Food and Drug Administration

Department of Health and Human Services

FY 2003 Budget Summary

From the
FY 2003 Justification of Estimates
for Appropriations Committees

February, 2002

Promoting Public Health Through Patient, Food and Consumer Safety

Agency Mission Overview

As a part of the Department of Health and Human Services (DHHS), FDA's mission is to promote and protect the public health by ensuring that safe and effective products reach the market in a timely way, and to monitor products for continued safety after they are in use. FDA's work is a blending of law and science directed at protecting consumers by focusing on patient, food and consumer safety.

Program Objectives

The public trusts FDA to ensure that food on the family table will be safe and wholesome; new medical products, drugs, biological products, medical devices, and radiological products are available in a timely manner with demonstrated benefits that outweigh risks; and, product information is useful and understandable.

For FY 2003, FDA's budget request is $1.727 billion, a net increase of $123 million. The request includes $155 million in program increases, and $32 million in decreases as a result of completed projects. The request also includes full funding for retirement pay accruals of $63.205 million. Without proposed accruals, the total request is $1.664 billion. This request supports total FTE of 10,548, which includes 89 reimbursable FTE.

FDA's budget requests the following programmatic changes:

Countering Terrorism: $1.176 million

- Total funding for counter terrorism activities of $159.048 million is requested, an increase of $1.176 million over the FY 2002 current estimate, which includes the FY 2002 appropriation plus the emergency supplemental. This includes $7 million in program increases and a decrease of $6 million resulting from completed security upgrades.

- The FY 2002 emergency supplemental provided funding for FDA's counter terrorism activities; the FY 2003 budget provides funds to maintain these counter terrorism activities.

- The attacks of September 11 and subsequent national events resulted in an accelerated and intensified need for attention to activities related to counter terrorism. FDA activities include surveillance, investigation and laboratory support for detection and management of product contamination; provision of regulatory guidance to manufacturers and other government agencies to assure the availability of medical products, including blood; and establishment of a communications network that optimizes emergency preparedness within FDA and across the federal government.

- Funding will continue activities begun with supplemental money. FDA's focus is in three key areas: food safety, safe and effective medical products, and physical security. Food safety activities include, among other initiatives, expanded inspection and surveillance of imports. Activities related to safe and effective medical products include working with industry to develop more

measures to help patients exposed to terrorist agents such as anthrax, smallpox and plague. Funding will also enhance physical security requirements at all FDA facilities nationwide.

- FDA is responding to potential threats by hiring additional investigators for border oversight of imports; and recruiting and training expert scientific reviewers to provide expedited review of products used to manage patients exposed to biological, chemical, and nuclear agents of intentional use.

- FDA has responded to the public health needs presented by the threat of terrorism with the following:

    - Consistent availability and sound guidance on food safety and security to the food industry and the general public intensified and accelerated after September 2001;

    - Approval of the drug Cipro in August 2000. Cipro is the first antibiotic to be approved prior to recent terrorist events. It is for the treatment of post-exposure inhalational anthrax;

    - Expert regulatory guidance availability 24 hours, 7 days a week to move forward the federal government contracting for a new smallpox vaccine: September through November 2001;

    - Additional options for the management of patients exposed to aerosolized anthrax spores. In November 2001 published a Federal Register notice providing dosing recommendations and scientific background for the use of doxycyline and penicillin; and,

    - Intensive commitment to the availability of the anthrax vaccine, culminating in preparation for and conduct of a successful manufacturer inspection in December 2001.

- Collaboration with other government agencies, both military and civilian, is integral to FDA's public health mission. The Agency provides regulatory guidance to research groups in the Department of Defense (DOD) and the National Institute of Health (NIH), and assures availability and gives regulatory guidance to the Centers for Disease Control and Prevention (CDC), holder of the National Pharmaceutical Stockpile.

Pay: $28.552 million

- FDA is a people intensive agency where payroll accounts for over 60 percent of the budget. Forty-five percent of that workforce is dedicated to "front line" efforts such as inspections, coordination with states and cooperative education programs. An increase in FY 2003 will contribute to the FDA's capability to address new and emerging hazards since the events of September 11, 2001. For FY 2002, Congress provided funds to cover pay raises which will allow FDA to more efficiently and effectively carry out its mission.

Patient Safety/Medical Errors: $5.0 million

- Medical Errors may cost the lives of up to 100,000 Americans annually, accidentally injure 1.3 million people, account for more than 3 million hospital admissions, and increase the nation's hospitalization bill by up to $17 billion each year. The FY 2003 increase builds

on the medical error related activities of FY 2002 that provided FDA with resources to further enhance the identification of risks associated with the use of medical products and to reduce the occurrence of adverse events. It also provides for the enhancement of the adverse events data system and linkages with other health care systems -- a first line defense system to identify possible intentional tampering.

