors include the need to adhere to the review queue structure, timeliness of inspections of the manufacturing plants, and legal issues raised late in the review process. In addition to these factors, CDER continues to examine every aspect of the review process to try to identify problem areas that need to be addressed. OGD also plans to revise the current system for amendment designation, major versus minor, to improve total review times.

Postmarket Assurance

The second strategic goal of the Human Drugs Program in FY 2001 was to prevent unnecessary injury and death to the American public caused by adverse drug reactions, injuries, medication errors, and product problems.

CDER evaluates the ongoing safety profiles of drugs available to American consumers using a variety of tools and disciplines. The Center maintains a system of postmarketing surveillance and risk assessment programs to identify adverse events such as adverse reactions, drug-drug interactions, and poisonings.

As CDER discovers new information about a drug's safety profile, the Center makes risk assessments and decisions about the most appropriate way to manage any new risk or new perspective on a previously known risk. Risk management methods include new labeling, "Dear Health Care Practitioner" letters, restricted distribution programs, or product marketing termination.

CDER uses a powerful, state-of-the-art tool for detecting signals: AERS. This system combines the voluntary adverse drug reaction reports from MedWatch and the required reports from manufacturers. These reports often form the basis of "signals" that there may be a potential for serious, unrecognized, drug-associated events. After the signal is generated, further testing of the hypothesis is undertaken using various epidemiological and analytic databases, studies, and other instruments and resources. AERS offers paper and electronic submission options, international compatibility, and pharmacovigilance screening. Information is provided on CDER's improvement of AERS.

Performance Goal

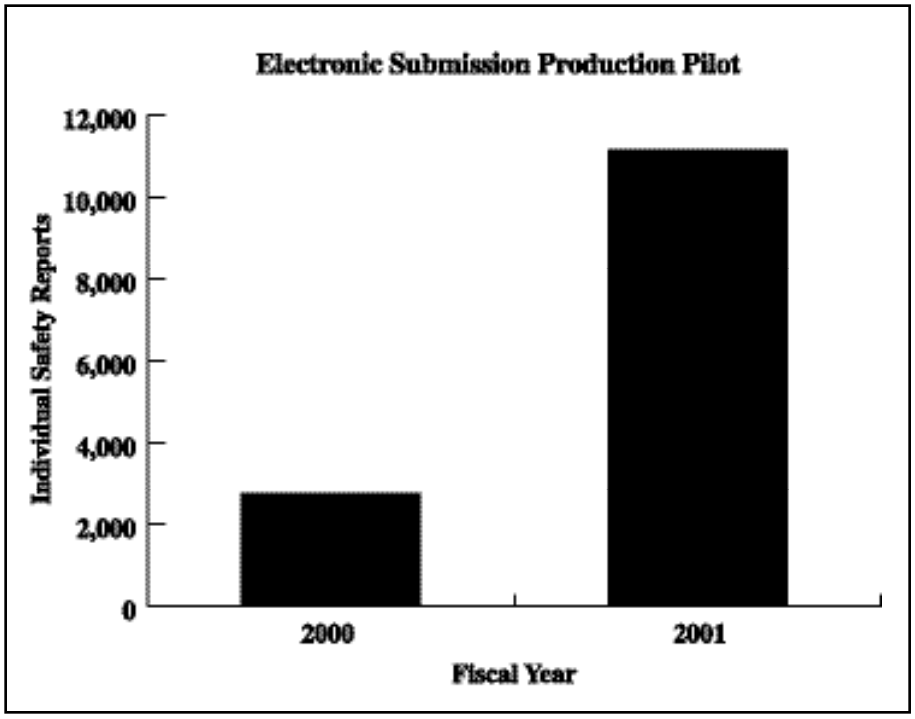
Expedite processing and evaluation of adverse drug events through implementation of AERS that allows for electronic periodic data entry and acquisition of fully coded information from drug companies.

Results

AERS version 2.1, completed in February 2001, enhanced the compliance and Freedom of Information portions of AERS by making it more accessible to compliance staff and improving compliance-related search capabilities.

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. Over 11,000 individual case safety reports were submitted electronically under the pilot program in FY 2001 (see Figure 8 on next page).

Figure 8



AERS version 2.2 was implemented in May 2001, enhancing the ability of the system to accept electronic submissions. Also in May 2001, a draft guidance for industry, "Providing Regulatory Submissions in Electronic Format - Postmarketing Expedited Safety Reports" was released.

The Electronic Submission Product Test Pilot for AERS is part of a step-level implementation program for the electronic submission of postmarketing surveillance information. The pilot allows CDER to identify and resolve several process issues while regulatory and infrastructure changes are implemented. 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.

FDA Press Release, December 21, 2000

PHYSICIAN LABELING PROPOSAL

The Food and Drug Administration today proposed a new format for prescription drug labeling that will help reduce medical errors, which according to the National Academy of Sciences may be responsible for as many as 98,000 U.S. deaths annually. FDA believes that this new, user-friendly format will reduce errors in drug prescribing.

"Today's proposal is FDA's latest initiative to improve the labeling of the products it regulates," said Dr. Jane E. Henney, [former] FDA Commissioner. "This proposal is particularly valuable because it will make important information available in a clear, consistent, and readable format that is essential to proper prescribing practices."

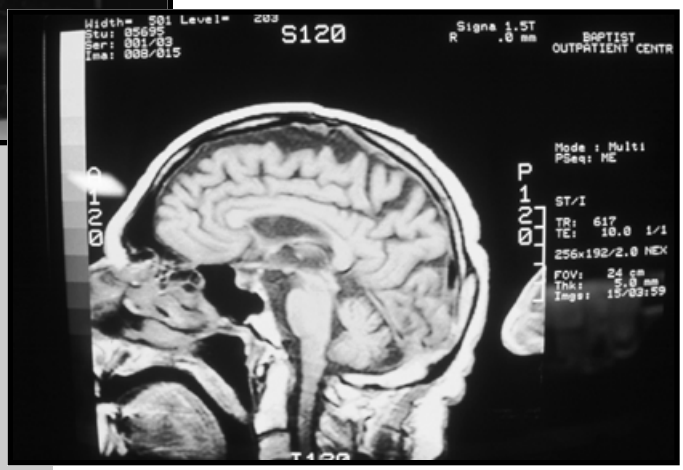
Prescription drug product labeling, also known as the package insert, represents a primary means of providing critical information about drugs to practitioners. As part of the drug review process, FDA reviews and approves drug product labeling that is initially proposed by manufacturers.

A FDA study showed that practitioners found drug product labeling to be lengthy, complex, and hard to use. The proposed new format would provide user-friendly labeling that would allow practitioners to quickly find the most important information about the product. One major change is inclusion of a new introductory "Highlights" section of bulleted prescribing information. This section would include the information that practitioners most commonly refer to and view as most important, and it would provide the location of further details elsewhere in the labeling.

The proposed new labeling is expected to reduce practitioners' time spent looking for information, decrease the number of preventable medical errors, and improve treatment effectiveness. The information will be easier to find, read, and use, and it should also enhance the safe and effective use of prescription drugs and reduce medical errors caused by inadequate communication. Because these labeling revisions represent considerable effort and are most critical for newer and less familiar drugs, the proposal will apply only to relatively new prescription drug products.

FDA Programs

Medical Devices and Radiological Health



Medical Devices and Radiological Health Program

Background

The Medical Devices and Radiological Health Program is administered by the Center for Devices and Radiological Health (CDRH) with support from ORA. The program is responsible for ensuring the safety and effectiveness of medical devices as well as eliminating unnecessary human exposure to man-made radiation from medical, occupational, and consumer 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, and medical ultrasound and x-ray machines.

Growth in the size of the medical device industry and in the complexity of new medical devices will continue to challenge FDA to stay up-to-date with breakthrough medical devices and to maintain high quality timely reviews, required interactions with industry, and current review guidance. Since 1982, the number of Device Manufacturers has increased by a factor of five (2,194 in 1982 to 11,495 in 2001). Quantum leaps in device miniaturization, microprocessor software control, artificial intelligence decision support, remote operation, and drug/biologics tissue combinations are already revolutionizing medical care.

The pace of technology innovation in this country and around the world requires the Center's cadre of scientists to keep up with the latest technology and scientific advances, in both the development of medical technology and scientific methodologies. Only by doing so can personnel provide high quality, timely, and science-based regulatory actions on the safety and effectiveness of new medical products and the causes of inferior performance including public health impact. FDA intends to emphasize the need to maintain high quality scientific decision making. This is especially critical for emerging technologies like computer-related technology; molecular medicine; home-care and self-care devices; minimally-invasive technology; combination device-drug combination products; and pioneering organ replacement and patient assist devices.

FDAMA has had a major impact on the Medical Device and Radiological Health Program. FDAMA requires the Agency to: conduct more timely and interactive application reviews; improve the quality and timeliness of postmarket surveillance data; expand participation in international harmonization activities; and improve information and education for industry and health professionals. In order to implement these mandates, CDRH has identified and concentrated on high-risk, high-impact products and work areas where its direct intervention can help consumers and health care professionals the most. CDRH is building its device science base to maintain and update the organizational capability to make timely regulatory decisions.

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 Costs (000s)
2001	$223,320
2000	$203,773
1999	$192,600

The Medical Device and Radiological Health Program experienced an 9.6 percent increase in net costs in FY 2001. This increase is attributed to premarket review activities and for inspections. The net cost includes the total expenses for a program, including the allocation of overhead expenses (such as the Office of the Commissioner's costs [e.g., administrative and policy direction], ORA's field operations' costs, rent, and other overhead), less exchange of revenue.

Selected Initiatives, Goals, and Accomplishments

During FY 2001, 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 the Center feels will have a major impact on patient care:

Fetal Oxygen Monitor

This device is a new type of fetal monitor that measures oxygen saturation in the baby's blood as a sign of fetal health during delivery. The device is extremely useful when a single fetus is of at least 36 weeks gestation, the mother's water has broken, and the baby is in the normal head down position for delivery

Glucose Test for Adult Diabetics

The new glucose test product is a wristwatch device that provides adult diabetics with more information for managing their disease. The device is intended for use along with, not as a replacement for, finger-prick blood tests to monitor glucose. The "GlucoWatch" extracts fluid through the skin by sending out tiny electric currents. Glucose levels are measured using this fluid every 20 minutes for 12-hours even during sleep. The device sounds an alarm if the patient's glucose reaches dangerous levels, thus helping patients manage a potential problem.

Middle Ear Surgical Implant

A surgically implanted hearing device, this product is intended to help adults with moderate to severe nerve hearing loss. The device is an alternative to traditional hearing aids and offers patients another choice which may improve hearing.

Robotic-Assisted Surgery

This robotic device enables a surgeon to perform certain types of surgery while seated at a console with a computer and video monitor. This robot gives surgeons additional manipulation ability during minimal invasive laparoscopic surgery, enabling easier, more intricate motion of surgical tools. The device is an alternative to several procedures including open heart surgery and the treatment of gall bladder disease.

Digital Mammography

The approval of Digital Mammography is a x-ray system that employs a digital receptor to capture images of the breast. These images can then be printed to film or be displayed at a high-resolution computer workstation for interpretation by a qualified mammographer. This device offers an alternative to traditional screening and diagnostic mammography.

Performance Plan Goals [10]

The first strategic goal of the Medical 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 employs 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. CDRH reviews the following types of applications.[11]

- Premarket Approval Application (PMA) and PMA supplement - ensures the data submitted by the manufacturer demonstrates 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.

[10] The premarket goals of the Medical 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 2000 performance data since the FY 2001 results are not available.

[11] 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."

- Product Development Protocol (PDP) – provides alternatives to PMAs in which the manufacturer makes a mutual and binding agreement with FDA 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)] - ensures the data submitted demonstrate that the device is substantially equivalent to an eligible product already on the market.

- Investigational Device Exemption (IDE) application - ensures proposed investigational studies will be well controlled and will safeguard the rights and safety of human subjects.

All devices are classified into three categories, depending on the level of regulation required to ensure safety and effectiveness, see Table 4.

Table 4

Class I Devices	Subject to general controls, such as good manufacturing practices, requirements, labeling requirements, and registration with FDA.
Class II Devices	Subject to special controls, such as performance standards, special postmarket surveillance efforts, and patient registries.
Class III Devices	Required to undergo premarket evaluation and receive FDA approval prior to being marketed.

Premarket Approval Applications

Premarket approval applications involve new products that represent the highest potential risk and benefit to consumers. As such, FDA has redirected its limited 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 FDAMA 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).

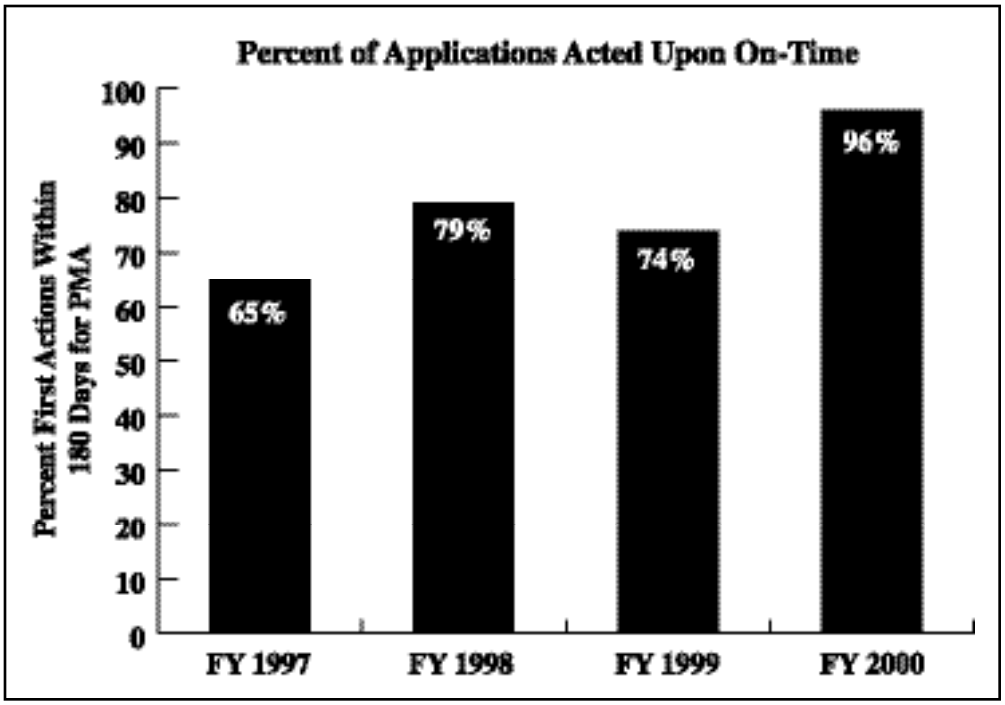
Performance Goal

The FY 2000 performance goal was to review and complete an on-time percentage of 85 percent of PMA first actions within 180 days.

Results

CDRH achieved its goal by completing 96 percent of the first actions on 43 PMAs received in FY 2000. FDA improved its performance considerably from FY 1999 when the on-time percentage was 74 percent. The chart below (Figure 9) presents CDRH's improving performance over the past four years.

Figure 9



In addition, there were no backlogs for new product submissions and turnaround times for processing these submissions improved across the board. PMA average total review time from filing to approval was 76 days for FY 2000 and remained the same as FY 1999. In FY 1996, average review time was 146 days.

Premarket Notifications

A premarket notification [510(k)] is for a device found by FDA to be substantially equivalent to a device already on the market for which premarket approval is not required. About 98 percent of the medical devices marketed in the U.S. are 510(k) devices.

As a result of FDAMA, CDRH continues to implement improvements to the 510(k) review system to make it more efficient and less resource intensive, without compromising the public's health.

In FY 2000, CDRH updated the list of third parties to perform selected 510(k) reviews for low-to-moderate risk devices. FDA is proposing an expansion of the program that would allow third party review of all (460) Class II devices. A Federal Register Notice announcing the proposed expansion was issued on July 18, 2000.

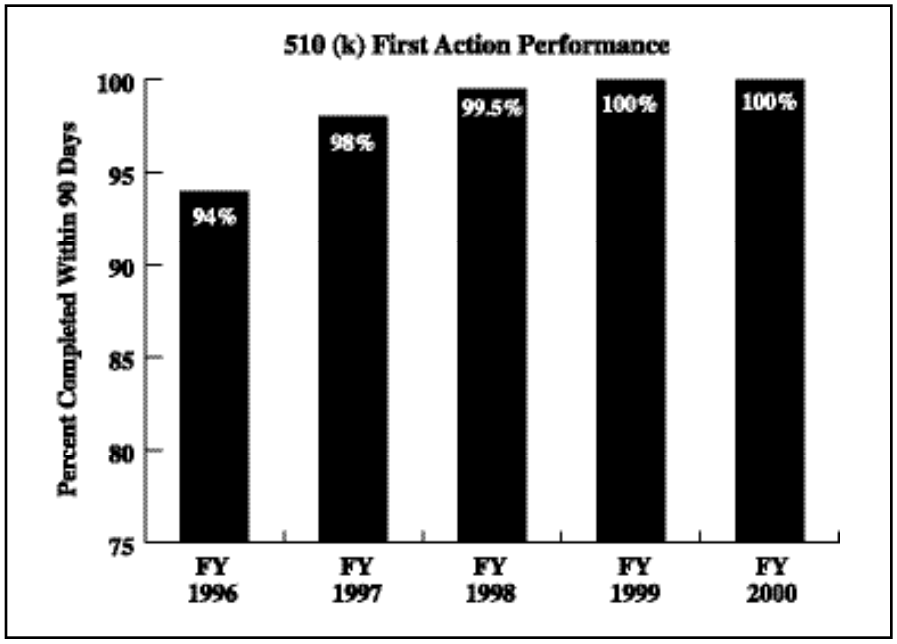
Performance Goal

Review and complete 90 percent of 510(k) (Premarket Notification) first actions within 90 days[12].

Results

CDRH achieved its FY 2000 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 10 shows FDA's improved timeliness in completing 510(k) first actions.

Figure 10



12 Even though CDRH dropped this goal in FY 2000, the Center continued to report on its accomplishment. The goal was re-instated for the FY 2001 – 2003 period because it provides a meaningful measure of performance in this area.

Mammography

The second strategic goal of the Medical Device 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 Mammography Quality Standards Act of 1992 (MQSA)

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 the areas of equipment, personnel, quality assurance, record keeping, and reporting. It is unlawful for any facility to perform mammography without a certificate.

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

1. Requiring all mammography facilities to send reports written in lay person's terms to all patients receiving mammography services;
2. Clarifying the responsibility of the mammography facility to retain mammogram records so women have the ability to obtain the original record of their mammogram;
3. Mandating direct written notification to all patients of their exam results in lay person's terms; and
4. 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 one-third of such facilities will need re-certification annually.

Performance Goal

The FY 2000 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 mammography facilities complying with inspection standards. During FY 2001, FDA inspected 9,931 mammography facilities compared to 9,891 in FY 2000.

From March 22, 2001 Press Release, "FDA News"

FDA APPROVES NEW GLUCOSE TEST FOR ADULT DIABETICS

The Food and Drug Administration today approved a wristwatch-like device that provides adult diabetics with more information for managing their disease. It is intended for use along with, not as a replacement for, finger-prick blood tests to monitor glucose.

The GlucoWatch Biographer, made by Cygnus Inc., of Redwood City, Calif., extracts fluid through the skin by sending out tiny electric currents. Glucose levels are measured using this fluid every 20 minutes for 12 hours-even during sleep. The device sounds an alarm if patient's glucose reaches dangerous levels, thus helping patients manage a potential problem.

The FDA approved the GlucoWatch, which is available only by prescription, to detect trends and track patterns in glucose levels in adults age 18 and older.

"Today's action heralds the advent of new technologies that promise dramatic improvements in the quality of life for the millions of Americans who have diabetes," said Secretary of Health and Human Services Tommy G. Thompson.

"New technology for monitoring glucose levels in diabetics is moving ahead rapidly, and the FDA has been working with a number of companies to help bring it to market," said Acting Principal Deputy Commissioner of Food and Drugs Bernard A. Schwetz, D.V.M., Ph.D. "The GlucoWatch is one of the first steps in developing new products that may one day completely eliminate the need for daily finger-prick tests."