Generic Drugs: $4.582 million

- The increase will provide for improvements to the generic drug review program and allow FDA to set a more challenging performance goal of reviewing Abbreviated New Drug Applications within six months after the submission date. The funds would also increase the field's capacity to conduct more timely inspections, especially of foreign sites. The Congressional Budget Office reported in a study completed in 1998 that the purchase of generic drugs reduced the cost of prescriptions (at retail prices) by roughly $8 to $10 billion dollars.

New Financial System: $5.2 million

- In FY 2003, FDA plans to continue participation in the DHHS unified financial management system effort. The new system is planned to reduce costs, mitigate security risks, and provide timely and accurate information internally at FDA and across DHHS Operating Divisions. The system will replace five legacy accounting systems currently used across the Operating Divisions. The UFMS will integrate the Department's financial management structure to provide DHHS and FDA leaders with a more timely and coordinated view of critical financial management information, including more accurate assessments of the cost of HHS programs. It will also promote the consolidation of accounting operations and thereby reduce substantially the cost of providing accounting services throughout HHS. Similarly, UFMS, by generating timely, reliable and consistent financial information, will enable FDA and other DHHS agency heads and program administrators to make more timely and informed decisions regarding their operations. FDA will be one of the first two DHHS agencies to benefit from this effort as its systems are among the oldest in the Department.

User Fees: $295.164 million

- The budget request includes $272.038 million in new user fees to reauthorize and expand the Prescription Drug User Fee Act (PDUFA). Of this amount, $7.818 million is for retirement accruals.

- FDA is negotiating with industry on a proposal to reauthorize PDUFA in FY 2003 and beyond and make enhancements to it.

- The budget also includes resources of $23.126 million, with $636,000 for retirement accruals, for other user fees for mammography inspections, export and color certifications.

Building and Facilities: -$26.281 million

- The budget also proposes a $26 million reduction in facilities costs. Twenty-three million dollars is associated with the completion of the Los Angeles Laboratory; the remainder reflects a pause in work at Arkansas Regional Laboratory.

Management Initiatives

President's Management Plan: -$2.578 million

- The FY 2003 Budget assumes savings of $2.578 million and 25 FTE associated with efficiency improvements and consolidations of administrative functions relative to the advancement of the President's Management Plan.

Accrued Retirement and Health Benefits Costs

- The budget includes $63.205 million ($54.751 million in budget authority and $8.454 million in user fees) in FY 2003 for accrued retirement and health benefits is associated with the proposed Managerial Flexibility Act of 2001. This legislation requires agencies, beginning in FY 2003, to pay the full Government share of the accruing cost of retirement for current CSRS, CIA and Foreign Service employees, and the Coast Guard, Public Health Service and NOAA Commissioned Corps. The legislation also requires agencies to pay the full accrual cost of post-retirement health benefits for current civilian employees. The intent of the legislation is to budget and present the full costs of Federal employees in the accounts and programs where they are employed. This legislation is part of an initiative to link budget and management decisions to performance by showing the full cost of each year's program operations together with the output produced that year.

Secretary's Transfer Authority

- The request seeks to include FDA as part of the Secretary's existing authority to transfer a portion of discretionary funds appropriated for the current year, subject to advance notification of the Congress. The budget proposes that the limit on the appropriation account receiving a transfer be increased from three percent to ten percent, and that the restriction of transferring funds only between accounts within the Labor/HHS/Education appropriation be revised to include transfers of discretionary funds between HHS appropriations in all Acts.

- This change would give the Secretary needed flexibility to move significant funds to areas of need quickly and efficiently allowing him to effectively respond to any contingency and to carry out Departmental priorities.

Consolidation of Public and Legislative Affairs

- In FY 2003, FDA will begin to transfer certain functions to the Department to improve communication and achieve cost savings. The first phase will be for the Office of Public Affairs and the Office of Legislation to be consolidated at the Office of the Secretary. As a result, $7.317 million and 80 FTE appear in the budget of the Office of the Secretary that would otherwise appear in the FDA budget.

Why Is FDA's Contribution So Important?

Decisions made by FDA affect every single American every day. Last year, consumers spent $1 trillion -- more than 20 percent of all consumer expenditures -- on products FDA regulates.

- FDA strives to assure a safe food supply through critical science-based prevention strategies; ensures medical product safety by monitoring products, and their use and consumption by millions of Americans; monitors emerging hazards

to prevent health and safety threats; and, brings safe and effective new technologies to a world-wide market.

- FDA's food safety responsibilities extend from farm to table, and employ research and risk assessment and prevention strategies through a nation-wide inspection and surveillance partnership program with the states.

- FDA is speeding the development of new bioterrorism tools by accelerating the availability of medical products necessary to public health preparedness.

- FDA is responsible for monitoring the safety of about eight million import shipments that enter the United States (FY 2002 estimate).

- FDA ensures that products are safe throughout their entire life cycle, by conducting plant and product inspections, and by using surveillance systems to monitor the safety of the products, their use and consumption.

- FDA must be vigilant in assessing and then quickly and effectively reducing risks associated with unexpected and potentially widespread health and safety threats to the U.S. public. Some of these hazards include terrorism, and antibiotic resistance. FDA works to assure a safe supply of vaccine and blood products.

- FDA funded $24.259 million in extramural research grants in FY 2002 to entities in 30 of the 50 states.

FDA's budget is shown on the following page.

Consequences of Not Achieving the Objectives

Scientific breakthroughs and a plethora of innovative products mean ever-increasing challenges for FDA. This rapidly changing environment includes:

- The rapid transformation of the science and technology that generate the products FDA must regulate;

- Increasing expectations of consumers with changing demographics and consumption habits to easily obtain medical and risk-related information;

- The expanding and evolving composition of global trade and production; and,

- Emerging public health threats.

Ensuring a safe food supply has become increasingly difficult in the United States. New challenges such as the increased variety of foods grown or produced in distant places, more meals eaten outside the home, new and more deadly pathogens, and an increasingly vulnerable population have all contributed to the 76 million foodborne illnesses each year resulting in 325,000 hospitalizations and 5,200 deaths annually.

One of the critical challenges facing FDA is that its inspection force is charged with monitoring a regulated industry in an environment that has changed rapidly and become significantly more complex.

Industry's research and development pipelines abound with blueprints for hundreds of new and innovative products and processes that can literally transform life's experience, as we have known it. Such marvels of science as cell and gene therapy;

FY 2003 Budget Summary

(Dollars in 000s)

	FY 2002	FY 2002 Comparable	FY 2003
BA S&E	$1,334,770	$1,378,977	$1,424,136
GSA Rent (non-add)	*(98,876)*	*(98,571)*	*(98,556)*
B&F	34,281	34,281	8,000
BA, Total	$1,369,051	$1,413,258	$1,432,136
UF S&E	$177,247	$185,147	$288,024
GSA Rent (non-add)	6,240	6,240	7,140
UF Total	$183,487	$191,387	$295,164
Program Level	**$1,552,538**	**$1,604,645**	**$1,727,300**
FTE	9,982	9,900	10,459

Notes: Includes FY 2003 funding for retirement accruals.
FY 2002 Comparable shows 2002 impact of administrative transfer and retirement accruals had these been in effect that year.
BA=Budget Authority; S&E=Salaries and Expenses; UF=User Fees; and B&F=Building and Facilities.
FTE do not include 89 in each year for reimbursables.

FDA FY 2003 Budget Summary

(Dollars in 000s)

Program	Center	Field	Total
Foods			
Budget Authority	*$153,445*	*$276,571*	*$430,016*
Human Drugs			
Budget Authority	*$198,530*	*91,843*	*290,373*
User Fees:			
PDUFA	*170,083*	*15,747*	*185,830*
Biologics			
Budget Authority	*$122,917*	*$29,983*	*152,900*
User Fees:			
PDUFA	*62,277*	*2,047*	*64,324*
Animal Drugs & Feeds			
Budget Authority	*$59,888*	*$32,874*	*$92,762*
Devices and Radiological Health			
Budget Authority	*$142,726*	*$55,958*	*$198,684*
User Fees:			
MQSA	*5,128*	*11,094*	*16,222*
NCTR			
Budget Authority	*$42,677*	*-0-*	*$42,677*
Other Activities			
Budget Authority	*$81,670*	*-0-*	*$81,670*
User Fees:			
PDUFA	*14,744*		*14,744*
MQSA	*205*		*205*
Other Rent & Rent Related Activities			
Budget Authority	*$36,498*	*-0-*	*$36,498*
GSA Rent			
Budget Authority	*$98,556*		*$98,556*
User Fees:			
PDUFA	*7,140*	*-0-*	*7,140*
B & F	*$8,000*	*-0-*	*$8,000*
Export Certification			
User Fees	*$1,582*	*-0-*	*$1,582*
Certification Fund			
User Fees	*$5,117*	*-0-*	*$5,117*
S & E			
Budget Authority	*$801,853*	*$487,229*	*$1,289,082*
User Fees	*259,136*	*28,888*	*288,024*
Rent/B&F BA	*$143,054*	*-0-*	*$143,054*
Rent/B&F User Fees	*7,140*	*-0-*	*7,140*
Total BA	*$944,907*	*$487,229*	*$1,432,136*
Total User Fees	*266,276*	*28,888*	*295,164*
Agency Total	*$1,211,183*	*$516,117*	*$1,727,300*

Note: Dollars include full funding for retirement accruals.

genomics-based drugs; surgical robotics; and bioengineered plants and animals have the potential for saving lives, improving the quality of life and enhancing the economy. Along with their benefit comes a potential for harm if these new technologies are not appropriately overseen by individuals who fully understand them. FDA's ability to effectively oversee these products must be maintained.