FDA Programs

Biologics

Biologics Program

Background

The Biologics Program, administered by the Center for Biologics Evaluation and Research (CBER) and supported by ORA, is responsible for ensuring the safety, efficacy, potency, and purity of vaccines, blood products, certain diagnostic products, and other biological and biotechnology-derived human products. Such products are for the treatment, prevention, or cure of diseases in humans, as well as the safety of the Nation's supply of blood and blood products. The program's activities include:

- evaluating biological products before marketing, including monitoring pre-clinical and clinical testing of new biological products;
- licensing biological products and manufacturing establishments, including plasma pheresis centers, blood banks, and vaccine and biotechnology manufacturers;
- managing the Acquired Immune Deficiency Syndrome (AIDS) program and policy activities, including research on AIDS therapeutic products, diagnostic tests, and vaccines;
- performing regulatory research to establish product standards and development of improved testing methods to assess the safety of biological products;
- providing regulatory oversight for licensed biological manufacturing establishments;
- regulating the safety and quality of domestic and imported products; and
- reviewing and investigating post-market reporting of product adverse experiences.

Costs

Fiscal Year	Net Program Costs (000s)
2001	$160,889
2000	$132,860
1999	$146,773

The Biologics Program has experienced a 21.1 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 total expenses for a program, including the allocation of overhead expenses (such as the Office of the Commissioner’s costs [e.g., administrative and policy direction], ORA’s field operations’ costs, rent, and other overhead), less exchange of revenue.

Selected Initiatives, Goals & Accomplishments

Countering Bioterrorism Initiative

The Countering Bioterrorism initiative is comprised of a number of essential elements for which CBER plays an integral role. One role is developing and licensing products to diagnose, treat, or prevent outbreaks from exposure to the pathogens identified as bioterrorist agents. These products must be reviewed and approved prior to the large-scale productions necessary to create and maintain a stockpile. Staff must guide the products through the regulatory process, including manufacturing, pre-clinical testing, clinical trials, and licensing and approval. This process is complex and early involvement by FDA staff in the development process is crucial to the success of the expedited review process.

Another role is developing a cohesive and comprehensive response in conjunction with other Federal agencies. CBER participates in numerous meetings, briefings, and conferences representing FDA, with staff from the Department of Defense, the DHHS, the Department of Veterans Affairs, and the Office of Management and Budget. CBER also works with other DHHS agencies, including the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC).

CBER is also developing new regulatory models to accommodate the need for preparedness in the case of an emergency attack. For example, procedures and protocols are being developed to enable the use of INDs in a highly controlled, safe manner for particular emergency situations, such as responding to a bioterrorist attack that exposed individuals to the agent that causes anthrax.

Human Subject Protection Initiative

The Bio-Research Monitoring (BIMO) program was established in the 1970's to oversee the conduct of clinical trials and the operation of non-clinical laboratories and to ensure that the reporting of research information submitted to the FDA was not fraudulent or falsified. Under the BIMO program, FDA inspects non-clinical laboratories, clinical investigators, institutional review boards, sponsors, contract research organizations, and clinical trial monitors. The compliance goals of the program are achieved through a combination of surveillance, enforcement, and education.

The Biologic's BIMO program has focused on strengthening, and thereby enhancing, the FDA's ability to promote the development and availability of safe and efficient clinical and non-clinical environments, exacting protocols, and investigational products protecting human subjects, and rendering accurate and reliable data. These efforts promote uniformity of action across FDA and provide a comprehensive, integrated BIMO program to oversee emerging products and technologies.

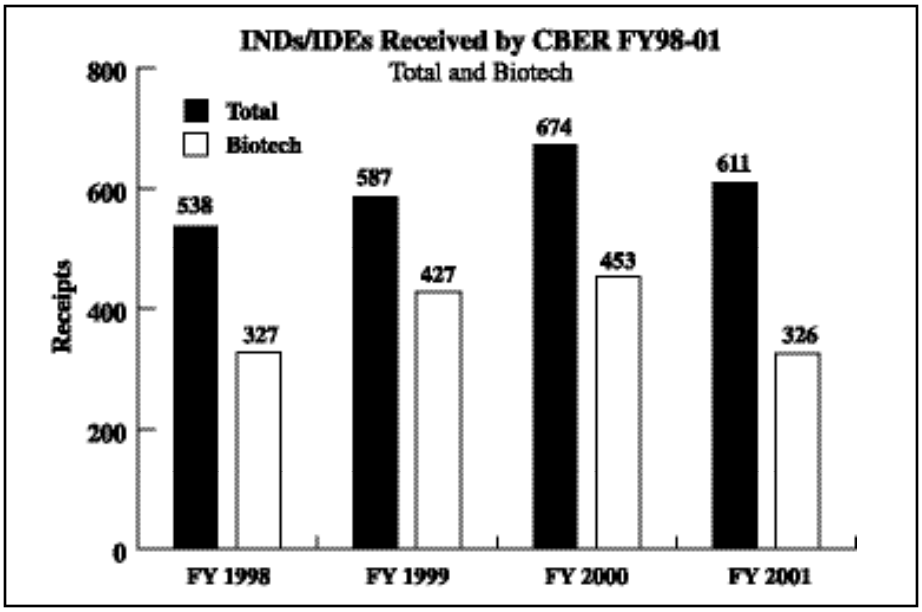
As part of ongoing efforts to ensure human subject protection in gene therapy trials, FDA and NIH are working together to establish gene therapy adverse event and patient tracking systems.

FDA and NIH have taken both individual and cooperative actions to achieve greater adherence by researchers to existing requirements and guidance and to bolster the protection of study participants and the integrity of gene therapy trials. These include:

- conducting more inspections to increase oversight of INDs in gene therapy;
- issuing a proposed rule on the public disclosure of information regarding gene therapy clinical trials that would provide more information on these trials to the general public;
- enhancing regulatory research to improve product safety; and
- providing guidance documents to industry and other interested parties on gene therapy products and taking action to build upon existing guidance.

The chart in below (Figure 11) shows the magnitude of investigational research. The number of INDs and IDEs received by CBER has increased since FY 1998. INDs/IDEs are submitted by sponsors, prior to clinical trials, to determine their safety and efficacy, and to request FDA authorization to administer an investigational drug or biological product to humans.

Figure 11



Biotechnology-produced products have increased dramatically in recent years. The number of INDs received by CBER rose from five in FY 1980, to 326 in FY 2001. During FY 2001, FDA received 11,355 investigational amendments for biotechnology INDs. Much of this growth has been in the area of somatic cell/gene therapy and xenotransplantation products for which there were nine INDs in FY 1989, increasing to 118 INDs in FY 2001. Adjunct procedures used in gene therapy, such as stem cell isolation, are also rapidly increasing, leading to a secondary rise in device and biological submissions related to this area.

Performance Plan Goals [13]

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[14] , which are primarily vaccines and therapeutics. CBER also has responsibility for reviewing and approving biologic products not covered by PDUFA. The non-PDUFA biological products are primarily 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 terms of cohorts, e.g., the FY 2000 cohort includes applications received from October 1, 1999, through September 30, 2000[15].

Information is provided on two performance goals that cover PDUFA and non-PDUFA products.

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[13] 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 2000 performance data since the FY 2001 results are not available until 12 months after the cohort year.

[14] 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.

[15] 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, 10 or 12 months after the last submission received in FY 2001, depending upon the category of submission (for 12-month standard applications – November 2002, for ten-month standard applications – September 2002, and for priority original applications – April 2002).

Performance Goal

The FY 2000 cohort review performance goals covered under PDUFA for New Drug Applications (NDA), Product License Application (PLA), and Biologics License Application (BLA) are:

- Review and act on 90 percent of standard original NDAs/PLAs/BLAs filed during FY 2000 within 12 months of receipt and review and act on 50 percent within 10 months of receipt and review.
- Review and act on 90 percent of priority original NDAs/PLAs/BLAs filed during FY 2000 within six months of receipt.

Results

CBER has met or exceeded its performance goals in FY 1994 through FY 2000. Table 5 shows CBER's performance on the PDUFA FY 2000 cohort. The data provided are as of September 30, 2001.

The FY 2000 first-action performance goal is to review and issue a comprehensive action letter within the goal on at least 90 percent of the new product applications submitted and filed during FY 2000, and 50 percent within 10 months of receipt. This means that not more than 10 percent of new product applications received and filed during FY 2000 should be overdue[16] 12 months after receipt (50 percent should be reviewed and acted on within 10 months of receipt).

Table 5

Biologics Program FY 2000 PDUFA Cohort as of 9/30/01

Application Type	Number Submitted	Number Filed	RTF,UN or WF	First Action w/in Goal (%)		Submissions Overdue (%)
New Product Standard	11	10	1	10 months	100%	0
				12 months	100%	0
New Product Priority	4	4	4	100		0

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

[16] Overdue is defined for standard new product as not having issued a comprehensive action letter within the specified timeframe (10 or 12 months) of receipt and filing of the application, and for priority original new products, it is defined as not having issued a comprehensive action letter within 6 months of receipt and filing of the application.

Performance Goal

The FY 2000 cohort review performance goal for non-PDUFA products are:

- Review and act on 85 percent of complete blood bank and source plasma PLA/BLA submissions filed during FY 2000 within 12 months of receipt.
- Review and act on 90 percent of PLA/BLA major supplements within 12 months after submission date.

Results

CBER reported that its actual FY 2000 performance for blood bank and source plasma PLA/BLA and PLA/BLA major supplements exceeded their target. CBER achieved results of 100 percent in both instances.

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 (CGMP) 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.

Results

CBER reported that it had exceeded its performance measure. Fifty-seven percent of its audience (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 certain manufacturing facilities once every two years. There are currently 2,790 establishments in the

Biologics Program inventory covered under this statute. There are 2,898 additional establishments in the Biologics Program inventory not covered under this statute.

This year's result is the same as FY 2000. In FY 2000, FDA inspected 57 percent of the establishments in the Official Establishment Inventory, exceeding the goal of 50 percent.

From March 7, 2001 Press Release, "FDA News"

NEWLY FORMULATED DTaP (DIPHTHERIA, TETANUS, AND PER TUSSIS) VACCINE APPROVED WITH ONLY TRACE AMOUNTS OF THIMEROSAL

Today, the FDA approved a newly formulated version of Tripedia, a diphtheria and tetanus toxoids and acellular pertussis (DTaP) vaccine without preservatives and with only a trace amount of thimerosal.

"This approval is significant because now all routinely recommended pediatric vaccines will be available as either completely thimerosal free or without any significant amounts of thimerosal, a preservative that contains mercury," said Dr. Bernard Schwetz, Acting Principal Deputy Commissioner. "Although thimerosal is a very effective preservative, the Public Health Service recommended that thimerosal should be reduced or eliminated from vaccines as soon as possible to minimize the exposure of infants and young children to mercury."

Tripedia now contains less than 0.5 micrograms of mercury per dose, a greater than 95% reduction in the amount of thimerosal per dose compared to the original version of Tripedia.

The pediatric vaccines that are recommended for routine use are: DTaP, hepatitis B, Haemophilus conjugate (Hib), pneumococcal conjugate, inactivated poliovirus, varicella, measles, mumps and rubella. Since 1999, pediatric formulations of hepatitis B vaccines that either contain no thimerosal (Recombivax HB) or trace amounts (EngerixB) have been approved.

In recent years, various federal agencies have been addressing the health risks of mercury, which is found in the environment, in food and in household products. Although no harmful effects have been reported from thimerosal at doses that were used in vaccines, the PHS agencies, the American Academy of Pediatrics, and vaccine manufacturers agreed that thimerosal should be reduced or eliminated in vaccines to make already safe vaccines even safer.

FDA Programs

Animal Drugs and Feeds

Animal Drugs and Feeds Program

Background

The mission of the Animal Drugs and Feeds Program, administered by the Center for Veterinary Medicine (CVM) and supported by ORA, is to protect the health and safety of all food producing, companion or other non-food animals; and, to assure that food from animals is safe for human consumption.

The Animal Drugs and Feeds premarket program works to:

- Increase the availability and diversity of safe and effective products for use in both food producing and non-food producing animals by the veterinary community;
- Assure that only safe and effective animal drugs, devices, feeds and feed additives are approved for marketing; and,
- Assure that foods from animals that are administered drugs, in accordance with label directions, are safe for human consumption.

The Animal Drugs and Feeds postmarket program monitors marketed products and their manufacturers. This is accomplished through science-based review of drug experience reports, nationwide monitoring systems, and compliance programs implemented by FDA field offices. The field offices perform inspections, sample collections and analyses, and investigations. Regulatory actions are taken as needed and allowed by statute to control violative goods and firms.

In addition, the Animal Drugs and Feeds Program's educational initiative actively pursues partnerships with the major groups representing the feed and animal drug industries, state government regulators, and professional organizations. The education initiatives are designed to increase understanding and knowledge of animal drugs and feeds regulations among our stakeholders, which will help to improve compliance and overall program efficiency for CVM and its customers.

Costs

Fiscal Year	Net Program Costs (000s)
2001	$83,106
2000	$63,591
1999	$62,579

The Animal Drugs and Feeds Program has experienced a 30.7 percent increase in net costs in FY 2001. This increase is attributed to funding for food safety initiative, for inspec-

tions, and for premarket review activities. The net cost includes the total expenses for a program, including the allocation of overhead expenses (such as the Office of the Commissioner's costs [e.g., administrative and policy direction], ORA's field operations' costs, rent, and other overhead), less exchange of revenue.

Selected Initiatives, Goals, & Accomplishments

Food and Drug Administration Modernization Act (FDAMA) Implementation

Section 116 of FDAMA amended the Federal FD&C Act by adding section 506A describing the requirements and procedures for making and reporting post approval manufacturing changes to approved human and animal drug applications. FDAMA required CVM to amend the guidance on supplemental new animal drug applications to harmonize with the CDER and CBER requirements and procedures for making and reporting manufacturing changes to approved drug and license applications. In February 2001, CVM and CDER jointly published a guidance document for Industry entitled "BACPAC I: Intermediates in Drug Substance Synthesis – Bulk Actives Postapproval Changes: Chemistry, Manufacturing and Controls Documentation".

In addition, during FY 2001, Section 403 of FDAMA was implemented with the publication of a guidance document entitled "The Use of Published Literature in Support of New Animal Drug Approval". Section 403 of FDAMA concerns the approval of supplemental applications for approved products. Among other things, Section 403 required FDA to issue guidance that defines supplemental applications that are eligible for priority review status, and specify data requirements that will avoid duplication of previously submitted data by recognizing the availability of data previously submitted in support of an original application. In FY 2001, CVM completed reviews of 1,223 NADA and 155 ANADA manufacturing supplements and reactivations.

Activities Related to Prevention of Bovine Spongioform Encephalopathy (BSE)

Since January 1998, FDA has conducted over 10,000 inspections on renderers, feed mills, ruminant feeders, dairy farms, protein blenders, feed haulers, and distributors to determine compliance with the 1997 feed rule entitled, "Animal Proteins Prohibited from use in Animal Feed". Nearly, 90 percent, up from three-quarters of these establishments were found to be in compliance. In January 2001, FDA planned to re-inspect those firms that were not in full compliance with the rule. As of October 26, 2001[17], 719 re-inspections were reported, and of these, only 108 (or 86 percent) were found still to be out of compliance with the rule. Firms previously found to be not in compliance have corrected

[17] To provide accurate and consistent information, the latest update of October 26, 2002, is used. This information has already being reported in other public documents.

violations through a variety of ways, including further training of employees about the rule, developing systems to prevent co-mingling, re-labeling their products properly, and adhering to record keeping regulations. Other firms have achieved compliance by eliminating prohibited materials from their operations.

On April 24, 2001, the Acting Principal Deputy Commissioner approved the FDA Transmissible Spongiform Encephalopathies (TSE) Action Plan, which includes Bovine Spongiform Encephalopathy (BSE) and Chronic Wasting Disease (CWD) to protect the American public health by:

- Strengthening FDA's efforts to keep BSE out of the American cattle and keep it from amplifying in the herd were it ever to be found in American cows;
- Improving FDA's vigilance to keep potentially TSE-infected foods and other FDA-regulated products from Americans; and
- Enhancing the research needed to better understand TSEs and to develop needed diagnostic tools, therapies, and preventive measures for humans and animals.

Food Safety Initiative

CVM participates in surveillance, research, risk assessment and education and outreach activities under the Food Safety Initiative (FSI).

Under surveillance activities, CVM has developed and coordinates the National Antimicrobial Resistance Monitoring System (NARMS) in collaboration with the United States Department of Agriculture (USDA) and Centers for Disease Control and Prevention (CDC). The system was initiated in response to public health issues associated with the approval of fluoroquinolone products for use in poultry. NARMS is designed to identify changes over time in the susceptibility of bacteria that cause foodborne diseases in humans to the antibiotics used to treat them. The system monitors antibiotics used in both humans and animals. The NARMS monitors antimicrobial susceptibility to 17 antibiotics in Salmonella and E. Coli bacteria and eight antibiotics in Campylobacter organisms. Animal and human isolates currently monitored in NARMS are non-typhoid Salmonella, Campylobacter, E. coli, and Enterococci. Human isolates also include Salmonella typhi and Shigella. Listeria and Vibrio were added to the list of human isolates in 2001.

In FY 2001, CVM expanded the NARMS program into sample testing of retail meats. Retail meats are collected and sampled for isolation of enteric organisms that may cause food borne illness and antimicrobial susceptibility testing of those organisms. A pilot study is currently being conducted in Iowa and planning and coordination is ongoing to conduct further monitoring of retail meats by five FoodNet sites through a NARMS interagency agreement with CDC.

An animal feed component was added to NARMS in FY 2001. Planning was completed

between CVM, ORA and CDC on a project to monitor animal feeds for enteric organisms that cause food borne illness. The project includes FDA/ORA approval of the sampling protocol.

Also, the NARMS Mexico project has been expanded into a three-year cooperative agreement with four sites in Mexico. The FDA pilot project with Mexico monitoring antimicrobial resistance in salmonella was completed in FY 2001. The study results indicated:

a. 10 percent of healthy, asymptomatic children in Mexico are shedding Salmonella;

b. Prevalence of Salmonella in retail pork is higher than in retail poultry;

c. Resistance patterns in Salmonella isolates from humans and retail meat are very similar;

d. There is a high prevalence of ciprofloxacin-resistant E. coli in both humans and retail meat, particularly poultry; and

e. Both Salmonella and E. coli from meat tend to be more multi-drug resistant than these isolates from humans.

Under research activities, CVM is funding cooperative agreements to study the microbiological hazards associated with the food animal production environment, which includes animal feeds. In addition, the expansion of NARMS required a third testing site in order to handle the increased number of isolates. Hence, the CVM Office of Research microbiology facility was selected to isolate, identify, and susceptibility test retail food samples.

CVM conducted a quantitative risk assessment due to new evidence that drugs used in poultry can cause antibiotic resistant infections in humans, and to better estimate the risks posed from the use of antimicrobials in food producing animals. In November 2000, CVM finalized the quantitative risk assessment entitled "The human health impact of fluoroquinolone resistant Campylobacter associated with the consumption of chicken." Based partly on the results of the Campylobacter risk assessment, CVM proposed to withdraw approvals of the two new animal drug applications for use of the fluoroquinolone antimicrobial drugs in poultry. One of the two sponsors, Abbott has voluntarily withdrawn the product. Bayer is requesting a hearing. If the approval is withdrawn, this drug would no longer be legally marketed for this indication. Other approval uses of fluoroquinolones in cattle, dogs, and cats are not affected by this proposal.

In April 2001, CVM decided to conduct a quantitative risk assessment on the human health impact of the development of the streptogramin (quinupristin/dalfopristin) resistant Enterococcus faecium in humans that is associated with the use of streptogramins (virginiamycin) in food-producing animals. CVM completed a feasibility study and determined that there was sufficient data either available or forthcoming to support a quantitative risk assessment of the human health impact from the use of virginiamycin in food-producing animals.

An advance notice of public rulemaking (ANPRM) for import tolerances was published in the Federal Register in August 2001. The notice seeks comments on the CVM plan to propose a regulation for establishing drug residue (import) tolerances for imported food products of animal origin for drugs that are used in other countries, but that are unapproved animal drugs in the U.S. The issues and questions developed for the ANPRM regarding import tolerances will be the subject of a meeting of the Veterinary Medicine Advisory Committee scheduled for January 22, 23 and 24, 2002.

Under educational and outreach activities, CVM focused on food safety education with the production of two videos, "Keeping Your Guard Up" and "Safeguarding America's Health". In addition, four brochures were printed and distributed on the prudent and judicious use of antimicrobials for dairy, beef, poultry, and swine practitioners; two brochures were printed and distributed on judicious use of antimicrobials for pork and poultry producers. Also, throughout the year, CVM participated in numerous consumer, industry and government conferences (in the United States and overseas) in order to discuss antimicrobial resistance and other food safety initiatives.

Performance Plan Goals

Premarket Review

The first strategic goal the Animal Drugs and Feeds Program presented in the FDA FY 2001 Performance Plan was to increase the availability and diversity of safe and effective animal drugs and feeds.

CVM strives to increase the availability and diversity of animal drugs and feeds by being involved throughout the new animal drug approval process. The Agency is committed to improving the review time for new animal drug application, and improves review time by working with industry sponsors. "Phased review" provides industry sponsors with timely feedback on product applications and may also detect application deficiencies early in the drug approval process. Efforts such as pre-submission conferences, electronic submissions, and guidance documents also help increase industry and FDA efficiency, thereby reducing overall developmental costs.

During FY 2001, CVM processed 5,600 submissions for new animal drug applications (NADAs), abbreviated new animal drug applications (ANADAs), investigational new animal drug files (INADs), generic investigational new animal drug (JINADs) files, master files, and general and related correspondences. The processed submissions included 65 NADAs and ANADAs (original and reactivations) and 1,444 for supplements (original and reactivations) to previously approved NADAs and ANADAs. In addition, 264 phased data review submissions under INADs and JINADs to support approvals were

completed by the Center during FY 2001.

In FY 2001, CVM published 40 documents in the Federal Register regarding significant NADA and ANADA approvals, and a food additive petition. Significant approvals included: two new chemical entities, seven products for use in a new animal species/class, two new dosage forms of a previously approved product and one product available in a new dosage (with flexible administration). In addition, other approvals included eight original generic approvals and three new product indications.

Performance Goal

Review and act on 75 percent of New Animal Drug applications (NADAs) and Abbreviated New Animal Drug Applications (ANADAs) within 180 days of receipt.

Results

CVM reviewed and acted on approximately 50 percent of New Animal Drug applications (NADAs) and Abbreviated New Animal Drug Applications (ANADAs) within 180 days of receipt.

CVM found it necessary to shift focus in its performance regarding animal drug application review in FY 2001. The Office of New Animal Drug Evaluation (ONADE) needed to reduce the backlog of overdue documents. This required working on the oldest, already overdue documents. Decreasing the backlog was necessary in order to move CVM back on track towards meeting statutory and stakeholder requirements for new animal drug application review. By taking the step of closing out the most overdue documents, CVM's on time completion rate for NADAs and ANADAs was adversely affected this year. Although approximately 50 percent of NADAs and ANADAs were reviewed on time in FY 2001, CVM reduced its backlog of pending overdue documents by 1,334 from 2,234 to 900.

Postmarket Activities

The second strategic goal the Animal Drugs and Feeds Program identified in the FDA FY 2001 Performance Plan was to reduce the risks associated with marketed animal products.

Once animal drugs and feeds are marketed, FDA continues to manage public health risks through activities such as inspections and antimicrobial resistance monitoring. Surveillance of marketed products and industry is accomplished through review of drug experience reports, and nationwide monitoring and compliance programs. The field office performs inspections, sample collections and analysis, investigations and other activities. FDA surveillance systems identify potential human and/or animal health hazards. The surveillance systems provide information that assists FDA in the development of strategies to prevent, minimize, or contain problems (such as withdrawing marketed drugs to

protect human and animal health).

Performance Goal

Maintain biennial inspection coverage by inspecting 50 percent of registered animal drug and feed establishments.

Results

The goal was not met in FY 2001. The program did accomplish 37 percent biennial inspection coverage of registered animal drug and feed establishments.

The need to perform BSE inspections became a higher priority in FY 2001 because of the increase in reported cases of BSE in Europe. To minimize the risk of BSE introduction into U.S. cattle herds and to protect the health of American citizens, the program received contingency funding. After re-establishing priorities within the field portion of the Animal Drugs and Feeds Program, BSE inspections were instituted to ensure that 100 percent of renderers, protein blenders, and feed mills were inspected; and to conduct sample analysis to assure compliance with the BSE regulation. The BSE crisis in England and Europe made it apparent that 100 percent of renderers, protein handlers, and feed mills handling prohibited material would need to be inspected every year to continue to protect US cattle herds from BSE and the health of American citizens.

Based on this change in priorities, the goal for FY 2002 has been changed to include re-inspection of 100 percent of firms found to be out of compliance, 100 percent of renderers, protein handlers, and feed mills, handling prohibited material, and as many other firms in these businesses, as resources allow, that we currently have listed as not handling prohibited materials, and to conduct sample analysis as needed to assure compliance with the BSE regulation.

From FDA Consumer Magazine, January-February 2001

A New Kind of Fish Story: The Coming of Biotech Animals

Potatoes with built-in insecticide. Rice with extra vitamin A. Decaf coffee beans fresh off the tree. Just when Americans have begun to digest the idea of custom-built crops, along comes another major advance in biotechnology that could make an even bigger splash onto the dinner plate: genetically engineered fish.

Using the same type of gene transfer techniques that give plants new, more desirable traits, scientists have created a genetically engineered variety of Atlantic salmon that grows to market weight in about 18 months, compared to the 24 to 30 months that it normally takes for a fish to reach that size. For fish farmers, raising these so-called transgenic fish could be faster and cheaper because it takes less feed and about half the time to produce a crop they can send to market.

Despite these benefits, genetic engineering of animals has met with some of the same resistance already aimed at designer crops. Critics cite ecological concerns, ethical objections and food-safety issues.

But no matter how transgenics is applied, the Food and Drug Administration will play a key role in regulating the products resulting from this rapidly emerging genetic technology. This means that any drug or biologic created through transgenic techniques will need to undergo the same FDA scrutiny as any other treatment that a company wants to market, including clinical trials that demonstrate safety and effectiveness. And while it's still too soon to tell how quickly foods derived from transgenic animals will move to the market, FDA has already begun to focus on how it will ensure that they meet the same safety standards as traditional foods.

Making a transgenic animal is deceptively simple, especially when compared to traditional breeding approaches. With genetic engineering, scientists possess the tools to isolate and manipulate single genes in the laboratory. In recent years, researchers have learned to insert single genes into the fertilized eggs of animals in such a way that the new gene is turned on in the resulting adult.

However, when it works, the result is a new individual of a variety of animals with a characteristic never before seen. The individual animal can then be multiplied by conventional breeding. The resulting animal may be enormously valuable. But even though the medical applications of transgenics remain intriguing, the animal health and food production applications seem to be generating most of the new excitement and considerable concern.

The best example so far of the transgenic strategy in food animals, and its success, is the faster-growing salmon.

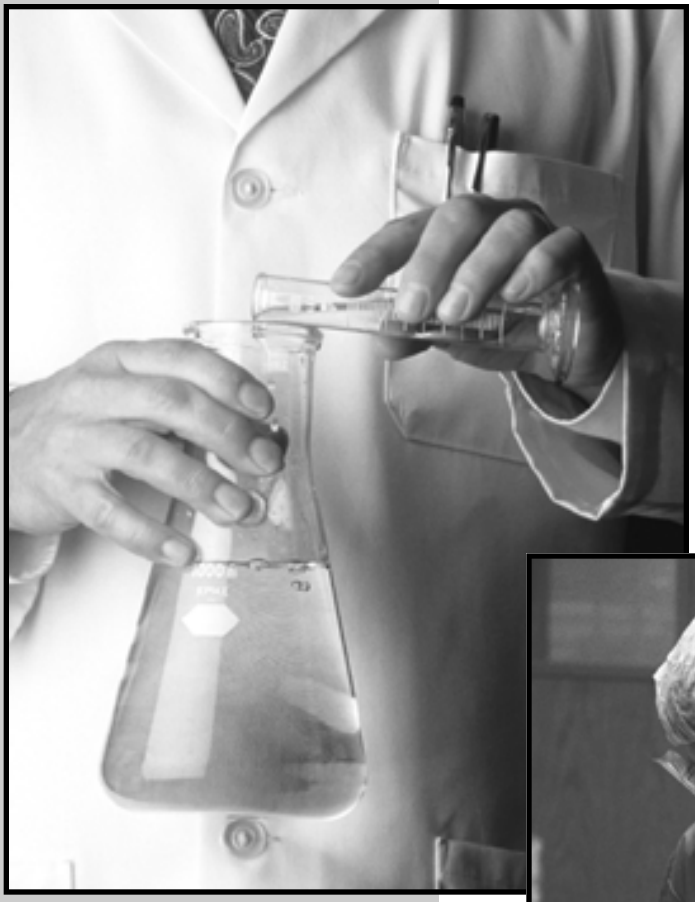
In general, CVM's [John] Matheson, [toxicologist] says that for animal safety, the goal of regulating products of animal biotechnology is to ensure healthful surroundings, proper medical treatment, discovery of any special management measures needed, and freedom from pain and suffering. FDA already has the legal authority to regulate most products derived from transgenic animals, whether they are used as drugs, as human food, or as animal feed. Therefore, only guidances or regulations that cover specific aspects of animal biotechnology may need to be added-not whole new statutory frameworks for regulating the products.

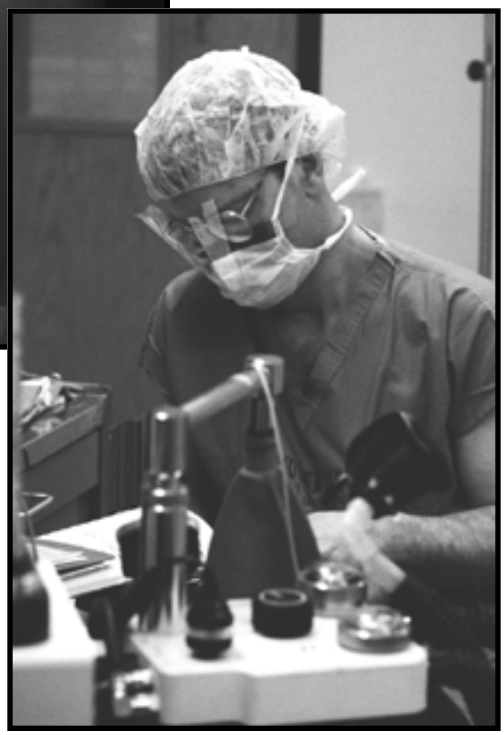
Most of the gene-based modifications of animals for food production fall under CVM regulation as new animal drugs. The genetically modified growth hormone for the fish, for example, will be regulated the same way the agency regulates bovine somatotropin, the genetically engineered bovine growth hormone that makes cows produce more milk. Transgenics simply provides another means to add growth hormone to an animal.

At this time, no transgenic animals have been approved to enter the human food supply, but a few individual transgenic animals have been allowed to be rendered and used in animal feed.

FDA Programs

Toxicological Research





Toxicological Research

Background

The National Center for Toxicological Research (NCTR) 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. Specific aims of NCTR's research are:

- To develop new strategies, methods, and systems to predict toxicity and anticipate new product technology in order to support FDA's commitment to bring this technology to the market rapidly.
- To understand mechanisms of toxicity and design better risk assessment/detection techniques and methods for use in premarket review and product health surveillance.

NCTR provides FDA with a high-quality, cost-effective, health science research program, that supplies new scientific knowledge through the application and leveraging of research findings from NIH, partnerships with other federal agencies, national and international organizations and academia to enhance the Agency's regulatory practices.

As a critical resource for enhancing the science base of the FDA, the NCTR Center Director and scientists foster scientific forums with NCTR's stakeholders, namely the FDA Centers and ORA. These recurring discussions allow NCTR the opportunity to present and validate its planned/ongoing research, as it relates to the Agency's priorities, as well as to solicit the anticipated research needs of the product centers and ORA.

Costs

Fiscal Year	Net Program Costs (000s)
2001	$43,033
2000	$43,347
1999	$40,420

The Toxicological Research Program experienced a 0.7 percent decrease in net costs in FY 2001. This decrease is due in part to the large amount of exchange revenue received by the program. The net cost includes the total expenses for a program, including the allocation of overhead expenses (such as the Office of the Commissioner's costs [e.g., administrative and policy direction] and other overhead), less exchange of revenue.

Selected Initiatives, Goals and Accomplishments

New Internet Journal to Foster Regulatory Research

In July 2001, NCTR launched an Internet journal entitled, Regulatory Research Perspectives: Impact on Public Health. This journal is meant to provide FDA scientists a means of communicating specific information to colleagues within the Agency and the scientific and public community in general. Contributions are solicited from every FDA Center and the Office of the Commissioner. It is hoped that these articles are written in plain language so that the topics that are of significance to FDA may reach a broad audience. The first article is summarized on page I-74 [see box] and may be found at www.fda.gov/nctr/science/journals/Default.htm.

Performance Plan Goals

Risk Assessment for Regulated Products

As identified in the FDA FY 2001 Final Performance Plan, the first strategic goal of NCTR 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 human products. This capability is critical to the Agency's ability to carry out its mission to analyze the safety and efficacy of FDA-regulated products during the premarket application 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 human risk using appropriate animal and non-animal models.

Performance Goal

Introduce the knowledge of new genetic systems and computer-assisted toxicology (bioinformatics) into the application review process. The performance measure for FY 2001 is to provide peer reviewed articles on new genetic and transgenic systems and knowledge to product reviewers.

Currently, industry has been submitting drug applications with data from transgenic systems. It is critical that NCTR scientists in collaboration with Agency reviewers understand and accurately interpret data derived from these systems in safety assessments.

NCTR is developing, evaluating, and comparing in vivo and in vitro transgenic systems and computer-assisted technology knowledge bases for this purpose. Reviewer requests for data or information on transgenic systems will be the measure of applicability to the review process.

Results

NCTR geneticists have developed a new in vivo assay for the evaluation of mutant induction. This assay was modeled after the in vitro assay, the mouse lymphoma assay, already used internationally for hazard identification. The assay uses the thymidine kinase gene (tk) and the in vitro assay has been extensively evaluated for its mechanistic basis shown to detect most, if not all, of the mutational events important to the induction of cancer and other human diseases.

FY 2001 performance results include:

- Submission of the findings of the mouse targeted $Tk^{+/-}$ in vivo system for publication in the peer-reviewed Journal of Environmental and Molecular Mutagenesis;
- Submission of a manuscript reflecting the results of the transgenic model for mutation detection using fluorescent markers for review; and
- Publication of a manuscript in the journal Mutation Research that describes the evaluation of genotoxicity of phytoestrogens in the AHH-1-human lymphoblastoid system.

Methods for Use in FDA Standards Development and Product Risk Surveillance

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

FDA has continuously sought to strengthen its scientific basis for food safety policies and regulatory decisions through the development of novel, vigorous risk assessment (models and techniques), and through the use of artificial intelligence and computational science for risk assessment.

Performance Goal

Develop methods and build biological dose-response models to replicate bacterial survival in the stomach. The FY 2001 performance measure is to provide a model to replicate bacterial survival in the stomach.

NCTR is developing methods to identify markers of foodborne pathogens and to assess whether these microorganisms are undergoing change, thus becoming more virulent. To

address the question of human risk from food pathogens, NCTR scientists have worked to build biologically based dose-response models of microbial infection to assess survival, growth, and infectious components of microbial risks. Research within this goal capitalizes on partnerships with other FDA centers (CVM and CFSAN) and with other agencies such as the U. S. Department of Agriculture.

Results

In collaboration with CVM, NCTR microbiologists have been performing pre-validation studies on an in vitro system that examines the effect of low-level antibiotic residues on the human intestinal microflora by using a chemostat to model the human intestinal tract. The effect of the antibiotic residues is determined by (a) change in cell numbers of target intestinal microflora species, (b) changes in the metabolic activity of the fecal flora, (c) development of bacterial strains resistant to the test antibiotic, and (d) disruption of the resistance to colonization by pathogenic microorganisms (barrier effect). Using this in vitro system, three different concentrations of the fluoroquinolone antibiotic ciprofloxacin were tested. Studies clearly indicate that the in vitro culture system can be a valuable tool to evaluate the effects on the human intestinal microflora of low levels of antimicrobial agents in food.

The spread, transfer, and prevalence of antibiotic-resistant pathogenic microbes may have a major public health impact and the cost of treatment could strain the public health care system. NCTR scientists are equipped and will continue to find scientific solutions to this emerging public health issue.

Performance Goal

Use new technologies (bioinformatics, imaging, proteomics, and metabonomics) for diagnosis of toxicity. This is a new performance goal for FY 2001. The performance measure is to develop at least three concept papers exploring new technologies for the assessment of toxicity.

Staying abreast of new technologies in science is important for the Agency to protect public health. These new technologies have great promise on the mechanistic understanding of toxicity responses in the human as well as in rodent surrogate systems and will establish core competencies within FDA that can form a foundation for future high technology science.

Results

Three concept papers submitted and approved under this performance goal include:

- Design and analysis of gene array expression data. This protocol includes developing

statistical and computational procedures for the design, analysis, and interpretation of gene expression data from microarray experiments.

- Development of glass-slide based oligonucleotide microarrays for rat and human genes. This project includes developing, printing, and establishing the methodology for using a “rat chip” containing approximately 4,000 genes and a “human chip” containing approximately 8,300 genes.
- Two-dimensional micro-LC-proteonomics using stable-isotope affinity tags for differential display of toxicity-induced biomarkers. This project addresses the need to develop biomarkers of toxicity, disease progression/regression, and efficacy of drug treatment.

Techniques developed under this goal will further utilize the emerging knowledge of the human genome and rapid biological analyses to improve human health, and to insure the safety of marketed products.

FDA/NCTR, Regulatory Research Perspectives: Impact on Public Health, July 2001, Volume 1, Issue 1

Human Health Impact and Regulatory Issues Involving Antimicrobial Resistance in the Food Animal Production Environment

Antibiotics are the “miracle drugs” used for treatment and prevention of disease in humans, pets, and in food producing livestock, poultry, and fish. Reports of antibiotic-resistant bacteria isolated from farms and animal carcasses are raising concerns that antibiotic use in agriculture may play a role in selecting for antibiotic resistance among foodborne bacteria. Emergence of antimicrobial resistance is a very controversial issue.

Some contend that the indiscriminate use of antibiotics in agriculture creates a reservoir of resistant microorganisms in the environment that could infect humans through the food chain. Others contend that the abuse of antibiotics in human medicine may instead be largely responsible for the increase in antibiotic resistance. Animal drug industry representatives feel that there is not enough evidence to conclusively demonstrate a link between the use of antibiotics in food animals and the emergence of antibiotic-resistant bacteria. Thus, the research and regulatory issues on anti-microbial used in food-producing animals are of great importance to the FDA and the NCTR.

To address issues involving antibiotic resistance, NCTR has established collaborative research agreements with the FDA's Center for Veterinary Medicine (CVM), the Arkansas Poultry and Livestock Commission, and the Department of Poultry Sciences, University of Arkansas, Fayetteville, Arkansas. In addition, the NCTR has established collaborative agreements with chicken and turkey growers. Specifically, NCTR microbiologists:

- developed simple, rapid, sensitive detection techniques to identify pathogenic, drug resistant strains of bacteria;
- developed a standardized assay for determining the effectiveness of competitive exclusion products; and
- are developing new in vitro systems to assess the safety of drug residues.

NCTR provides results of its investigations to the FDA to assist in formulating regulations to help contain the spread of drug-resistant microorganisms and protect the efficacy of the “miracle drugs” for future use.