This is a "front line" personnel intensive effort, necessitating increased human resource levels in specific scientific disciplines -- a challenge for the Agency. FDA has often been limited to replacing positions lost due to attrition. Approximately 45 percent of FDA's workforce are dedicated to "front line" efforts such as import monitoring and inspections, coordination with states' efforts, and cooperative education programs with industry, states and consumers. Front line positions added in the emergency supplemental, as well as the support Congress provided in FY 2002, will greatly alleviate this situation.

The President's Management Plan describes how the Agency is addressing the five presidential initiatives to further enhance our citizen focus and bring us closer to the consumer on a day-by-day basis. FDA's plan includes many innovative ideas within each initiative.

FDA Headquarters is located in 40 buildings at 18 locations. As a part of the FDA Revitalization Act, FDA has embarked on a multi-year plan to relocate the major portion of its headquarters personnel to White Oak, Maryland. This project, coupled with on-going efforts to reduce supervisory ratios, consolidate administrative functions and delayer headquarters staff, will afford FDA maximum flexibility to move resources closer to the day-to-day "front line" programmatic work of the Agency.

FDA places a high priority on the planning, development, operation, and governance of information technology (IT) systems. IT plays a vital role in support of FDA's mission. In FY 2003, the Agency will continue deployments and enhancements of ongoing IT projects that include the Adverse Event Reporting Systems (AERS), the Unified Financial Management System (UFMS), and the Operational and Administrative System for Import Support (OASIS). The Agency is integrating information systems and databases where possible, with related DHHS systems, and external stakeholders, such as health providers, academia, other government agencies, regulated industry, and consumers.

Smart consumer decisions require accurate and timely information. To provide this level of information, FDA must expand on its current activities to provide benefits directly to consumers and health care professionals. This is done via Consumer- and Health Professional-friendly internet information; public hearings and educational campaigns; and, toll-free hot lines connecting directly to FDA professionals.

FDA's international harmonization activities ensure that the international community's food and medical product standards meet U.S. statutory requirements necessary to protect this nation's public health.

FDA is also relying on the FY 2003 request to accomplish its critical Restructuring Plan Activities. These vital activities involve FDA's ability to respond more rapidly to citizen needs, improve accountability for results, increase public meetings, and improve coordination with regulated industry.

Consumers trust FDA and look to the Agency to assure the safety of the nation's foods, drugs, biological products, animal drugs, medical devices and radiological products. FDA needs the in-house support provided by the offices within the Other Activities budget activity to give a coherent direction to the Agency and serve as a liaison between the scientific program centers and FDA's many stakeholders.

How Are We Doing?

FDA's success in meeting its responsibilities can be seen in the results it produces and the public trust it generates. By almost any standard, the U.S. enjoys the safest foods, medicines and medical products of any country in the world. Americans have access to new and promising therapies as early or earlier than any other country. People care about these kinds of results.

FDA has worked hard to ensure that everyone affected by the Agency's actions has a voice, and that each voice is heard. Some of FDA's outreach efforts include:

- Maintaining up-to-date information for the 100 million people who consulted the internet for medical advice last year. Seventy percent of these people took that advice seriously;

- Expediting FDA's product review processes by ensuring sponsors know what is required, eliminating unnecessary requirements, and soliciting proposals and nominations for consensus standards from manufacturers to use to satisfy some review requirements;

- Forming a Least Burdensome Steering Committee to identify the approach least burdensome to industry for medical device development and evaluation;

- Working with consumer groups and industry to develop and provide guidance for bioengineered corn; and,

- Working closely with other DHHS agencies to produce a Departmental Action Plan that outlines activities to strengthen and improve the transmissible spongiform encephalopathy (TSE)/BSE safety net.

The latest Pew Foundation study reported that 72 - 85 percent of consumers, health professionals, patients, and industry representatives say that they trust FDA to make the right decisions -- more than twice the approval rate for government as a whole.

There is much more to be done to ensure safe products are always available for American consumers. Despite these positive signs, FDA must work to remain ever vigilant in its responsibilities to the American public. FDA's collaborative efforts will help ensure that the safest and most effective products possible are made available in a timely manner, and that critical product safety information is relayed to the American public and health care professionals quickly.

The FY 2003 budget request will allow FDA to strengthen its partnerships and linkages with consumers, industry, and federal and state partners that will result in more front-line assistance to these stakeholders, all in the name of improved public health protection. Additionally, this budget request reflects FDA's commitment to continue strengthening the public health protection by focusing on counter terrorism and other urgent public health hazards as well as major performance goals emphasized by

Congress. The following table reflects the Agency's base resources in the areas where FDA proposes increased spending.