Financial Management and Analysis

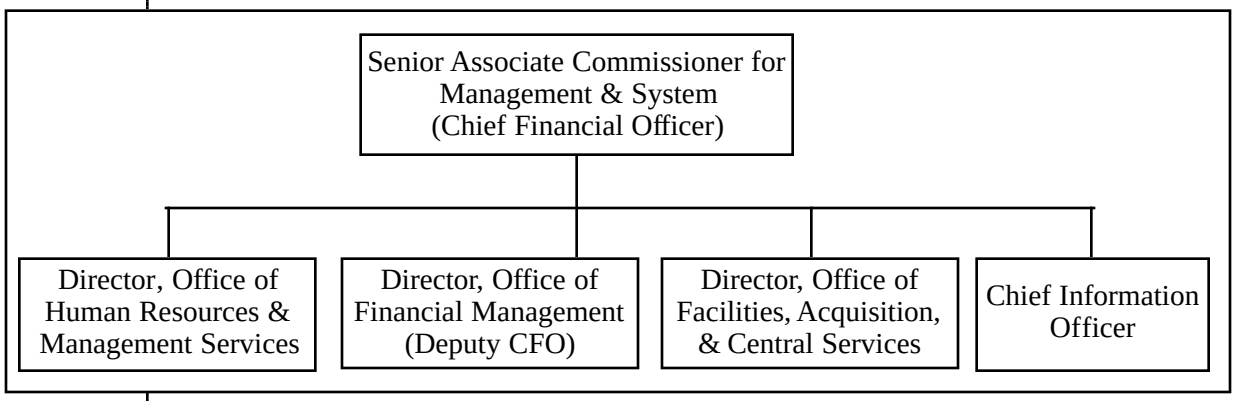
Financial Management and Analysis [18]

The purpose of this chapter is to provide an overview of FDA's Chief Financial Officer's organization, highlight key financial performance results and select administrative accomplishments, and review the status of FDA's systems, controls and legal compliance. The chapter will also examine FDA's principal consolidated financial statements – highlighting significant changes from the prior year.

FDA's Chief Financial Officer's Organization

The Senior Associate Commissioner for Management and Systems serves as FDA's Chief Financial Officer and head of the Office of Management and Systems (OMS) within in the Office of the Commissioner. The OMS provides the infrastructure and support for FDA's programs to conduct their work. These programs include human resource management, budget preparation and financial management, procurement and grants management, logistical and facilities services, and information networks and systems. See Figure 12 for organizational chart.

Figure 12



The FDA CFO measures financial management performance to comply with external requirements, improve internal processes, and strengthen management controls and systems. The results provide timely and accurate information on FDA's financial condition, cost of operation, and future resource assessments.

Financial management performance goals are developed in a number of ways:

- Good management practice within the OMS. The FDA CFO reports on select administrative accomplishments through the annual OMS performance report that describes the major OMS initiatives and results achieved during FY 2001.

[18] The Department's Accounting Manual, Chapter 5-20, "HHS 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.

- FDA's submission to the DHHS Financial Management Plan. This is a forward looking document spanning a five year period by which DHHS and its operating divisions seek to improve financial management processes and systems, and implement new financial requirements.

Since 1990, there has been an explosion of laws impacting financial management. The list of legislation[19] requiring action related to financial management includes:

- Chief Financial Officers Act of 1990
- Government Performance and Results Act of 1993
- Government Management Reform Act of 1994
- Federal Acquisition Streamlining Act of 1994
- Federal Financial Management Improvement Act of 1996
- Debt Collection Improvement Act of 1996
- Information Technology Management Reform Act of 1996
- Travel and Transportation Reform Act of 1998
- Federal Activities Inventory Reform Act of 1998
- Federal Financial Assistance Management Improvement Act of 1999
- Reports Consolidation Act of 2000

- Corrective Action Plans arising from annual financial statements audit reports. These plans contain process improvement goals for correcting identified conditions found in the financial statement audits.

Selected Initiatives, Goals, and Accomplishments

Selected several initiatives that were accomplished during FY 2001. These are described below.

Complete the roll-out of the Enterprise Administrative Support Environment (EASE) to the entire Agency.

The Office of the Information Resources Management (OIRM) reported that it completed its objective—over 9,000 employees are on the EASE system, except for multiple appointment consultants who are still being paid manually at this time.

The completion of this goal will permit the full migration to electronic time and attendance—thereby improving efficiency of processing time records and improving the effectiveness in regards to accuracy of records inputted into the system.

[19] See Appendix 2 for a description of the laws affecting Federal financial management today.

Improve network management through a variety of process improvements.

The FDA wide area network was migrated from the Federal Telecommunication System 2000 to the FTS 2001 contract. The network topology was reengineered for better performance. OIRM also implemented new equipment that can support performance and security features.

Survey the FDA workforce to determine the quality of work life satisfaction.

The Office of Human Resources and Management Services reported that 80 percent of the employees say that they are able to balance their work and family life due to programs such as "any 80 hours worked, flexiplace arrangements, and alternative work schedules." FDA has eighteen percent of the workforce participating in some sort of work at home program. When compared to the overall Federal participation of three percent, FDA is one of the leaders in using alternative programs.

Improve the labor management by participating in initiatives that promote well-being of FDA employees.

The FDA and National Treasury Employees Union established a national labor-management partnership council in early FY 2001. During the past year, they developed a joint Collective Bargaining Agreement training, established the FDA Smoking Cessation Program; and developed the FDA Child Care Subsidy Program.

Create a FDA Facilities Operation Plan

The Office of Facilities, Acquisition, and Central Services (OFACS) implemented a facilities operations plan that will enable them to improve the level of service to FDA Centers and to ORA. This plan has a number of operational changes that will improve communications, improve performance and solicit customer feedback which should increase the level of trust and confidence in the Centers and ORA in OFACS's provision of services to these organizations.

Improve FDA's Security Program

OFACS recruited and hired a highly qualified Director of Security Operations, Policy, and Planning for the Agency. It also developed a FDA contingency of operations plan (COOP).

OFACS established enhanced security measures at FDA headquarters and Field locations after the terrorist attack of September 11, 2001; and is conducting an assessment of security needs at each FDA facility.

Improve communication with budget stakeholders inside and outside of the Department.

The Office of Financial Management (OFM) and other units within the Agency worked closely to improve the communication of FDA resource issues and mission priorities with Departmental, OMB, and congressional staffs. OFM facilitated informational briefings and visits to FDA facilities to improve the understanding of FDA's mission.

Funds Control

OFM developed a new training manual on procedures for implementing reimbursable inter-agency agreements where FDA receives income from other agencies. Training sessions were conducted for all of FDA components.

Gainsharing Initiative

Working with the Office of Human Resources and Management Services and the FDA's Union, National Treasury's Employees Union, OFM established a travel gainsharing program in FDA. The new General Services Administration (GSA) approved effort allows employees to share in the savings when they contribute Frequent Flyer miles to defray the cost of TDY transportation, or stay in lodging that is less than GSA approved amounts.

Travel Manager Project

OFM is implementing "Travel Manager," an off-the-shelf software system throughout FDA. This software is used throughout the federal government for automating the travel process. The software includes:

- Generating Travel authorization and vouchers with electronic signature approval;
- Initiating electronic payments to travelers; and
- Provide updated per diem rates and carrier rates.

Accomplishments for FY 2001 include:

- Initiated Phase II of the Travel Manager project where the goal is to have the FDA traveler paid within 48 to 72 hours after final approval of the voucher. To achieve this goal, a set of audit rules was established where the authorization and voucher were actually audited within Travel Manager eliminating the need for an audit of the voucher;
- Developed an accounting interface that eliminated duplicate data entry of obligations into FDA's accounting and Center Financial Management systems. This eliminated the main cause for delays in paying FDA travelers; and

- Trained the EASE Help Desk in resolving user related Travel Manager problems, leveraging the Help Desk already established in support of the EASE project.

Streamlining Financial Processing in the Field

To meet the requirements for the new DHHS unified financial management system, OFM is consolidating its Treasury payment and collection operations from 15 agency location codes (ALC) to one, and reducing the number of field office accounting points from 25 to seven. This centralization would enable OFM to manage the payment disbursement and receivable collections from one location. This will facilitate the preparation and generation of Treasury reports, but more importantly, allow OFM to meet the increasing demands from DHHS and OMB, support compliance to the Federal Financial Management Improvement Act and OMB Circular A-127, and enhance security by meeting the internal controls recommended by OMB Circular A-130. The one ALC structure is consistent with JFMIP approved off the shelf Core Accounting Systems. A project team has developed a concept of operations model to scope out the type of financial management that should be performed by OFM and other components.

Financial Management Performance Measures and Results

Financial Statements Audit

OFM prepares annual financial statements as set forth by the requirements of OMB Bulletin 97-01, "Form and Content of Agency Financial Statements," as amended, 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 issues 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 6 for the past four years with the number of findings in parenthesis.

Table 6

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

For the five reporting periods (FY 1997 through 2001), FDA has received four unqualified [20] 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 past four periods, FDA received no material weaknesses.[21] FDA has made considerable progress in resolving three material weaknesses that were declared in the FY 1997 CFO audit report. In the subsequent audit reports, these prior findings were lowered to the level of reportable conditions due to corrective efforts implemented by FDA.

In the FY 2000 audit report, FDA received a reportable condition in FDA's information systems controls and a finding of non-compliance to the Federal Financial Management Improvement Act (FFMIA). A series of short-term and long-term actions was implemented to address these findings. The long-term actions addressed the eventual replacement of FDA's financial management system with a system that meets all of the Executive Branch requirements. In June 2001, the Secretary of HHS, in keeping with his one "DHHS" centralization theme, decided against decentralized accounting systems proposed by DHHS operating divisions. He chose an approach that included two financial management systems that would serve the Department and its operating divisions. Since the Secretary's announcement, FDA personnel have actively participated in the Department's planning efforts for the unified system to help ensure that the system satisfies FDA's financial requirements.

The FY 2001 audit report included one reportable condition in FDA's information system controls and the same FY 2000 finding of non-compliance to the FFMIA. FDA made improvements to address the deficiency in FDA's information systems controls. Some of these included the completion of certification and accreditation statements for FDA's general support system, and implementation of new procedures covering tracking software changes, dial-up point-to-point account management, and test plan standards. To address the continued FFMIA non-compliance, FDA is working to ready itself for the eventual implementation of the DHHS system by consolidating accounting reconciling and reporting functions, conducting data assessment and clean up, and preparing the Agency financial community for the coming changes.

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[20] 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 applicable to the entity.

[21] 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 or Required Supplementary Stewardship Information 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.

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 facilitate reconciliation process, and to improve collection procedures for monies that are owed to DHHS.

Compliance with Prompt Payment Act

FDA had a FY 2001 target of 96 percent of commercial vendor payments made on time. FDA reported that it had achieved a payment rate of 98.7 percent which meant it had met its objective.

In a related matter, the Division of Accounting conducted a process reengineering initiative examining invoice payments, specifically those that require receiving reports prior to payment. The process improvement team included members from OFM and the Centers. This collaborative effort resulted in reduced interest payments and increased customer satisfaction by maximizing the use of e-mail notification to match or follow-up on receiving reports, by providing training to OFM staff, and by establishing a central contact point to focus on receiving report issues. The result will be reduced interest penalties paid by the Agency.

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. This requirement became effective in DHHS during the middle of FY 2000. 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 any problem area.

The FY 2001 target of timely payment of approved travel vouchers within 30 calendar days of submission to first-level reviewing officials is 95 percent. During FY 2001, 97 percent of approved travel vouchers were paid within 30 calendar days, which exceeded the goal.

Improve collection of debt owed to FDA

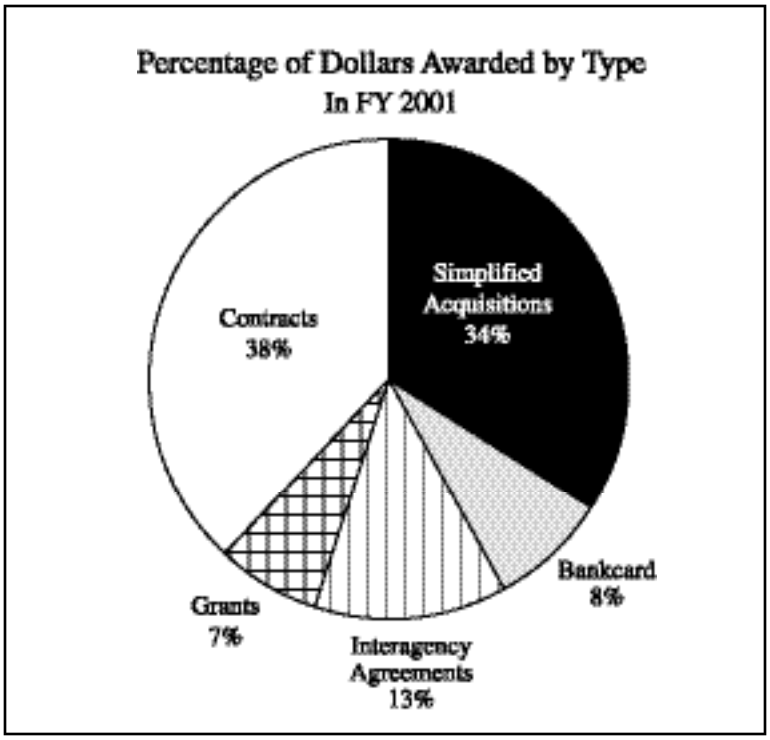
Collection of debts owed to FDA is also an important aspect of sound financial management and business practice. FDA will continue to focus on increasing collections as part of its compliance with the Debt Collection Improvement Act of 1996.

The FY 2001 target was to increase collections by ten percent over the prior year. FDA accomplished this target in FY 2001.

Contracting Program

OFACS administers contracts, small purchases, Bankcard (credit card) program, and grants. In FY 2001, the total of the contracting program was $145.6 million in contracts, $131.5 million in simplified acquisitions, $29.4 million in Bankcard transactions, $51 million in interagency agreements, and $26.1 million in grants. See Figure 13 for a graphic representation.

Figure 13

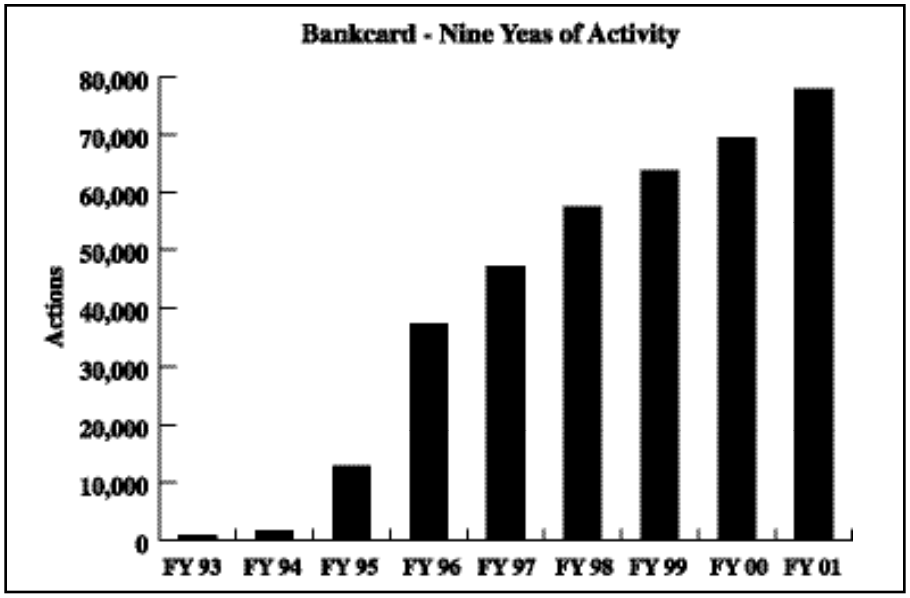


Bankcard Actions

FDA has participated in this purchase card program since 1989. Currently, all FDA components are using the cards. Cardholders are authorized for transactions of no more than $2,500 per single purchase (with some exceptions), and are subject to monthly cumulative limits. Cardholders can acquire 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 2001, FDA completed 77,926 purchase card transactions. The Agency's usage trend can be seen graphically in Figure 14 on next page. Improvements for FY 2001 include the development of a web-based training for cardholders, approving officials and central control points.

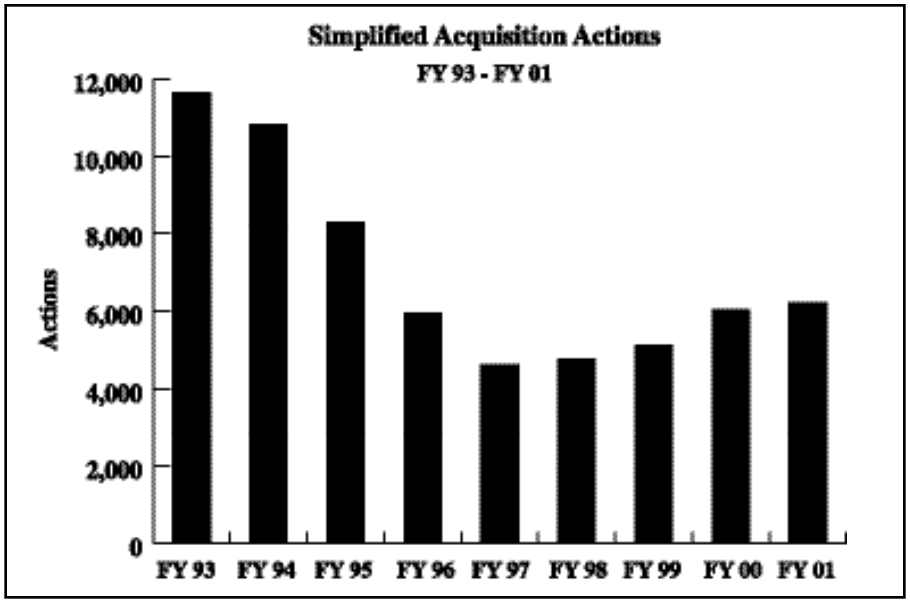
Figure 14



Simplified Acquisition Actions

The term, "Simplified Acquisitions," apply 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 off of the GSA Schedule under $2,500 may be purchased without further competition; however, purchases over $2,500 must be competed amongst GSA Schedule vendors. In FY 2001, FDA experienced some growth in this purchase type. See Figure 15 to display nine years of simplified acquisitions actions.

Figure 15



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[22] that support the preparation of financial statements and financial documentation. This is accomplished 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 all levels of management throughout FDA to become involved in the FMFIA review and reporting process. This approach utilizes 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. As such, 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.

Management Controls Review

During FY 2001, 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 FY 2001 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 currently conform to these requirements because the prior year's Chief Financial Officer's (CFO) Act audit findings reveal several instances of non-compliance to the FFMIA.

The Offices of Financial Management and Facilities, Acquisition, and Central Services developed a corrective action plan outlining the actions needed to remove the finding of non-compliance to FFMIA. Since the Secretary's June 2001 announcement creating a unified financial management system (UFMS), FDA personnel have actively participated in the development and implementation of the system. Additionally, FDA has undertaken specific activities, such as streamlining accounting functions and consolidating Treasury disbursing activities in field locations, to prepare for the deployment of the UFMS.

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22 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.

Financial Analysis

The purpose of this section is to provide a discussion on the principal financial statements highlighting significant changes from the prior year conditions.

Financial statement reporting is required to be displayed in several formats as specified by the Federal Accounting Standards Advisory Board and OMB Bulletin 97-01, "Form and Content of Agency Financial Statements," as amended. The purpose of the five required financial statements are summarized in Table 7:

Table 7

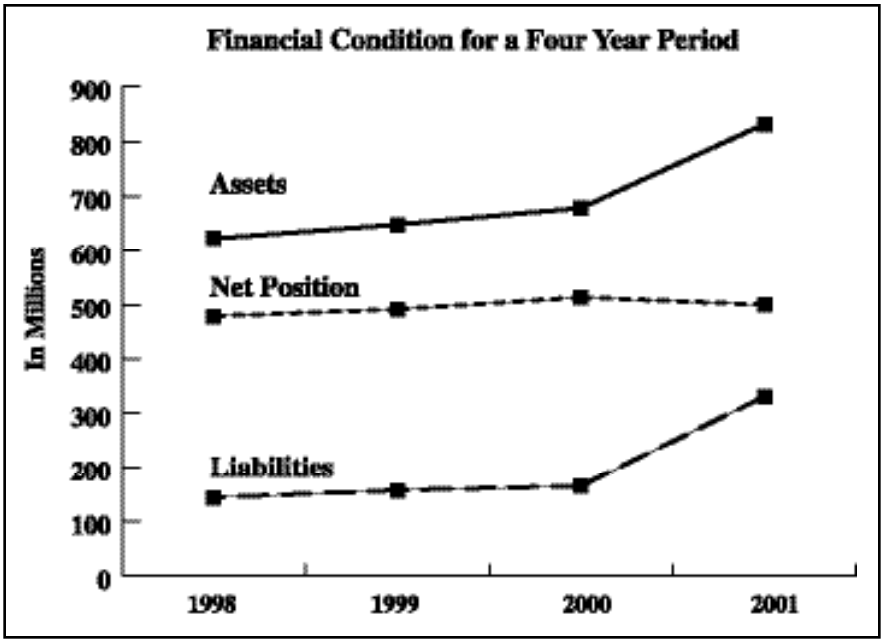
Financial Statement	Description
Balance Sheet	Reports the operating assets, liabilities, and net position. Provides a "snap-shot" of FDA's financial condition as of the fiscal year-end.
Net Cost	Breaks down total expenses by the seven major programs of FDA's budget, net of exchange revenues and after allocation of indirect expenses such as administrative, field operations, rent, and other overhead.
Changes in Net Position	Provides information on the changes in financial position from year to year and the causes of the changes.
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.
Budgetary Resources	Provides information on total budgetary resources available, the status of those resources, and outlays. Helps to assess budget execution and whether budgetary accounting rules are being followed. One must be careful to recognize the differences between expenses recorded on an accrual basis of accounting as compared to obligations reported on the Statement of Budgetary Resources.

Discussion on Select Financial Statements

Agency's Financial Condition

The balance sheet reflects a positive net position (assets less liabilities). When compared to the past three fiscal years (FYs 1998, 1999, and 2000), the growth of net position as shown in Figure 16 is due to a variety of reasons. FDA has been revitalizing its physical infrastructure for several years. New state-of-the-art scientific equipment, office furniture, counter-bioterrorism initiative, and building related systems were acquired to outfit new regional laboratories (ORA's New York and Arkansas Regional Laboratories) and headquarters consolidation (the Center for Food Safety and Applied Nutrition is moving to College Park, Maryland in February 2002). FDA received additional appropriated monies for premarket review activities. However, the most significant reason is the civil monetary penalties derived from Federal court-approved consent decrees. For FY 2001, more than $100 million in resources payable to the Treasury Department flowed to FDA.

Figure 16



Costs

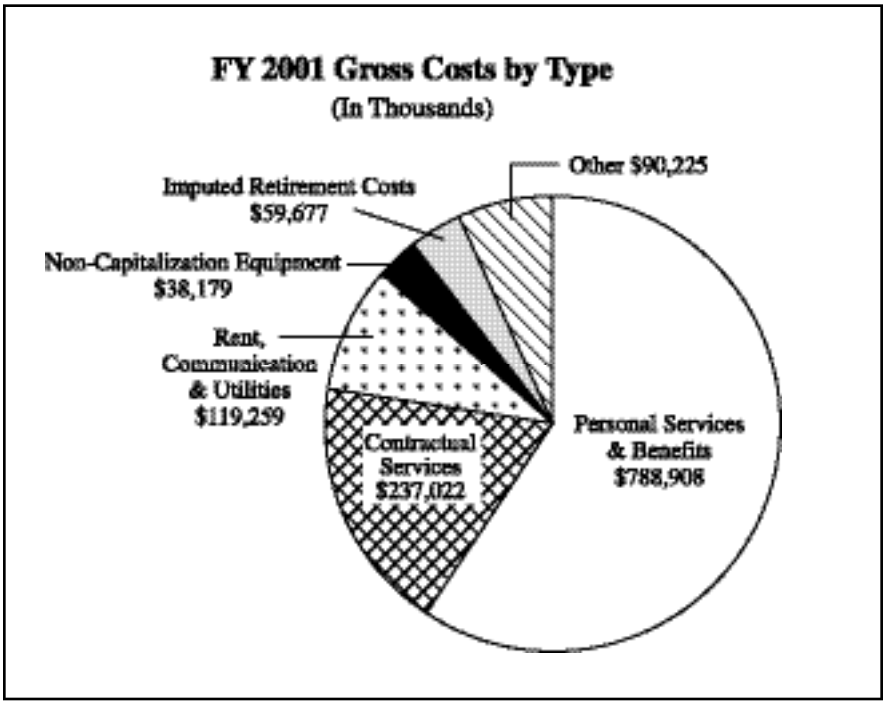
Gross FY 2001 expenses were $1.33 billion, which includes projects funded by user fees. Deducting $177 million in earned revenues, FY 2001 net costs were $1.15 billion. This compares with gross expenses of $1.25 billion and net costs of $1.07 billion for FY 2000. Figure 17[23] and Figure 18[24] (on following pages), illustrate FDA's expenses by type and

[23]Source: Supplemental Statement of Net Cost by Expense Type and Program, FY 2001. Please note that some rounding differences may show a different total than the supplemental statement.

[24]Source: Supplemental Statement of Net Cost by Program Costs by Appropriation, FY 2001. Please note that Tobacco program area is not shown in Figure 21. Its net program cost was $297,000 in FY 2001.

program. These are the budget programs reported under GPRA, which represent FDA's major responsibility segments. Amounts reported on the Statement 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.

Figure 17

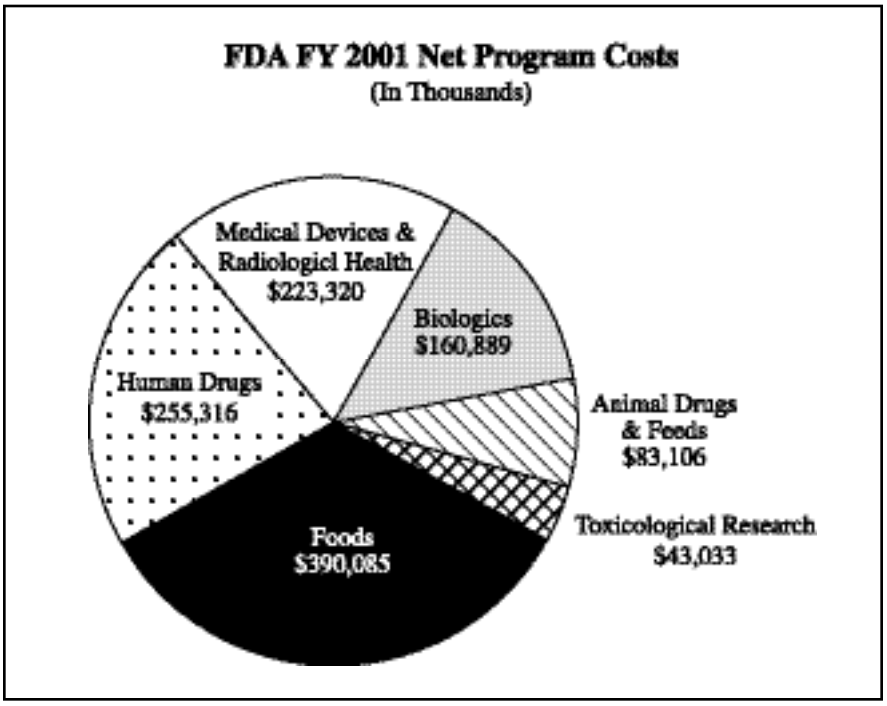


- Personal Services & Benefits rose by 6.6 percent from $740 million in FY 2000 to $788.9 million in FY 2001, due to increases from the Congress on funding the food safety initiative, premarket application review processes, inspections, enforcement of Internet drug sales, counter-bioterrorism activities, and improving generic drug application review and approval times.

- Contractual Services increased by 8.5 percent from $218 million in FY 2000 to $237 million in FY 2001, due to increases from the Congress on funding the orphan product grants, food safety initiative, and establishing an agricultural products testing laboratory with the New Mexico State University.

- Non-capitalized equipment (formerly called expendable equipment) increased by 36.4 percent from $28 million in FY 2000 to $38 million in FY 2001. This increase is due to the additional funding increases approved by the Congress.

Figure 18



- The Animal Drugs and Feeds Program's FY 2001 net costs increased by 30.7 percent from the FY 2000 due to funding increases for the food safety initiative and for premarket application review activities.

- The Biologics program's FY 2001 net costs increased by 21.1 percent due to funding increases for counter-bioterrorism initiative and for premarket application review activities.

- The Medical Device and Radiological Health Program's net costs increased by 9.6 percent from the FY 2000 due to a funding increase for the premarket application review activities.

- The Foods Program's net costs increased by 6.9 percent due to continued funding of the food safety initiative, increases for dietary supplements, and the relocation of CFSAN to its new facility located in College Park, Maryland.

- The Human Drugs Program's net costs grew by 1.6 percent due to increases in user fees authorized by PDUFA II and a Congressional increase for FDA's premarket application review processes.

Financing

The Consolidated Statement of Financing is designed to report the difference in accrual based measures used in the Statement of Net Cost and obligation-based measures used in the Statement of Budgetary Resources. In order 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 Statement 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 mainly of three items: change in budgetary resources obligated but goods or services not yet received, resources that finance the acquisition of assets or liquidation of liabilities, and resources that fund expenses recognized in prior periods.

FDA's budgetary resources obligated but not yet received increased by $37.3 million from FY 2000 to FY 2001 and represent obligations recorded during FY 2001 for which expenses will not be incurred until a subsequent period. The acquisition of assets or liquidation of liabilities totals $35 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 previous periods, totaling $3.6 million, represent unfunded expenses recognized in prior periods but paid with FY 2001 obligations.

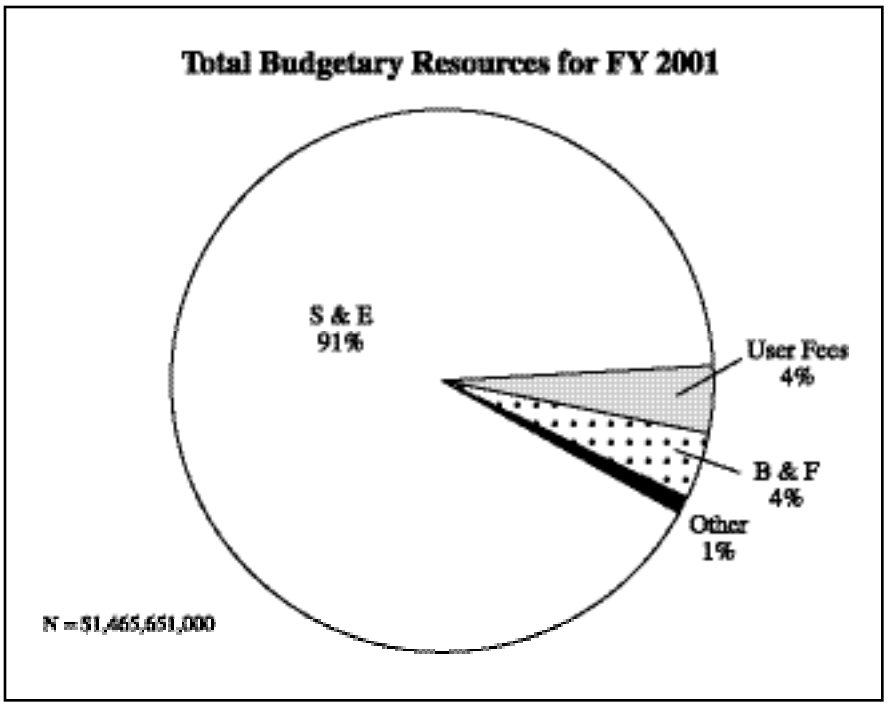
Costs that do not require current year resources are costs that do not require financing by either budgetary or non-budgetary resources. FDA's primary cost in this category is depreciation and amortization totaling $15.4 million. Depreciation and amortization should be added in the reconciliation because it is part of the net cost of operations but not included in current year obligations, as adjusted, and non-budgetary resources.

The costs of the Federal government are not always funded in the period the costs are incurred. Costs of this nature are incurred in the current reporting period, but are normally funded through appropriations in subsequent years. Costs which are funded in future periods total $10.1 million as of September 30, 2001, and represent an increase in financing sources yet to be provided. The primary items in this category are unfunded annual leave expense and actuarial FECA liabilities. Both categories experienced increases of $5.3 million and $1.9 million, respectively. The increase in costs funded in future periods is included 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

As presented in the Statement of Budgetary Resources, FDA's budget authority for FY 2001 was $1.126 billion, not including spending authority of $190 million from user fee and reimbursable collections. Total budget authority as of September 30, 2001, including offsetting collections, carry-over balances from prior years and adjustments, was $1.466 billion. Of this amount, $1.38 billion had been obligated during FY 2001. Figure 19 shows the total of budgetary resources[25] by major type -- salaries and expenses; user fees; buildings and facilities; and other minor accounts, such as certification fund and royalties.

Figure 19

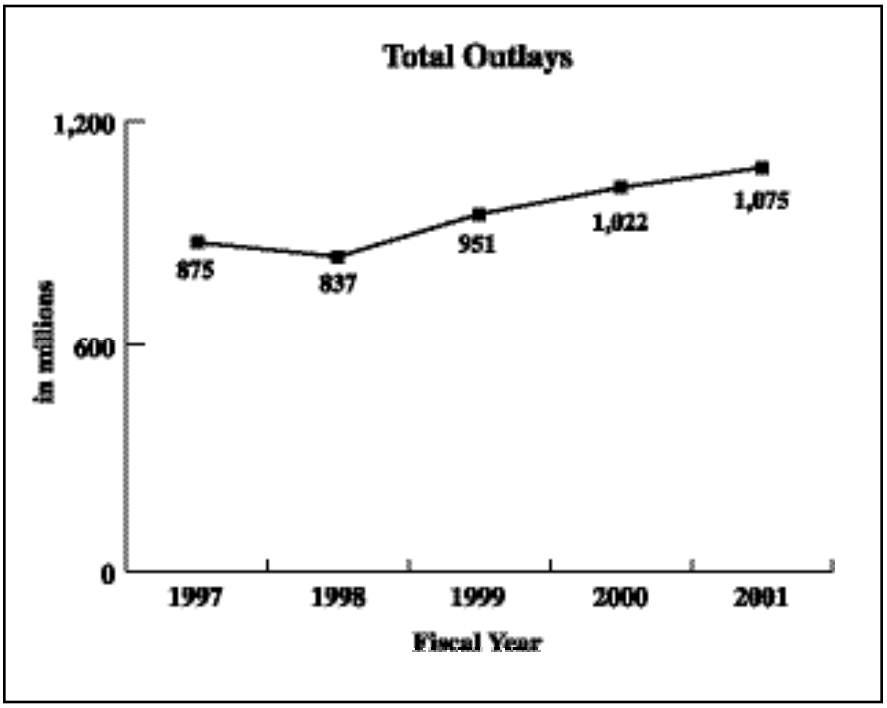


Total outlays were approximately $1.07 billion during FY 2001, which represents a 5.1 percent increase over FY 2000 total outlays of $1.02 million.

25 Source: Combining Statement of Budgetary Resources for the Year Ended September 30, 2001.

Figure 20 shows FDA's outlay trend over the past five fiscal years. For FY 2001, FDA received budgetary increases to cover the food safety initiative, premarket review activities, inspections, enforcement of Internet drug sales, counter-bioterrorism, dietary supplements, constructing the Los Angeles Laboratory, improving generic drugs' review, and improvements to FDA's post-approval surveillance to identify adverse events associated with products on the market.

Figure 20



26 Source: Combined Statement of Budgetary Resources, FY 2001

Use of Financial Statements

For the preparation of the Food and Drug Administration (FDA)'s annual financial report, the Office of Management and Budget (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 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 97-01 and are unaudited.

Consolidated Principal Financial Statements

U.S. Department of Health and Human Services

Food and Drug Administration

CONSOLIDATED BALANCE SHEETS

As of September 30, 2001 and 2000

(In Thousands)

	2001	2000
ASSETS		
Intragovernmental:		
Fund Balances with Treasury (Note 2)	$465,572	$455,618
Accounts Receivable (Note 3)	129,788	6,314
Other Assets (Note 6)	14,258	14,257
Total Intragovernmental Assets	**609,618**	**476,189**
With the Public:		
Accounts Receivable, Net (Note 3)	13,799	13,617
Cash (Note 4)	155	155
General Property, Plant & Equipment, Net (Note 5)	208,004	188,762
Other Assets (Note 6)	54	348
Total Assets With the Public	222,012	202,882
TOTAL ASSETS	**$831,630**	**$679,071**
LIABILITIES		
Intragovernmental:		
Accounts Payable	$ 10,107	$ 14,524
Environmental and Disposal Costs (Note 7)	2,774	2,807
Accrued Payroll and Benefits (Note 9)	10,249	9,460
Resources Payable to Treasury	122,378	-
Other Liabilities (Note 11 & 15)	4,130	985
Total Intragovernmental Liabilities	**149,638**	**27,776**
With the Public:		
Accounts Payable	56,115	23,283
Accrued Payroll and Benefits (Note 9)	95,669	88,140
Federal Employee and Veterans' Benefits (Note 8)	23,011	21,087
Environmental and Disposal Costs (Note 7)	2,213	2,927
Accrued Grant Liability, Net (Note 10)	3,215	2,182
Other Liabilities (Note 11, 14 & 15)	1,285	1,783
Total Liabilities With the Public	**181,508**	**139,402**
TOTAL LIABILITIES	**331,146**	**167,178**
Commitments and Contingencies (Note 14)		
NET POSITION (Note 12)		
Unexpended Appropriations	329,498	329,795
Cumulative Results of Operations	170,986	182,098
Total Net Position	**500,484**	**511,893**
TOTAL LIABILITIES AND NET POSITION	**$831,630**	**$679,071**

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, 2001 and 2000

(In Thousands)

	2001				
	Intra-Governmental		With the Public		
Program/Activity	Gross Costs	Less: Exchange Revenue	Gross Costs	Less: Exchange Revenue	Net Program Costs
Net Program/Activity Costs					
Foods	$ 105,900	$ 1,414	$ 290,216	$ 4,617	$ 390,085
Human Drugs	73,822	2,936	304,504	120,074	255,316
Medical Devices and Radiological Health	62,225	2,525	176,466	12,846	223,320
Biologics	42,001	2,216	136,563	15,459	160,889
Animal Drugs and Feeds	25,291	223	58,122	84	83,106
Toxicological Research	7,800	14,821	50,063	9	43,033
Tobacco	159	-	138	-	297
Net Cost of Operations	**$ 317,198**	**$ 24,135**	**$ 1,016,072**	**$ 153,089**	**$ 1,156,046**

	2000				
Net Program/Activity Costs					
Foods	$ 91,459	$ 1,703	$ 279,449	$ 4,291	$ 364,914
Human Drugs	75,938	798	287,598	111,495	251,243
Medical Devices and Radiological Health	57,073	4,869	165,442	13,873	203,773
Biologics	40,522	5,985	121,303	22,980	132,860
Animal Drugs and Feeds	16,660	230	46,944	(217)	63,591
Toxicological Research	9,775	13,679	47,379	128	43,347
Tobacco	3,208	8	2,236	2	5,434
Net Cost of Operations	**$ 294,635**	**$ 27,272**	**$ 950,351**	**$ 152,552**	**$ 1,065,162**

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, 2001 and 2000

(In Thousands)