Summary of Base Resources for Requested Changes in FY 2003

Requested Increases in FY 2003 by Activity	FY 2001 Resources by Activity	FY 2002 Current Estimate	FY 2003 Request Level[2/]	FY 2003 Changes by Activity
Counter Terrorism [1/]	**$8,205,000**	**$157,872,000**	**$159,048,000**	**+ $1,176,000**
Pay Related Inflationary Costs				**+ $28,552,000**
Patient Safety/Medical Errors	**$48,035,000**	**$58,035,000**	**$63,035,000**	**+ $5,000,000**
Generic Drugs	**$35,155,000**	**$41,220,000**	**$45,802,000**	**+ $4,582,000**
President's Mgmt. Agenda				
Management Efficiencies				**($2,578,000)**
UFMS		**$3,100,000**	**$8,300,000**	**+ $5,200,000**
Buildings & Facilities	**$31,281,000**	**$34,281,000**	**$8,000,000**	**($26,281,000)**
User Fees – PDUFA	**$160,713,000**	**$161,716,000**	**$264,220,000**	**+ $102,504,000**
User Fees – Non-PDUFA	**$18,123,000**	**$21,771,000**	**$22,490,000**	**+ $719,000**
BA Retirement Accruals	**$46,877,000**	**$51,182,000**	**$54,751,000**	**+ $3,569,000**
User Fee Retirement Accruals	**$7,287,000**	**$7,900,000**	**$8,454,000**	**+$554,000**
Consolidation of Legislation/Public Affairs	**($6,546,000)**	**($6,975,000)**	**($7,317,000)**	**($342,000)**
Totals with comparability				**+$122,655,000**

Note: Table reflects changes from 2002 to 2003 on a comparable basis for the consolidation of legislative and public affairs and retirement accruals, meaning that the 2002 numbers are shown as though those proposals had been in effect in 2002.

[1/]The FY 2001 amount does not include $4.750 million one-time funding for vaccine research and development from the Public Health Social Services Emergency Fund for counter terrorism, but does include $1.75 million for physical security from the Public Health Service Emergency Fund.

[2/]The FY 2003 request level does not include inflationary costs by each increase.

Counter Terrorism

Desired Outcome

Protection of FDA regulated products, including foods and animal feed, medical devices, radiological products, blood, drugs, and vaccines, from terrorist contamination, tampering or deleterious uses; and,

Availability of safe and effective medical products (drugs, vaccines, and devices) for diagnosis, treatment, and prevention of disease resulting from the intentional use of biological, chemical, or nuclear agents.

Program Objectives

A combination of public health and law enforcement responsibilities requires FDA 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 counter terrorism goals. These include:

- Detection, deterrence, investigation, and interdiction on efforts of intentional contamination or tampering with any FDA regulated product;
- Availability of safe and effective medical countermeasures for the diagnosis, treatment, and prevention of disease resulting from the intentional use of biological, chemical, or nuclear agents;
- Emergency preparedness and response; and,
- Safety from radiation exposure, including exposure resulting from public health emergencies or from the use of devices used to detect potential terrorist hazards.

Why is FDA's Contribution so Important?

In FY 2002, FDA budgeted $6.772 million on efforts to combat terrorism. The funding history is shown below:

Increases for FY 2002

(Dollars in $000)

PROGRAM	FY 2001 Current Estimate[1/]	FY 2002 Appropri-ation	FY 2002 Supple-mental	FY 2002 Current Estimate
Foods	$378	$397	$92,550	$92,947
Human Drugs	$775	$813	$14,250	$15,063
Biologics	$3,113	$3,266	$19,800	$23,066
Animal Drugs and Feeds	$408	$428	$3,500	$3,928
Devices and Radiological Health	$1,043	$1,094	$1,500	$2,594
NCTR	$438	$459	$5,800	$6,259
Other Activities	$300	$315	$750	$1,065
Rent and Rent-Related Activities	$1,750	-0-	$12,950	$12,950
TOTAL	$8,205	$6,772	$151,100	$157,872

[1/] Includes $1.75 million from the Public Health Service Emergency Fund for physical security, which has been annualized in the FY 2003 request, but does not include $4.750 million one-time funding for vaccine research and development.

The many facets of FDA's counter terrorism mandate were demonstrated by FDA's response to the September 11 terrorist attacks on U.S. citizens and symbols. These attacks include the anthrax outbreak of October and November, the onset of war in a region where U.S. troops are at risk for exposure to biological, chemical, and nuclear weapons of mass destruction; and a period when it was thought that FDA's own facilities had been contaminated with anthrax spores. All these incidents illustrate

the many roles FDA serves in the public health and law enforcement responses to acts of terrorism.