	2001	2000
Net Cost of Operations	$1,156,046	$1,065,162
Financing Sources (other than exchange revenue)		
Appropriations Used	1,085,470	1,009,451
Imputed Financing	59,677	47,838
Financing Sources Transferred In Without Reimbursement	105	258
Financing Sources Transferred Out Without Reimbursement	(318)	(44)
Net Results of Operations	(11,112)	(7,659)
Prior Period Adjustments (Note 13)	-	(2,328)
Net Change in Cumulative Results of Operations	(11,112)	(9,987)
Increase or (Decrease) in Unexpended Appropriations	(297)	29,694
Change in Net Position	(11,409)	19,707
Net Position - Beginning of Period	511,893	492,186
Net Position - End of Period	**$ 500,484**	**$ 511,893**

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 FINANCING

For the Years Ended September 30, 2001 and 2000

(In Thousands)

	2001	2000
RESOURCES USED TO FINANCE ACTIVITIES:		
Budgetary Resources:		
Obligations incurred	$1,379,935	$1,307,501
Less: Spending authority from offsetting collections and recoveries	(257,719)	(256,017)
Obligations net of offsetting collections and recoveries	$1,104,216	1,051,484
Less: Offsetting receipts	(25)	-
Net Obligations	1,104,191	1,051,484
Non-budgetary Resources:		
Property received from others without reimbursement	105	258
Property given to others without reimbursement	(318)	(44)
Costs incurred by others for the entity without reimbursement	59,677	47,836
Net non-budgetary resources used to finance activities	59,464	48,052
Total Resources Used to Finance Activities	**1,163,655**	**1,099,536**
RELATIONSHIP OF TOTAL RESOURCES TO THE NET COST OF OPERATIONS:		
Increase in budgetary resources obligated to order goods and services not yet received or benefits not yet provided	(37,259)	(58,599)
Adjustments other than collections made to compute net budgetary resources that do not affect cost of operations:		
Recoveries of prior-year authority	37,475	30,110
Decrease (increase) in unfilled customer orders	3,177	(56)
Resources that fund expenses recognized in prior periods	(3,635)	(7,709)
Resources that finance the acquisition of assets or liquidation of liabilities	(35,433)	(25,316)
Other resources used to fund items not part of net cost of operations	-	921
Total Resources Used to Fund Items Not Part of the Net Cost of Operations	**(35,675)**	(60,649)
Resources Used to Finance the Net Cost of Operations	**1,127,980**	**1,038,887**
COMPONENTS OF NET COST OF OPERATIONS THAT DO NOT REQUIRE OR GENERATE RESOURCES DURING THE REPORTING PERIOD:		
Expenses or exchange revenue related to the disposition of assets or liabilities, or allocation of their costs over time:		
Depreciation and amortization	15,411	14,095
Decrease or (increase) in exchange revenue received from the public	1,827	(4,528)
Losses on disposition of assets	705	1,833
Subtotal	17,943	11,400
Expenses that will be financed with budgetary resources recognized in future periods:		
Annual leave expense from increase in annual leave liability	5,295	4,831
FECA, Environmental Cleanup Costs and Legal Contingencies	4,828	10,044
Subtotal	10,123	14,875
Total Components of Net Cost of Operations That Do Not Require or Generate Resources During the Reporting Period	**28,066**	**25,275**
Net Cost of Operations	**$1,156,046**	**$1,065,162**

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, 2001 and 2000

(In Thousands)

	2001	2000
Budgetary Resources:		
Budget authority	$1,125,823	$1,053,083
Unobligated balances - Begining of Period (Note 16)	104,735	120,322
Spending authority from offsetting collections	190,119	181,958
Adjustments:		
Recoveries of prior year obligations	85,600	74,059
Temporarily/Permanently unavailable - rescissions/cancellations	(40,626)	(17,186)
Total budgetary resources	**$1,465,651**	**$1,412,236**
Status of Budgetary Resources:		
Obligations incurred	$1,379,935	$1,307,501
Unobligated balances - available	69,870	88,550
Unobligated balances - not available	15,846	16,185
Total status of budgetary resources	**$1,465,651**	**$1,412,236**
Outlays:		
Obligations incurred	$1,379,935	$1,307,501
Less: spending authority from offsetting collections and adjustments	(275,719)	(256,017)
Obligated balance, net - Begining of Period (Note 16)	365,057	336,305
Less: obligated balance, net - End of Period	(394,029)	(365,057)
Total Outlays	**$1,075,244**	**$1,022,732**

The accompanying notes are an integral part of these statements.

Notes to 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, 2001 and 2000
(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 seven "programs" as follows: Foods, Human Drugs, Biologics, Medical Devices & Radiological Health, Animal Drugs & Feeds, Toxicological Research, and Tobacco. 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
75X6875.6	Anti-Terrorism Supplemental
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, 2001 and 2000

(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 97-01, Form and Content of Agency Financial Statements, as amended. GAAP for Federal entities are the standards prescribed by the Federal Accounting Standards Advisory Board (FASAB), which is the official accounting standards setting body for the Federal Government. The consolidated statements are different from the financial reports, also prepared by FDA, pursuant to OMB directives, used to monitor and control the use of budgetary resources. FDA has no material intra-entity transactions that need to be eliminated from the financial statements.

C. Basis of Accounting

FDA records transactions on the accrual accounting basis and budgetary basis. Under the accrual method, revenues are recognized when earned and expenses are recognized when a liability is incurred, without regard to receipt or payment of cash. Budgetary accounting principles, on the other hand, are designed to recognize the obligation of funds according to legal requirements, which, in many cases, is prior to the occurrence of an accrual-based transaction. Budgetary accounting provides a means to track the status of budgetary authority to help avoid over expending or over obligation of appropriations. Budget authority is the authority to acquire goods and services 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 Combining Statement 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 2001, FDA received approximately $1.9 million ($1 million for FY 2000).

U.S. Department of Health and Human Services
Food and Drug Administration
NOTES TO CONSOLIDATED PRINCIPAL FINANCIAL STATEMENTS
As of September 30, 2001 and 2000
(In Thousands)

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 reported no non-entity assets in FY 2000, and has one non-entity asset for accounts receivable related to civil monetary penalties (CMPs) to report for FY 2001. Therefore, assets reported on the financial statements are entity assets that FDA is able to use in its operations, except for FY 2001 accounts receivable related to CMPs as further described in Note 3 and Note 17.

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 Balance with Treasury

Fund balance with Treasury is 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 disbursements, either directly or through the DHHS Payment Management System (PMS).

G. Accounts Receivable, Net

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

Public accounts receivable primarily represent amounts due from organizations for 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. 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." Advances are reported net of

accrued grantee expenditures, and "Accrued Grant Liability" is reported when accrued expenditures exceed advances as of September 30. All advances are considered current payments made to FDA employees and are reported in Note 6, "Other Assets." Advances are reported net of accrued grantee expenditures, and "Accrued Grant Liability" is reported when accrued expenditures exceed advances as of September 30. All advances are considered current assets.

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

PP&E is capitalized at cost if the initial acquisition cost is $25 or more and 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 majority of space and property that FDA occupies is provided by the General Services Administration (GSA), which charges rent based on commercial rental rates for similar properties. Therefore, the cost of GSA owned properties is not recorded on 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.

U.S. Department of Health and Human Services
Food and Drug Administration
NOTES TO CONSOLIDATED PRINCIPAL FINANCIAL STATEMENTS
As of September 30, 2001 and 2000
(In Thousands)

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.

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. Civil monetary penalties collected and receivable from private organizations are considered non entity and a corresponding non-entity liability payable to the Department of Treasury's miscellaneous receipt account is recorded. For FDA's Revolving Fund for Certification and Other Services, all liabilities are funded by offsetting collections.

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 performs the daily 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 bills they 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. It is calculated with a data regression model that uses historical grantee advance and expenditure data.

To estimate the second component, expenses incurred but not reported (IBNR), DHHS gathered information on

spending patterns from four different groups 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 for accrued grants.

N. Deferred Revenue

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 adjusted quarterly to reflect current pay rates. Sick leave and other types of non-vested leave are expensed as taken.

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 on its Consolidated Balance Sheet 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. The 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.

U.S. Department of Health and Human Services
Food and Drug Administration
NOTES TO CONSOLIDATED PRINCIPAL FINANCIAL STATEMENTS
As of September 30, 2001 and 2000
(In Thousands)

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 $270, and $361 as of September 30, 2001 and 2000, 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 non-exchange 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 (1) firms submitting applications to FDA for review of new human drugs and biologics and manufacturers of 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 on FDA's Consolidated Statement of Net Cost and serve to reduce the reported cost of operations borne by the taxpayer. Non-exchange revenue derives from the

U.S. Department of Health and Human Services
Food and Drug Administration
NOTES TO CONSOLIDATED PRINCIPAL FINANCIAL STATEMENTS
As of September 30, 2001 and 2000
(In Thousands)

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. 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 on the Consolidated Statement of Net Cost, and an imputed financing source is recognized on the Consolidated Statement 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. With the exception of pending, threatened, or potential litigation, 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. For pending, threatened, or potential litigation, a liability is recognized when a past transaction or event has occurred, a future outflow or other sacrifice of resources is more likely than not to occur, 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.bilities at the date of the financial statements,

(In Thousands)

and the reported amounts of revenues and expenses during the reporting period. Actual results may differ from those estimates.

U. Reclassifications

Certain FY 2000 balances reported last year have been reclassified to conform to FY 2001 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.

Note 2 - Fund Balances with Treasury

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

	2001	2000
Appropriated General Funds	$432,230	$401,556
Other Funds	28,649	49,997
Revolving Funds	4,693	4,065
Total Fund Balances with Treasury	$465,572	$455,618

No restrictions on Fund Balances with Treasury exist at September 30, 2001 and 2000.

U.S. Department of Health and Human Services
Food and Drug Administration
NOTES TO CONSOLIDATED PRINCIPAL FINANCIAL STATEMENTS
As of September 30, 2001 and 2000
(In Thousands)

Note 3 - Accounts Receivable, Net

Accounts Receivable, Net consist of the following:

	2001		
	Gross Receivable	Allowance	Net Receivable
Intragovernmental			
Civil Monetary Penalties	$122,378	$ -	$122,378
Interagency Agreements	7,410	-	7,410
Total Intragovernmental	$129,788	-	$129,788
With the Public			
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
With the Public	15,256	1,457	13,799
Total Accounts Receivable	$145,044	$ 1,457	$143,587

	2000		
	Gross Receivable	Allowance	Net Receivable
Intragovernmental			
Interagency Agreements	$ 6,314	$ -	$ 6,314
With the Public			
Prescription Drug User Fee Act	9,521	825	8,696
Mammography Quality Standards Act	2,921	200	2,721
Travel Refunds & Miscellaneous	1,690	17	1,673
Export Reform & Enhancement Act	498	7	491
Other	36	-	36
Total With the Public	14,666	1,049	13,617
Total Accounts Receivable	$20,980	$ 1,049	$ 19,931

U.S. Department of Health and Human Services
Food and Drug Administration
NOTES TO CONSOLIDATED PRINCIPAL FINANCIAL STATEMENTS
As of September 30, 2001 and 2000
(In Thousands)

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 three percent 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 2001 total $61,619 net of DOJ fees of approximately $1,906. Receivables arising from CMPs are recorded when the penalties are assessed by FDA/DOJ. FDA has recorded intragovernmental accounts receivable totaling $122,378 based on settlement agreements or court decisions against private entities during FY 2001. A corresponding non-entity custodial liability payable to the Department of Treasury is recorded for the same figure. CMP receivables were not recorded in FY 2000 due to immateriality.

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, 2000, is $155.

U.S. Department of Health and Human Services
Food and Drug Administration
NOTES TO CONSOLIDATED PRINCIPAL FINANCIAL STATEMENTS
As of September 30, 2001 and 2000
(In Thousands)

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

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

2001

Classes of Fixed Assets	Service Life (Years)	Acquisition Value	Accumulated Depreciation	Net Book Value
Personal Property:				
Laboratory and 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

U.S. Department of Health and Human Services

Food and Drug Administration

NOTES TO CONSOLIDATED PRINCIPAL FINANCIAL STATEMENTS

As of September 30, 2001 and 2000

(In Thousands)

2000

Classes of Fixed Assets	Service Life (Years)	Acquisition Value	Accumulated Depreciation	Net Book Value
Personal Property:				
Laboratory and Office Equipment	10	$ 64,929	$ 39,597	$ 25,332
ADP and Telecom Equipment	8	21,476	11,485	9,991
Capital Lease - Security System	20	1,380	63	1,317
Total Personal Property		87,785	51,145	36,640
Real Property:				
Buildings, Facilities, & Structures	5 - 50	210,466	80,174	130,292
Capital Lease - Structure	30	806	54	752
Land	N/A	8,957	-	8,957
Total Real Property		220,229	80,228	140,001
Construction in Progress	N/A	12,121	-	12,121
Total		$320,135	$131,373	$188,762

Note 6 - Other Assets

Other Assets is comprised of the following:

	2001		2000	
	Intra-governmental	With the Public	Intra-governmental	With the Public
Disputed Cash Advance over GSA Rent	$14,019	$ -	$14,019	$ -
Travel and Employee Advances	-	13	-	348
Prepaid Subscriptions	239	41	238	-
Total Other Assets	$14,258	$ 54	$14,257	$ 348

U.S. Department of Health and Human Services
Food and Drug Administration
NOTES TO CONSOLIDATED PRINCIPAL FINANCIAL STATEMENTS
As of September 30, 2001 and 2000
(In Thousands)

The majority of other assets consist of funds held pending dispute resolution with GSA. The dispute concerns GSA rent charged to FDA that exceeds the cap imposed by Congress for annual GSA rent charges. GSA rent expenses charged FDA through the Online Payment and Collection System that exceed the cap have been charged back to GSA and the resulting cash balance is treated similar to a cash advance.

Note 7 - Environmental and Disposal Costs

Environmental and Disposal Costs are the costs of removing, containing, or disposing of (1) hazardous waste from property, or (2) material or property that consists of hazardous waste at permanent or temporary sites selected for closure or shutdown. 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 either under the terms of the lease or by all applicable federal, state, and local environmental laws. With respect to the decommissioning of FDA laboratories, the Army Corps of Engineers has been providing technical guidance, based upon its prior base closure experience. FDA currently has several interagency agreements with the Army Corps of Engineers for scope-of-work development and remediation activities.

FDA recognized an estimated liability for government-related future cleanup of hazardous waste related to FDA operations. Such estimates do not consider the effect of future new technology, laws, or regulations. The method of assigning cost is based on estimated costs of similar remediation projects. The following table presents estimated FDA cleanup costs for decommissioned laboratories as of September 30, 2001 and 2000:

	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
2001	$ 879	$ 1,895	$ 2,774	$ 654	$ 1,559	$ 2,213
2000	$ 1,102	$ 1,705	$ 2,807	$ 729	$ 2,198	$ 2,927

U.S. Department of Health and Human Services

Food and Drug Administration

NOTES TO CONSOLIDATED PRINCIPAL FINANCIAL STATEMENTS

As of September 30, 2001 and 2000

(In Thousands)

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 subsequently seeks reimbursement 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 5.21 percent in the first year and thereafter for FY 2001 (6.15 percent in the first year, 6.28 percent in the second year, and 6.30 percent in the third year and thereafter for FY 2000).

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 or CPIMs) 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, 2001 and 2000, amounted to $23,011 and $21,087, respectively, and is considered a liability not covered by budgetary resources.

Note 9 - Accured Payroll and Benefits

Accrued Payroll and Benefits consist of the following:

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

U.S. Department of Health and Human Services
Food and Drug Administration
NOTES TO CONSOLIDATED PRINCIPAL FINANCIAL STATEMENTS
As of September 30, 2001 and 2000
(In Thousands)

2000

	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	$ -	$ -	$ -	$ 36,734	$ -	$ 36,734
Accrued Leave	-	-	-	-	51,406	51,406
Payroll Withholding	6,223	-	6,223	-	-	-
Accrued Workers' Compensation	-	3,237	3,237	-	-	-
Total	$ 6,223	$ 3,237	$ 9,460	$ 36,734	$ 51,406	$ 88,140

Note 10 – Accrued Grant Liability, Net

Grant advances are liquidated upon the grantee's reporting of expenditures on the quarterly SF-272 Report (Federal Cash Transaction Report). FDA also estimates and accrues amounts due grantees for their expenditures through September 30, in accordance with DHHS accounting procedures.

The Accrued Grant Liability, net of advances to grantees, as of September 30, 2001 and 2000, is as follows:

	2001	2000
Grant Advances Outstanding (before year-end grant accrual)	$ 5,674	$ 8,711
Less: Estimated Accrual for Amounts Due to Grantees	8,889	10,893
Accrued Grant Liability, Net	$ 3,215	$ 2,182

U.S. Department of Health and Human Services

Food and Drug Administration

NOTES TO CONSOLIDATED PRINCIPAL FINANCIAL STATEMENTS

As of September 30, 2001 and 2000

(In Thousands)

Note 11 - Other Liabilities

Other Liabilities consist of the following:

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

2000

	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	$ -	$ 985	$ 985	$ -	$ 728	$ 728
Contingent Liability	-	-	-	-	505	505
Deferred Revenue	-	-	-	409	-	409
Other	-	-	-	141	-	141
Total	-	$ 985	$ 985	$ 550	$ 1,233	$ 1,783

All other liabilities are considered current except for the capital lease liability. The portion of the total capital lease liability of $1,637 ($1,713 for FY 2000) considered current is $91 ($80 for FY 2000), and the remaining balance, $1,546 ($1,633 for FY 2000), is considered non-current. Also see Note 15 for more information on capital leases.

U.S. Department of Health and Human Services

Food and Drug Administration

NOTES TO CONSOLIDATED PRINCIPAL FINANCIAL STATEMENTS
As of September 30, 2001 and 2000
(In Thousands)

Note 12 - Net Position

Net position is the difference between assets and liabilities. This section contains two line items: Unexpended Appropriations, which includes unobligated appropriations and undelivered orders, and Cumulative Results of Operations. Unobligated appropriations are either available for obligation or not available (permanently or temporarily) pursuant to a specific provision in law. Undelivered orders represent appropriations obligated for goods or services ordered but not yet received. Cumulative results of operations represent the net difference between (1) expenses and losses and (2) financing sources, including appropriated capital used, revenues, and gains since the inception of the activity.

	2001			2000		
	Appropriated Funds	Revolving Funds	Total	Appropriated Funds	Revolving Funds	Total
Unexpended Appropriations:						
Unobligated:						
Available	$ 29,279	$ -	$ 29,279	$ 27,361	$ -	$ 27,361
Unavailable	14,055	-	14,055	14,130	-	14,130
Undelivered Orders	286,164	-	286,164	288,304	-	288,304
Total Unexpended Appropriations	329,498	-	329,498	329,795	-	329,795
Cumulative Results of Operations	166,263	4,723	170,986	177,966	4,132	182,098
Total Net Position	$ 495,761	$ 4,723	$500,484	$ 507,761	$ 4,132	$ 511,893

U.S. Department of Health and Human Services

Food and Drug Administration

NOTES TO CONSOLIDATED PRINCIPAL FINANCIAL STATEMENTS
As of September 30, 2001 and 2000
(In Thousands)

Note 13 - Prior Period Adjustments

FDA continues to perform various analyses of its account balances in an effort to improve the financial data recorded in its accounting records. Prior period adjustments, representing a $2,328 decrease in the September 30, 1999, net position, were recorded to correct errors in prior years' financial statements, and are detailed below.

	2001	2000
Unexpended Appropriations	$ -	$ 3,249
Personal Property Cost, Net	-	(1,035)
Real Property Cost, Net	-	781
Supplemental CSRS Adjustment	-	(667)
Total	$ -	$ 2,328

U.S. Department of Health and Human Services

Food and Drug Administration

NOTES TO CONSOLIDATED PRINCIPAL FINANCIAL STATEMENTS
As of September 30, 2001 and 2000
(In Thousands)

Note 14 - 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, 2001 and 2000, FDA's undelivered orders were $286,164 and $288,304, respectively. The entire balance has been funded with budgetary resources received in FY 2001 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
2002	$27,682
2003	28,149
2004	7,384
Total	$63,215

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, 2001, FDA has accrued $161 ($505 for FY 2000) for a legal contingent liability to be paid by the Treasury Judgment Fund. In this case, a judgment of as high as $16,000 could be awarded against FDA, but the final amount of this liability will be decided in future litigation.

In addition, there are various pending class action suits against DHHS. However, DHHS management and legal counsel are unable to determine the impact or the ultimate outcome of these suits at this time. Therefore, the potential impact on FDA's financial statements is unknown.

U.S. Department of Health and Human Services

Food and Drug Administration

NOTES TO CONSOLIDATED PRINCIPAL FINANCIAL STATEMENTS

As of September 30, 2001 and 2000

(In Thousands)

Note 15. Leases

Future lease payments are as follows:

Fiscal Year	Capital Leases	Operating Leases
2002	$ 240	$ 107,856
2003	223	112,018
2004	222	115,966
2005	222	120,101
2006	222	122,633
2007 and Thereafter	1,869	1,470 **
Total Future Lease Payments	2,998	$ 580,044
Less: Imputed Interest	(1,361)	
Total Capital Lease Liability (Note 11)	$ 1,637	

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

As of September 30, 2001 and 2000, FDA had one personal property capital lease for a security system used at its Jamaica, NY field office. The lease has 18 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, 2001 and 2000.

Operating leases for real property cover GSA and non-GSA leased assets. Operating leases comprise the majority of FDA's fiscal year 2001 and 2000 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 2001, FDA had five (eight for FY 2000) 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, 2001 and 2000, FDA maintained approximately 250 vehicles leased from GSA. GSA charges FDA rates which are less than commercial rates for comparable vehicles. FDA may elect to terminate these leases within 120 days notice to GSA, at any time.

U.S. Department of Health and Human Services
Food and Drug Administration
NOTES TO CONSOLIDATED PRINCIPAL FINANCIAL STATEMENTS
As of September 30, 2001 and 2000
(In Thousands)

Note 16 - Combined Statements of Budgetary Resources

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. FDA also has a multi-year appropriation to record collections and disbursements for patents and royalties.

FDA received 76.8 percent or $1,125,823 (74.6 percent, or $1,053,083 for FY 2000), of its total FY 2001 budgetary resources of $1,465,651 ($1,412,236 for FY 2000) through appropriations. FDA's S&E account was appropriated $1,091,524 ($1,040,638 for FY 2000), which accounts for 97 percent (99 percent for FY 2000) 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 13 percent of total FY 2001 (12.9 percent for FY 2000) budgetary resources. Unobligated carryovers represent amounts of spending authority that have not been committed or earmarked for expenditure. Carryovers represent about 7.1 percent of FY 2001 (8.5 percent for FY 2000) budgetary resources.

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 2001, FDA had funds of $3,040 temporarily not available for national public health emergencies. The FDA requested the use of $2,384 of the Contingency Fund balance to reimburse FDA for the extraordinary costs associated with the Bovine Spongiform Encephalopathy (BSE) threat. The total that was obligated for this effort was $1,880.

FDA was given the authority to obligate $4,750 in the DHHS/Public Health and Social Services Emergency Fund related to the purpose of supporting the DHHS bioterrorism effort. All accounting and costs associated with this amount have been included in the DHHS statements and not FDA's statements.

The FY 2000 Combined Statement of Budgetary Resources includes corrections and restatements of FY 1999 figures. During FY 2000, the beginning unobligated balances were decreased by $1 to correct for understated obligations (undelivered orders) in FY 1999. The obligated carryovers from FY 1999 were restated by $155 in the FY 2000 Statement of Budgetary Resources to correct an error in FY 1999. The obligated balance at September 30, 1999, incorrectly included FDA's imprest fund of $155. Outlays on the Statement of Budgetary Resources did not match the outlays reported on the reports submitted to Treasury. Therefore, the obligated balance at October 1, 1999, was adjusted to exclude the imprest fund in order to arrive at the correct outlay total as of September 30, 2000.

U.S. Department of Health and Human Services
Food and Drug Administration
NOTES TO CONSOLIDATED PRINCIPAL FINANCIAL STATEMENTS
As of September 30, 2001 and 2000
(In Thousands)

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.

Note 17 – 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 2001 were $61,619. CMP collections are immediately forwarded to the Department of Treasury when collected and cannot be used for FDA operations. Also see Note 5.

Required Supplementary Information

(Unaudited)

U.S. Department of Health and Human Services

Food and Drug Administration

Combining Statement of Budgetary Resources

For the Year Ended September 30, 2001

(In Thousands)

	User Fees Account 75X0500	CRADAs 75X5148	Building & Facilities 75X0503	Certification Fund 75X4309	GSA Bldg. Delegation 75X0501	Salaries & Expenses 75_0500	GSA Rent 75_0501	Royalties 75_/_0500	Total
Budgetary Resources:									
Budget authority	($103,345)	$ 1,924	$32,350	$ 0	$5,036	$1,189,833	$ 25	$ 0	$1,125,823
Unobligated balances - October 1, 2000	5,401	626	26,684	3,327	0	68,509	0	188	104,735
Spending authority from offsetting collections	153,120	5	84	4,530	0	31,837	0	543	190,119
Adjustments:									
Recoveries of prior year obligations	0	24	2,023	203	0	53,350	0	0	55,600
Permanently unavailable - rescissions/cancellation	0	0	(69)	0	0	(40,557)	0	0	(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	$ 15,798	$ 1,234	$33,207	$ 4,207	$5,036	$1,320,007	$ 25	$421	$1,379,935
Unobligated balances-available	38,219	1,345	27,865	2,062	0	89	0	310	69,870
Unobligated balances-not available	1,159	0	0	1,791	0	12,896	0	0	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
Outlays:									
Obligations incurred	$ 15,798	$ 1,234	$33,207	$ 4,207	$5,036	$1,320,007	$ 25	$421	$1,379,935
Less: spending authority from offsetting collections and adjustments	(153,120)	(29)	(2,107)	(4,733)	0	(115,187)	0	(543)	(275,719)
Obligated balance, net-October 1, 2000	0	433	10,283	739	0	353,902	0	0	365,057
Less: obligated balance, net-September 30, 2001	(794)	(839)	(26,254)	(841)	0	(365,301)	0	0	(394,029)
Total Outlays	($138,116)	$ 799	$15,129	($638)	$5,036	$1,193,121	$ 25	($122)	$1,075,244

U.S. Department of Health and Human Services

Food and Drug Administration

Combining Statement of Budgetary Resources

For the Year Ended September 30, 2000

(In Thousands)

	User Fee Account 75X0500	CRADAs 75X5148	Building & Facilities 75X0603	Certification Fund 75X4309	GSA Bldg. Delegation 75X0501	Salaries & Expenses 75_0500	GSA Rent 75_0501	Royalties 75_/_0500	Total
Budgetary Resources:									
Budget authority	($147,276)	$ 1,109	$11,350	$ 0	$4,946	$1,182,954	$ 0	$ 0	$1,053,083
Unobligated balances - October 1, 1999	75,843	279	24,126	2,611	0	17,332	0	131	120,322
Spending authority from offsetting collections	148,313	2	57	4,101	0	29,077	0	408	181,958
Adjustments:									
Recoveries of prior year obligations	0	10	1,876	870	0	71,303	0	0	74,059
Permanently unavailable - rescissions/cancelation	0	0	0	0	0	(17,186)	0	0	(17,186)
Total budgetary resources	$ 76,880	$ 1,400	$37,409	$ 7,582	$4,946	$1,283,480	$ 0	$539	$1,412,236
Status of Budgetary Resources:									
Obligations incurred	$ 14,111	$ 774	$10,725	$ 4,255	$4,946	$1,272,339	$ 0	$351	$1,307,501
Unobligated balances-available	59,729	626	26,684	1,272	0	51	0	188	88,550
Unobligated balances-not available	3,040	0	0	2,055	0	11,090	0	0	16,185
Total, status of budgetary resources	$ 76,880	$ 1,400	$37,409	$ 7,582	$4,946	$1,283,480	$ 0	$539	$1,412,236
Outlays:									
Obligations incurred	$ 14,111	$ 774	$10,725	$ 4,255	$4,946	$1,272,339	$ 0	$351	$1,307,501
Less: spending authority from offsetting collections and adjustments	(148,313)	(12)	(1,933)	(4,971)	0	(100,380)	0	(408)	(256,017)
Obligated balance, net-October 1, 1999	0	213	17,399	1,261	0	313,856	3,572	4	336,305
Less: obligated balance, net-September 30, 2000	0	(433)	(10,283)	(739)	0	(353,802)	0	0	(365,057)
Total Outlays	($134,202)	$ 542	$15,908	($194)	$4,946	$1,132,213	$ 3,572	($53)	$1,022,732

U.S. Department of Health and Human Services

Food and Drug Administration

SUPPLEMENTAL CONSOLIDATED STATEMENT OF NET COST

Program Costs by Appropriation

For the Year Ended September 30, 2001

(In Thousands)

(Unaudited)

Program Area	A800 User Fees	5148 CRADA & Other	0803 Bldgs. & Facilities	4308 Cert. Fund	A801 GSA Bldg. Delegation	0900 Salaries & Expenses	Royalties & Misc.	8247 Gift Fund	Consolidated Totals
Foods									
Gross Costs	$ 713	(20)	2,585	4,077	2,798	385,852	11	-	396,116
Less: Earned Revenues	-	-	-	(4,520)	-	(1,497)	(14)	-	(6,031)
Net Program Costs	$ 713	$ (20)	$ 2,585	$ (443)	$ 2,798	$ 384,355	$ (3)	$ -	$ 390,085
Human Drugs									
Gross Costs	1,186	228	748	-	365	375,750	39	-	378,326
Less: Earned Revenues	(122,107)	-	-	-	-	(814)	(89)	-	(123,010)
Net Program Costs	$(120,921)	$ 228	$ 748	$ -	$ 365	$ 374,946	$ (50)	$ -	$ 255,316
Medical Devices & Radiological Health									
Gross Costs	12,957	138	460	-	350	224,786	-	-	238,691
Less: Earned Revenues	(12,991)	-	-	-	-	(2,380)	-	-	(15,371)
Net Program Costs	$ (34)	$ 138	$ 460	$ -	$ 350	$ 222,406	$ -	$ -	$ 223,320
Biologics									
Gross Costs	233	184	1,237	-	146	176,366	371	25	178,564
Less: Earned Revenues	(15,211)	-	-	-	-	(1,999)	(440)	(25)	(17,675)
Net Program Costs	$ (14,978)	$ 184	$ 1,237	$ -	$ 146	$ 174,369	$ (69)	$ -	$ 160,889
Animal Drugs & Feeds		49							
Gross Costs	163	-	63	-	1,343	81,795	-	-	83,413
Less: Earned Revenues	(51)		-	-	-	(256)	-	-	(307)
Net Program Costs	$ 112	$ 49	$ 63	$ -	$ 1,343	$ 81,539	$ -	$ -	$ 83,106
Toxicological Research					34				
Gross Costs	23	197	3,719	-	-	53,890	-	-	57,883
Less: Earned Revenues	-	-	-	-	$ 34	(14,830)	-	-	(14,830)
Net Program Costs	$ 23	$ 197	$ 3,719	$ -		$ 39,060	$ -	$ -	$ 43,033
Tobacco									
Gross Costs	-	-	-	-	-	297	-	-	297
Less: Earned Revenues	-	-	-	-	-	-	-	-	-
Net Program Costs	$ -	$ -	$ -	$ -	$ -	$ 297	$ -	$ -	$ 297
Net Cost of Operations	$(135,035)	$ 774	$ 8,912	$ (443)	$ 5,038	$1,276,974	$ (122)	$ -	$1,166,048

U.S. Department of Health and Human Services

Food and Drug Administration

SUPPLEMENTAL CONSOLIDATED STATEMENT OF NET COST

Program Costs by Appropriation

For the Year Ended September 30, 2000

(In Thousands)

(Unaudited)

Program Area	A800 User Fees	5148 CRADA & Other	0503 Bldgs. & Facilities	4309 Cert. Fund	A601 GSA Bldg. Delegation	0500 Salaries & Expenses	Royalties & Misc.	Consolidated Totals
Foods								
Gross Costs	$ (112)	2	3,129	4,002	2,912	60,861	14	370,808
Less: Earned Revenues	-	-	-	(4,089)	-	(1,915)	(10)	(5,994)
Net Program Costs	$ (112)	$ 2	$ 3,129	$ (87)	$ 2,912	$ 369,046	$ 4	$ 364,914
Human Drugs								
Gross Costs	1,002	34	597	-	354	361,551	(2)	363,536
Less: Earned Revenues	(113,970)	-	-	-	-	1,677	-	(112,293)
Net Program Costs	$(112,966)	$ 34	$ 597	$ -	$ 354	$ 363,228	$ (2)	$ 251,243
Medical Devices & Radiological Health								
Gross Costs	12,428	13	753	-	399	208,922	-	222,515
Less: Earned Revenues	(13,716)	-	-	-	-	(5,026)	-	(18,742)
Net Program Costs	$ (1,288)	$ 13	$ 753	$ -	$ 399	$ 203,896	$ -	$ 203,773
Biologics								
Gross Costs	52	14	560	-	125	160,784	289	161,825
Less: Earned Revenues	(23,400)	-	-	-	-	(5,177)	(388)	(28,965)
Net Program Costs	$ (23,348)	$ 14	$ 560	$ -	$ 126	$ 155,607	$ (99)	$ 132,860
Animal Drugs & Feeds		-						
Gross Costs	(4)	-	316	-	1,122	52,170	-	53,504
Less: Earned Revenues	254		-	-	-	(267)	-	(13)
Net Program Costs	$ 250	$ -	$ 316	$ -	$ 1,122	$ 51,903	$ -	$ 53,591
Toxicological Research								
Gross Costs	(20)	483	3,202	-	31	53,412	46	57,154
Less: Earned Revenues	-	-	-	-	-	(13,797)	(10)	(13,807)
Net Program Costs	$ (20)	$ 483	$ 3,202	$ -	$ 31	$ 39,615	$ 36	$ 43,347
Tobacco								
Gross Costs	(1)	-	(1)	-	2	5,444	-	5,444
Less: Earned Revenues	-	-	-	-	-	(10)	-	(10)
Net Program Costs	$ (1)	$ -	$ (1)	$ -	$ 2	$ 5,434	$ -	$ 5,434
Costs Not Assigned to Programs	-	-	-	-	-	-	-	-
Net Cost of Operations	$(137,487)	$ 546	$ 8,556	$ (87)	$ 4,946	$1,188,729	$ (61)	$1,065,182

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	Drugs	Medical Devices	Biologics	Animal Drugs	Toxicological Research	Tobacco	TOTALS
Personnel Services and Benefits	$ 229,099	$ 246,101	$ 144,760	$ 102,361	$ 45,007	$ 21,516	$ 42	$ 788,906
Travel & Transportation	11,441	6,692	4,234	2,836	1,660	696	-	27,663
Rent, Communication, and Utilities	42,476	26,679	22,953	11,378	10,312	5,355	9	119,259
Printing & Reproduction	1,399	806	491	349	149	82	2	3,050
Contractual Services	61,053	60,607	39,810	37,855	15,763	21,944	240	237,022
Supplies and Materials	6,409	4,585	2,363	7,132	1,855	3,132	-	25,256
Non-Capitalized Equipment	10,201	12,396	5,467	5,550	2,693	1,872	-	38,179
Grants, Subsidies, Contributions	9,598	4,034	2,040	849	1,816	299	1	18,617
Insurance Claims & Indemnities	116	137	90	98	14	28	-	485
Depreciation	5,132	2,295	2,540	1,303	536	3,605	-	15,411
Bad Debts and Write-offs	106	115	91	54	24	18	-	408
Interest Expense	21	18	9	10	5	147	-	210
Imputed Retirement Costs	19,466	12,468	13,935	8,741	3,545	1,517	3	59,677
Loss on Disposition of Property	217	173	268	16	35	2	-	706
Applied Overhead	(510)	(667)	(82)	(84)	(27)	(24)	-	(1,374)
Other	(119)	(95)	(178)	(20)	(14)	-	-	(426)
Gross Costs	396,116	376,326	238,691	178,854	83,413	57,863	297	1,333,270
Less: Earned Revenues	(6,031)	(123,010)	(15,371)	(17,675)	(307)	(14,830)	-	(177,224)
Net Cost	$ 390,085	$ 255,316	$ 223,320	$ 160,859	$ 83,106	$ 43,033	$ 297	$ 1,156,046

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, 2000

(In Thousands)

(Unaudited)

Expense Type	Foods	Drugs	Medical Devices	Biologics	Animal Drugs	Toxicological Research	Tobacco	TOTALS
Personnel Services and Benefits	$ 214,915	$ 298,138	$ 134,962	$ 91,222	$ 36,741	$ 22,248	$ 1,850	$ 740,074
Travel & Transportation	11,339	6,706	4,352	2,869	1,485	669	30	27,430
Rent, Communication, and Utilities	44,695	27,516	22,034	10,613	8,366	2,817	126	116,367
Printing & Reproduction	642	480	397	328	79	47	104	2,077
Contractual Services	54,294	53,263	38,232	38,645	9,842	21,086	3,071	218,433
Supplies and Materials	5,286	4,136	2,129	5,770	1,127	2,707	106	21,261
Non-Capitalized Equipment	8,078	9,480	4,291	3,170	1,307	1,629	61	27,998
Grants, Subsidies, Contributions	11,904	7,967	3,485	2,684	1,942	1,012	47	29,041
Insurance Claims & Indemnities	(4)	(70)	85	261	(3)	(59)	(2)	208
Depreciation	4,690	2,032	2,244	1,149	417	3,556	1	14,095
Bad Debts and Write-offs	(159)	(329)	(94)	(122)	(27)	(27)	(1)	(759)
Interest Expense	51	45	23	20	9	48	-	196
Imputed Retirement Costs	15,049	14,142	9,835	5,572	2,330	1,364	51	48,343
Loss on Disposition of Property	626	340	688	59	62	59	-	1,834
Other	(704)	(290)	(148)	(415)	(53)	-	-	(1,610)
Gross Costs	370,906	383,536	222,515	161,825	63,604	57,154	5,444	1,244,986
Less: Earned Revenues	(5,994)	(112,293)	(18,742)	(28,965)	(13)	(13,807)	(10)	(179,824)
Net Cost	**$ 364,914**	**$ 251,243**	**$ 203,773**	**$ 132,860**	**$ 63,591**	**$ 43,347**	**$ 5,434**	**$ 1,065,162**

U.S. Department of Health and Human Services

Food and Drug Administration

REQUIRED SUPPLEMENTARY INFORMATION
As of September 30, 2000
(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 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, 2001 and 2000:

FY 2001

Category	Asset Condition	Cost to Return to Acceptable Condition	Critical Amount	Non-Critical Amount
Buildings	Fair to Poor	$29,356	$4,525	$24,831
Laboratories	Fair to Poor	$9,426	$3,090	$6,336
Utility Systems	Poor	$7,056	$1,940	$5,116
Total		$45,838	$9,555	$36,283

FY 2000

Buildings	Poor	$32,508	$4,125	$28,383
Laboratories	Fair	$9,486	-	$9,486
Utility Systems	Poor	$6,975	-	$6,975
Total		$48,969	$4,125	$44,844

U.S. Department of Health and Human Services

Food and Drug Administration

REQUIRED SUPPLEMENTARY INFORMATION
INTRAGOVERNMENTAL TRANSACTIONS
As of September 30, 2001 and 2000
(In Thousands)
(Unaudited)

Intragovernmental Assets

Agency	TFM Dept Code	Fund Balance w/ Treasury	Accounts Receivable	Other	Total
2001					
Department of Agriculture	12		$816		$816
Department of Commerce	13		10	$234	244
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		125,198		125,198
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	5	338
TOTAL		**$465,572**	**$129,788**	**$14,258**	**$609,618**
2000					
Department of Agriculture	12		$591		$591
Department of Commerce	13			$233	233
Department of Defense	17, 21, 57, 97		1,794		1,794
Department of Energy	89		240		240
Department of Health and Human Services	75		2,651		2,651
Department of Justice	15		608		608
Department of Transportation	69		157		157
Department of the Treasury	20	$455,618			455,618
Department of Veterans Affairs	36		31		31
Environmental Protection Agency	68		18		18
Federal Emergency Management Agency	58		47		47
General Services Administration	47		151	14,019	14,170
National Aeronautics & Space Administration	80		25		25
All Other Federal Agencies			1	5	6
TOTAL		**$455,618**	**$6,314**	**$14,257**	**$476,189**