FDA is responsible for ensuring the safety of much of the nation's food supply. Every drug, vaccine, or diagnostic test that is administered to humans must be reviewed and approved for marketing in the U.S. by FDA. If investigational, those products are administered to patients with the agency's oversight. FDA plays a central role in the national response to a large-scale radiation emergency, and regulates the use of radiation emitting devices. The continued operation of the FDA and the safety of its employees are fundamental to the Agency's public health and national security roles.

Congress, in providing $151.1 million in additional funding in FY 2002, recognizes the important role FDA plays in protecting the public health by ensuring the availability of safe and effective drugs, vaccines, blood products, medical devices, radiological products, animal health products, and by ensuring a safe food supply. The funds requested in FY 2003 will allow FDA to continue its efforts to deal with any potential counter terrorism incident.

Key Strategies

To protect the nation's food supply, FDA addresses aspects of food production, manufacture, and transport in the country of origin, at the U.S. port of entry, and in domestic commerce. FDA must enhance the frequency and quality of imported food inspections, and modernize its import data system to enable better detection and detention of contaminated food. These increased inspection and surveillance activities, especially at the border, will contribute to the assurance that our food supply is better protected.

The regulatory process is lengthy and complex. It is essential for FDA to engage early in the process of product development with sponsors for drugs, vaccines, medical devices, and radiological products needed to counter agents of terrorism. FDA maintains a proactive stance in working with manufacturers and other government agencies active in counter terrorism medical product development or stockpiling efforts. This includes outlining the individual steps that must be taken to obtain FDA approval; requirements for pre-clinical toxicity testing; regulatory guidance on the development of protocols for conducting clinical trials; review and analysis of the trial results, review of the proposed manufacturing procedures; and, inspection of the manufacturing process to assure compliance with Good Manufacturing Practices, as well as post-marketing surveillance of adverse events.

FDA appreciates the support from its stakeholders for recognizing the critical role, responsibilities and needs of the Agency in the event of a counter terrorist attack. With the supplemental funding, FDA will increase its ability to respond to a terrorist attack and address threats against the Nation's health.

The holistic approach presented in the FDA FY 2002 counter terrorism request best represents the dichotomy and cohesion of the activities undertaken by the Agency to protect the American public. The four initiative areas – protecting regulated products; deterrence, detection, investigation, and interdiction; medical counter measures; crisis management and emergency preparedness; and radiation safety -- cover and include all of the legislative mandates of FDA's mission to promote and protect the public health by ensuring that safe and effective products reach the market in a timely way; to monitor

products for continued safety after they are in use; and, protect consumers by focusing on patient and consumer safety.

The $151.1 million in FY 2002 counter terrorism supplemental funding allowed the Agency to begin to establish activities in the areas of deterrence, detection, investigation, and interdiction; medical counter measures; emergency preparedness and response; and radiation safety. With these FY 2002 supplemental funds, the Agency is:

Food Safety

Protecting Regulated Products: Deterrence, Detection, Investigation and Interdiction

- Hiring 673 new employees to improve the Agency's capacity to respond to terrorist threats and attacks. These will allow FDA to increase border presence by doing more field exams, sample collections and analysis, domestic inspections and laboratory analysis. All in support of the compliance, policy and enforcement actions anticipated from the more than doubling of Field import staff and the corresponding inspections, sampling, testing, wharf exams and the like, to match the current mix of employees in the review process. The Agency is making optimal use of every method available to quickly identify applicants and reduce the time to hire;

- Enhancing the Center for Food Safety and Applied Nutrition's Adverse Event Reporting Systems (CAERS). FDA will oftentimes receive the first indication of a hazardous agent from reports of an illness or clinical data describing symptomalogy and association with certain foods or ingredients. The AERS is designed to compile and assess large numbers of physician, health professional data and conclusions and provide likely associations and causative agents for follow-up through investigation and clinical testing;

- Expanding the number of State health laboratories and capabilities of current laboratories connected to the Electronic Laboratory Exchange Network (eLEXNET). eLEXNET's expansion effort will allow the laboratories to exchange data on select biological agents (possibly including anthrax, botulinum toxin, brucellosis and other potential infectious diseases) and food pathogens. This system is the first Internet-based food safety system that consolidates a repository of pathogenic findings in the nation's food supply by Federal, State, and local government labs;

- Developing rapid detection and assessment methods for bacterial strains of counter terrorist agents (pathogens/chemicals) through intramural and extramural research; and expanding academic collaboration and Centers for Excellence to provide dedicated research efforts; and,

- Enhancing the OASIS system which will better identify those imports warranting closer scrutiny with both initial and follow-up inspections and other surveillance activities and provide better access to data in other Agency systems.

Emergency Preparedness and Response

- Procuring High Performance Liquid Chromatography (HPLC) equipment needed for rapid analysis of suspect foods to assay for biological or chemical agents that could be intentionally introduced into a food. These rapid detection instruments, Bio-sensors, can be used in a variety of settings to detect food, environmental and waterborne

pathogens. These instruments are special ordered from a sole source supplier and will be tested under an agreement with New Mexico State University;

- Performing data cleanup on the inventory of food establishments. The effort entails evaluation and standardization of poor quality data and resolving duplicates, then applying the same logic in real-time to incoming records from U.S. Customs Service and the FDA field force;

- Streamlining techniques for the rapid detection and assessment of bacterial strains of counter terrorist agents (pathogens/chemicals). Providing tools necessary to identify bacterial proteins and markers of toxicity in foods; and,

- Purchasing equipment and training import inspectors to enhance and streamline import sample collections processes at ports of entry and to provide for more rapid identification of suspect agents.

Safe and Effective Medical Products

Medical Counter Measures

- Ensuring the availability of safe and effective medical products, to support the development, maintenance and deployment of stockpiles of medical counter-measures; to assist in assuring that sufficient quantities of medical products are available; and, to support post-event follow-up and data collection initiatives for these products, some of which may be investigational. These activities are accomplished through the regulation of the development and licensure of new drugs, vaccines, medical devices, and radiological products for protection and treatment against terrorism-related diseases;

- Establishing contracts for services to provide the necessary support for intramural programs directed at optimizing the availability of safe and effective new products for the treatment, prevention or cure of human diseases that result from exposure to biological terrorism agents;

- Entering into various research contracts and Interagency Agreements (IAGs) with other federal agencies, such as the Department of Defense (DOD), the National Institutes of Health (NIH), and the Centers for Disease Control and Prevention (CDC), to develop protocols, conduct animal studies, and define reference databases on treatment and alternative therapies for infectious diseases caused by the intentional use of biological agents; and,

- Improving internal scientific knowledge and capabilities, conducting research to assess in vitro diagnostic technology used to detect biothreat agents, conducting a market assessment to identify potential device shortages, and educating health professionals and consumers on the use of medical device biowarfare products.

Security

Protecting Regulated Products: Deterrence, Detection, Investigation and Interdiction

- Expanding existing service contracts for obtaining additional guards for a number of our facilities.

Medical Counter Measures

- Securing storage for select agents to prevent unauthorized use or theft, including lockable storage cabinets, refrigerators and freezers needed by labs;

- Upgrading designated laboratory facilities to a BioSafety Level 3 (BSL-3) to support microbial counter terrorism research. BSL-3 facilities have containment capability that allows work with indigenous or exotic agents that may cause serious or potentially lethal disease such as counter terrorist agents. By utilizing the expertise of a contractor, the upgrade of designated laboratory space can be expedited thus allowing microbial counter terrorism research to proceed quickly; and,

- Outfitting upgraded laboratory facilities with infrastructure to include containment hoods, and appropriate filtering and monitoring devices. The conduct of these studies will require agents/chemicals and laboratory supplies, which will allow researchers to characterize multiple strains, construct a library/database of constituent proteins and query the library/database to find toxin related markers.

FY 2003

In FY 2003, FDA requests $159.048 million for counter terrorism activities. This funding will allow the Agency to continue the efforts that the Department and Congress provided for in FY 2002. All of the activities and initiatives -- the protection of the food supply through deterrence, detection, investigation, and interdiction activities, the availability of medical counter measures; optimization of agency functions during crisis and emergency situations; and enhanced radiation safety -- will continue and be expanded in FY 2003.

FDA requests continuing resources in FY 2003 to fund those activities that have a direct impact upon the Agency's counter-terrorism mission of ensuring safe and effective medical devices and radiological products and a safe human and animal food supply. This is a clear and continuing threat that will require additional enhancements and safeguards in order for the Agency to fulfill its mission.

FY 2003 Total Request

(Dollars in $000)

Program	FY 2002 Current Estimate[1]	FY 2003 Request[1]	FY 2003 Change +/-
Foods	$92,947	$92,947	-0-
Human Drugs	$15,063	$18,097	$3,034
Biologics	$23,066	$25,578	$2,512
Animal Drugs and Feeds	$3,928	$4,876	$948
Medical Devices	$2,594	$6,016	$3,422
NCTR	$6,259	$3,417	($2,842)
Other Activities	$1,065	$1,417	$352
Rent and Rent- Related Activities	$12,950	$6,700	($6,250)
TOTAL	$157,872	$159,048	$1,176

[1]Includes base resources of $6.772 million.