U.S. Department of Health and Human Services

Food and Drug Administration

REQUIRED SUPPLEMENTARY INFORMATION

INTRAGOVERNMENTAL TRANSACTIONS

As of September 30, 2001 and 2000

(In Thousands)

(Unaudited)

Intragovernmental Liabilities

Agency	TFM Dept Code	Accounts Payable	Environmental Cleanup	Accured Payroll and Benefits	Other	Total
		2001				
Department of Agriculture	12	$60	$60			$120
Department of Defense	17, 21, 57, 97		2,616			2,616
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	98		967	7,482
Office of Personnel Management		30		5,109		5,139
All Other Federal Agencies		743			218	961
TOTAL		**$10,107**	**$2,774**	**$10,249**	**$126,508**	**$149,638**
		2000				
Department of Agriculture	12	$50	$64			$114
Department of Commerce	13	75				75
Department of Defense	17, 21, 57, 97	13	2,636			2,649
Department of Energy	89	205				205
Department of Health and Human Services	75	4,272				4,272
Department of Labor	16			$3,237		3,237
Department of State	19	13				13
Department of the Treasury	20			1,569		1,569
General Services Administration	47	9,587	107		$985	10,679
Nuclear Regulatory Commission	31	1				1
Office of Personnel Management	24	104		4,654		4,758
All Other Federal Agencies		204				204
TOTAL		**$14,524**	**$2,807**	**$9,460**	**$985**	**$27,776**

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 Education	91				
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**

U.S. Department of Health and Human Services

Food and Drug Administration

REQUIRED SUPPLEMENTARY INFORMATION
INTRAGOVERNMENTAL TRANSACTIONS
For the Year Ended September 30, 2000
(In Thousands)
(Unaudited)

Intragovernmental Revenues and Expenses

Agency	TFM Dept Code	Revenues	Imputed Financing	Net Transfers	Expenses
Department of Agriculture	12	$323			$2,296
Department of Commerce	13				166
Department of Defense	17, 21, 57, 97	2,029			1,401
Department of Education	91	8			
Department of Energy	89	536			4,838
Department of Health and Human Services	75	21,614		$(20)	48,696
Department of the Interior	14				21
Department of Justice	15	1,151			
Department of Labor	16				1,726
Department of State	19	8			
Department of Transportation	69	157			30
Department of the Treasury	20		$72		944
Department of Veterans Affairs	36	82			860
Environmental Protection Agency	68	1,114		199	39
General Services Administration	47	204		35	102,306
National Aeronautics & Space Administration	80	41			
Nuclear Regulatory Commission	31				67
Office of Personnel Management	24		47,766		127,609
All Other Federal Agencies		5			3,636
TOTAL		**$27,272**	**$47,838**	**$214**	**$294,635**

Required Supplemntary Stewardship Information

(Unaudited)

U.S. Department of Health and Human Services

Food and Drug Administration

RESEARCH & DEVELOPMENT

REQUIRED SUPPLEMENTARY STEWARDSHIP INFORMATION

For the Year Ended September 30, 2001 and 2000

(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.

U.S. Department of Health and Human Services

Food and Drug Administration

RESEARCH & DEVELOPMENT
REQUIRED SUPPLEMENTARY STEWARDSHIP INFORMATION
For the Year Ended September 30, 2001 and 2000
(Unaudited)

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 1998-2001 (including expenses related to the OPD Program's administration, Office of the Commissioner overhead, and grants awarded in previous fiscal years) for each of FDA's research and development activities:

U.S. Department of Health and Human Services

Food and Drug Administration

RESEARCH & DEVELOPMENT

REQUIRED SUPPLEMENTARY STEWARDSHIP INFORMATION

For the Years Ended September 30, 2001 and 2000

(Unaudited)

RESEARCH AND DEVELOPMENT EXPENSES
(In Thousands)

Program	TYPE	Fiscal Year			
		01	00	99	98
Orphan Product Development	Development	$ 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	20,813	4,752	6,990	8,159
Toxicological Research	Applied Research	--	--	--	33,233
Total		$25,856	$25,616	$18,692	$53,364

NOTE:
Pilot Clinical Pharmacology Program is excluded from FY 1999 through FY 2001 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 2001 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.

Reports on the Audit of FDA's FY 2001 Financial Statements

DEPARTMENT OF HEALTH & HUMAN SERVICES Office of Inspector General

MAR 13 2002

Memorandum

Date

From Deputy Inspector General
for Audit Services

Subject Report on the Financial Statement Audit of the Food and Drug Administration for Fiscal Year 2001 (A-17-01-00008)

To Jeffrey M. Weber
Chief Financial Officer
Food and Drug Administration

The attached final report presents the results of audit of the Fiscal Year 2001 financial statements of the Food and Drug Administration (FDA). A certified public accounting firm, KPMG L.L.P. undertook the audit in support of the Departmentwide financial statement audit by the Office of Inspector General (OIG) and in accordance with the Government Management Reform Act of 1994. The OIG exercised technical oversight and quality control over the audit.

The audit objectives were to determine whether (1) the FDA consolidated balance sheets as of September 30, 2001 and 2000, and the related consolidated statements of net cost, changes in net position, financing, and the combined statement of budgetary resources for the years then ended were fairly presented in all material respects; (2) FDA internal controls provided reasonable assurance that transactions were properly recorded and accounted for to permit the preparation of reliable financial statements; and (3) FDA complied with laws and regulations that could have a direct and material effect on the financial statements.

In the auditor's opinion, the financial statements referred to above present fairly, in all material respects, the financial position of FDA as of September 30, 2001 and 2000, 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.

The FDA is commended for sustaining their unqualified opinion. Furthermore, the report on internal controls noted no weakness 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 that are considered to be a repeat reportable condition. The two specific areas addressed are the Security Program and Access Controls.

The firm noted no instances, exclusive of the Federal Financial Management Improvement Act (FFMIA) of 1996, of noncompliance with laws and regulations which could have a

Page 2 - Jeffrey M. Weber

direct and material effect on the determination of the consolidated financial statement amounts, and certain provisions of other laws and regulations specified in Office of Management and Budget Bulletin 01-02. Related to FFMIA, the firm noted instances where FDA financial management systems (accounts receivable, cost management, and property) did not substantially comply with FFMIA Federal financial management systems requirements.

The firm has incorporated comments to the report where appropriate. Officials in your office have concurred with the recommendations and have or are in the process of taking corrective action. We would like to thank you and your staff for the outstanding cooperation and assistance in working with us and the firm on the FY 2001 financial statement audit.

We would appreciate your views and the status of any further action taken or contemplated on KPMG's recommendations within 60 days. Should you wish to discuss this report, please call me or have your staff contact Joseph E. Vengrin, Assistant Inspector General for Audit Operations and Financial Statement Activities, at (202) 619-1157. Please refer to the Common Identification Number A-17-01-00008 in all correspondence relating to this report.

Thomas D. Roslewicz

Attachment

KPMG

2001 M Street, N.W.
Washington, D.C. 20036

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, 2001 and 2000, 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 hereinafter 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 audit 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, 2001 and 2000, 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.

As discussed in note 1 to the consolidated financial statements, the FDA adopted the provisions of Statement of Federal Financial Accounting Standards No. 10, *Accounting for Internal Use Software*, effective October 1, 2000.

The information in the Management Discussion and Analysis, Required Supplementary Information, and Required Supplementary Stewardship Information sections is not a required part of the consolidated financial statements but is supplementary information required by the

KPMG

Federal Accounting Standards Advisory Board or OMB Bulletin No. 97-01, *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 DHHS's intragovernmental transactions and balances with non-DHHS trading partners, as required by OMB Bulletin 01-02. The DHHS 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.

In accordance with *Government Auditing Standards*, we have also issued reports dated December 14, 2001, 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 14, 2001

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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, 2001, and the related consolidated statements of net cost and changes in net position and combined statements of financing and budgetary resources for the year then ended, and have issued our report thereon dated December 14, 2001. 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 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 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 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.

Internal Controls Over Information Systems Should Be Enhanced

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

Security Program. In assessing FDA's security program, we noted that Office of Information Resource Management (OIRM) has completed a final draft of an entity-wide security plan titled "Strategic Information Security Plan". This plan is currently under review and is expected to be final by March 1, 2002. We also noted that the FDA Office of Financial Management (OFM) does not have a required entity wide security plan in place for all of its major financial applications, with the exception of the General Ledger Accounting System, the Automated Accounts Payable System, and the Travel Manger System, and that the required certification and accreditation statements have not been completed for all major financial applications. Therefore, we recommend that the FDA's OFM prepare and document a security plan that complies with OMB Circular A-130 and DHHS's Automated Information System Security Handbook for all major financial applications. We further recommend that certification and accreditation statements be completed for all major financial applications.

Access Controls. We assessed FDA's financial systems management's efforts and, although we noted continued improvement in this area, we believe that certain matters related to system monitoring and excessive administrative rights remain to be resolved. Matters related to account expiration, password management, and the issues identified during the penetration and vulnerability assessment have been resolved. Therefore, we recommend FDA OFM and OIRM collaborate in developing a plan to ensure security related events are recorded as defined by FDA's Information Systems Security Policies. We understand that a joint plan is being developed for both computer hardware jointly shared by OFM and OIRM, and for all other OFM hardware. In addition, OFM and OIRM should consider an audit plan to analyze trends and evaluate system performance. To ensure the integrity of the financial data affecting the financial statements and with the recent testing of the integrity of the Office of the Commissioner domain, we recommend that FDA conduct a feasibility study to segregate its financial applications into a separate application domain. It is our understanding that the FDA Windows 2000/Active Directory technical working group is working on an FDA-wide design and a migration plan to the Windows 2000 Active Directory structure. We also understand that FDA anticipates creating a separate domain in support of the financial software applications as the agency migrates to a Windows 2000 environment.

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 on such controls.

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 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 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 14, 2001.

This report is intended solely for the information and use of the FDA's management, the U.S. Department of Health and Human Services 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 14, 2001

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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, as of September 30, 2001, and the related consolidated statements of net cost and changes in net position and combined statements of financing and budgetary resources for the year then ended (collectively referred to as the "consolidated financial statements"), and have issued our report thereon dated December 14, 2001. 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 preceding 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, where the FDA's financial management systems did not substantially comply with the Federal financial management systems requirements.

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 revised 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.

We understand that the FDA is in the process of addressing this noncompliance through the implementation of a new AMS and is seeking budgetary authority to replace the FDA's current accounting system.

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 U.S. Department of Health and Human Services 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 14, 2001

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JAN 18 2002

To: Joseph Vengrin
Assistant Inspector General for Audit Operations
and Financial Statements

From: Senior Associate Commissioner for Management and System (Acting)
and Chief Financial Officer

Subject: FDA's Response to the FY 2001 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, 2001. 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 2001 consolidated financial statements with no material weaknesses in our internal control reporting. This accomplishment shows the steady progress that FDA has made in the past year in improving its financial systems and internal control structure. It also reflects the extensive effort among FDA staffs working together to produce timely and accurate financial statements.

However, FDA still must work to eliminate the remaining reportable condition and address recommendations made in the Management Letter. We will continue our efforts to resolve the findings. Our goal remains to continue to receive unqualified opinions on all of our future consolidated financial statements. To this end, we will work with your office, The Department of Health and Human Services, and KPMG LLP to develop a corrective action plan for the recommendations.

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 and we hope to put these recommendations in place as soon as possible as we continue to improve FDA's financial management.

Jeffrey M. Weber

Appendices

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 1997, 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 2001 was $160.7 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 2001, the amount of MQSA collections expended was $12.4 million.
Export	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 2001, the amount of user fees expended was $1.5 million. Export certificates issued for food products are subject to FD&C Act, but are not covered by EREA.
Certification and	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 2001, the amount of fees expended was $3.8 million.

Appendix 2

Financial Management Legislation

Chief Financial Officers Act of 1990

The Chief Financial Officers Act of 1990 focused attention on financial management improvements in the Federal Government by requiring the identification of a responsible official to advise on financial management. The law created a framework for financial organizations to focus on the integration of accounting, budget, and other financial activities under one umbrella; the preparation of audited financial statements; and the integration of financial management systems. It also requires federal agencies to prepare CFO strategic five-year plan. The Act required 14 Cabinet level Departments and ten major agencies to establish the position of a CFO who reports to the agency head.

Government Performance and Results Act of 1993

The Government Performance and Results Act (GPRA) which is to be fully implemented beginning in FY 1999, has placed new management expectations and requirements on federal agencies by creating a framework for more effective planning, budgeting, program evaluation and fiscal accountability for Federal programs. The intent of the Act is to improve public confidence in Federal agency performance by holding agencies accountable for achieving program results and to improve Congressional decision making by clarifying and stating program performance goals, measures and costs up front. Federal agencies are required to implement GPRA through their processes for strategic plans, annual performance plans, and annual performance reports. FY 1999 is the first year that annual performance plans are required. Actual accomplishments for FY 1999 are required to be reported in FY 2000.

Government Management Reform Act of 1994

The Government Management Reform Act (GMRA) amends the CFO Act and expands requirement for audited financial statements to cover all programs. It also provides OMB with the authority to streamline statutory reporting by Federal agencies, requires the use of electronic funds transfer for payments to Federal employees and beneficiaries, and creates the Franchise Fund Pilot program for studying the concept of government enterprise.

Federal Acquisition Streamlining Act of 1994

The Federal Acquisition Streamlining Act (FAS) of 1994 was enacted to revise and streamline the acquisition laws of the Federal government. FASA also expanded the definition of records, placed additional record retention requirements, and gave agencies statutory authority to access computer records of contractors doing business with the government.

Debt Collection Improvement Act of 1996

The Debt Collection Improvement Act (DCIA) of 1996, Public Law 104-134, was signed into law on April 26, 1996. The law's provisions will enhance and improve debt collection government-wide. Key provisions of the Act are:

- Enhanced administrative offset authority, the Treasury Offset Program
- Enhanced salary offset authority
- Taxpayer Identification Numbers required
- General extension of the Debt Collection of 1982 authorities
- Barring delinquent debtors from obtaining Federal credit
- Reporting to credit bureaus
- Government-wide cross servicing
- Establishment of debt collection centers
- Gainsharing
- Tax refund offset program
- Contracting with private attorneys
- Administrative wage garnishment
- Debt sales by agencies

Federal Financial Management Improvement Act of 1996

The Federal Financial Management Improvement Act (FFMIA) of 1996, Public Law 104-208, requires that each agency shall implement and maintain financial management systems that comply substantially with Federal financial management systems requirements, applicable Federal accounting standards, and the United States Government Standard General Ledger at the transaction level.

Information Technology Management Reform Act of 1996

Information Technology Management Reform Act (ITMRA) ensures that the Federal Government investment in information technology is made and used wisely. The law was designed to increase competition, eliminate burdensome regulations, and help the Government benefit from efficient private sector techniques.

ITMRA requires agencies to develop a formal process for maximizing the benefits of information technology acquisition, including planning, assessment, and risk management.

The Act created the statutory position of Chief Information Officer in major Federal Government agencies. It requires the Office of Management and Budget, the agencies, and the Chief Information Officers to improve information technology practices. It requires mission and program driven strategic planning for information technology. It requires senior user management guidance to ensure information technology activities align with agency plans and operations. It requires regular assessments of information technology skills inventory, skills

requirements, and skills development programs. In short, the ITMRA requires the development of an effective and efficient, mission-oriented, results-oriented information technology practice in each and every Federal agency.

Travel and Transportation Reform Act of 1998

The Travel and Transportation Reform Act of 1998 (TTRA), required Federal employees to use Federal travel charge cards for all payment of official Government travel, to amend title 31, United States Code, to establish requirements for prepayment audits of Federal agency transportation expenses, to authorize reimbursement of Federal agency employees for taxes incurred on travel or transportation reimbursements, and to authorize test programs for the payment of Federal employee travel expenses and relocation expenses.

Federal Activities Inventory Reform Act of 1998

The Federal Activities Inventory Reform Act (FAIRA) requires Federal agencies to list activities eligible for privatization and to make this list available to the public. FAIRA permits prospective contractors and other interested parties to challenge the omission of particular activities from the list. Nevertheless, although agencies are directed to review the list, FAIRA does not actually require agencies to review the activities on the list soon after the list has been made available to the public.

Federal Financial Assistance Management Improvement Act of 1999

The Federal Financial Assistance Management Improvement Act, Public Law 106-107, requires OMB and the Federal agencies to work together with the various grantee communities to streamline, simplify, and provide electronic options for the grants management processes employed by the Federal agencies. The purposes of this Act, signed into law on November 20, 1999, are to improve the delivery of services to the public and the effectiveness and performance of Federal grant programs. Federal agencies are working with OMB to: (1) develop uniform administrative rules; (2) develop common application and reporting processes; (3) replace paper with electronic processing in administration of grant programs; and (4) identify statutory impediments to grants simplification.

Report Consolidation Act of 2000

This legislation was enacted to authorize and encourage the consolidation of financial and performance management reports that are more meaningful and useful to the Congress, the President, and the public. The act provides for permanent authorization for consolidated reports, permits several alternative approaches to reporting, requires an Inspector General assertion on the agency's progress in addressing the most serious management and performance challenges, and requires the head of an agency to make an assertion on the completeness and reliability of the performance and financial data in the report(s).

Appendix 3

FDA-Related Acronyms and Abbreviations

AIDS	Acquired Immune Deficiency Syndrome
ANADA	Abbreviated New Animal Drug Application
ANDA	Abbreviated New Drug Application
BLA	Biologic License Application
CBER	Center for Biologic Evaluation and Research
CDC	Centers for Disease Control and Prevention
CDER	Center for Drug Evaluation and Research
CDRH	Center for Devices and Radiological Health
CFO	Chief Financial Officer
CFR	Code of Federal Regulations
CFSAN	Center for Food Safety and Applied Nutrition
CVM	Center for Veterinary Medicine
DHHS	Department of Health and Human Services
EFT	Electronic Funds Transfer
ELA	Establishment License Application
FDA	Food and Drug Administration
FFMIA	Federal Financial Management Improvement Act
FMFIA	Financial Managers' Financial Integrity Act
FDAMA	Food and Drug Administration Modernization Act
FSI	Food Safety Initiative
FTE	Full-Time Equivalency
FY	Fiscal Year
GAO	General Accounting Office
GLAS	General Ledger Accounting System
GMRA	Government Management Reform Act
GPRA	Government Performance and Results Act
GSA	General Services Administration
HACCP	Hazard Analysis and Critical Control Point
HDE	Humanitarian Device Exemption
HIV	Human Immunodeficiency Virus
INAD	Investigational New Animal Drug
IDE	Investigational Device Exemption
IND	Investigational New Drug
IMPAC	International Merchant Purchase Authorization Card
JINAD	Generic Investigational New Animal Drug
MQSA	Mammography Quality Standards Act
NADA	New Animal Drug Application
NCTR	National Center for Toxicological Research
NDA	New Drug Application
NIH	National Institutes of Health
NME	New Molecular Entity
NPR	National Performance Review
OFACS	Office of Facilities, Acquisitions and Central Services
OFM	Office of Financial Management
OIG	Office of Inspector General
OIRM	Office of Information Resources Management
OMB	Office of Management and Budget
OMS	Office of Management and Systems
OPDIV	Operating Division
PDP	Product Development Protocol
PDUFA	Prescription Drug User Fee Act
PHS	Public Health Service
PLA	Product License Application
PMA	Premarket Approval Application
PMIS	Property Management Information System
PMS	Payment Management System
SFFAS	Statement of Federal Financial Accounting Standards
SGL	Standard General Ledger
USC	United States Code
USDA	United States Department of Agriculture
Y2K	Year 2000
510 (k)	Premarket Notification

Key FDA Financial Management Officials

Jeff Weber
Senior Associate Commissioner for Management and Systems (Acting) and
Chief Financial Officer

Helen Horn
Director, Office of Financial Management (Acting) and
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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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