The FDA FY 2003 counter terrorism request is a comprehensive approach to addressing counter terrorist threats. The four objectives described above – protecting regulated products: deterrence, detection, investigation, and interdiction; medical counter measures; emergency preparedness and response; and radiation safety -- describe the counter-terrorism objectives. Specific strategies planned to meet these goals include:

Food Safety

Protecting Regulated Products: Deterrence, Detection, Investigation and Interdiction

- Expand FDA's coverage at the nation's busiest ports, increase FDA's ability to detain products that pose threats; and,

- Enhance FDA's ability to link import commercial intelligence with information on countries and products with suspected terrorist ties.

Emergency Preparedness and Response

- Provide multiple government agencies engaged in food safety regulatory activities with the ability to rapidly detect compare and communicate unusual findings in laboratory analyses through OASIS and eLEXNET;

- Increase State partnerships and matching grants for compliance and inspection activities; and,

- Increase FDA's presence in its retail, state audits and targeted inspection activities; and increase state partnerships and grant activities.

Safe and Effective Medical Products

Protecting Regulated Products: Deterrence, Detection, Investigation and Interdiction

- Expand FDA's coverage at the nation's busiest ports, including International Mail Facilities and Courier Hubs, sites that process high value medical products

- Increase FDA's ability to detain products that pose threats to the nation's supply of medical products; and,

- Enhance FDA's ability to link import commercial intelligence with information on countries and products with suspected terrorist ties.

Medical Counter Measures

- Expand regulatory and scientific assistance to industry and other government agencies to promote development of medical devices and radiological products, drugs, and biologics needed to counter the effects of a terrorist attack;

- Expedite review of new products, new uses of approved products, or new manufacturing sites for counter-terrorism uses;

- Develop test methods for DOD to test emergency devices for safe use on the battlefield and in civilian emergency care;

- Provide regulatory guidance for the use of investigational products in large scale military and civilian public health emergencies;

- Focus research programs on developing improved or novel testing methods for evaluation of diagnostic tests, drugs, vaccines, and blood products to ensure their safety, purity and effectiveness; and,

- Ensure the availability of safe blood and blood products at the time of an emergency.

Emergency Preparedness and Response

- Predict and manage potential shortages of drugs, vaccines, and devices so there are enough available to aid in any rescue efforts. An example is rubber gloves used to protect emergency workers and health care providers;

- Assure safety of approved medical devices and radiological products, drugs, and biologic products, including vaccines and blood products, to support the continued development, maintenance and deployment of stockpiles of medical countermeasures;

- Ensure the availability of sufficient quantities of medical countermeasures and appropriate follow-up in the event of an attack;

- Develop mechanisms to utilize FDA's medical material shortage experts to assist in acquisition of limited critical medical countermeasures during a terrorist event;

- Conduct inspections and consider alternative manufacturing sites to produce necessary animal drugs in the event of sabotage against existing animal drug manufacturing sites; and,

- Conduct a market assessment to identify manufactures and customers, and evaluate diagnostic test kit performance that detects warfare agents.

Radiation Safety

- Identify the needs of the Radiation Emergency Response Teams so they can effectively monitor for radiation threats and provide technical assistance where needed; and,

- Begin to develop and implement radiation safety standards for the safe use of people scanners in airports and other places.

Security

Emergency Preparedness and Response

- Certify bio-safety Level 3 Laboratories used for bioterrorism and decontamination and recertification of biological safety cabinets.

Consequences of Not Achieving the Objectives

Our FY 2003 request includes recurring costs for our counter terrorism activities. Without these funds, net gains in the counter terrorism program would be negatively offset because the FDA conducts both traditional and counter terrorism work. These activities cannot be separated. FDA's request includes funding for food safety, specifically to increase the number of food imports examinations and funds to speed the development of new medical products (i.e., drugs, devices, vaccines) necessary to protect the public health.

How Are We Doing

The Agency plays a pivotal role in counter terrorism preparedness and response with a combination of regulatory and law enforcement responsibilities mandated by the Federal Food, Drug and Cosmetic Act. FDA is a key player and point of contact for inter- and intra-agency activities, including:

- Works closely with the U.S. Customs Service to strengthen efforts in detection and interdiction of contaminated foods;

- Serves as project leader for National Food Safety System (NFSS). NFSS improves coordination and communication among public health and food regulatory officials at all levels of government;

- Participates in national surveillance and emergency response programs, including: Foodborne Disease Active Surveillance Network (FoodNet) which conducts active surveillance for foodborne diseases and related epidemiology studies, and is a collaborative project of CDC, USDA and FDA; and, PulseNet, a national network of public health laboratories that performs DNA "fingerprinting" on bacteria that may be foodborne;

- Facilitates the availability of safe and effective medical products for use in a public health emergency by identifying manufacturers and bulk suppliers of potentially important products, assessing inventories, and evaluating lead-time for increased production;

- Conducts advisory panels to discuss data requirements, including use of animal data developed by U.S. Army Medical Research Institute of Infectious Diseases, for approval of medical devices and radiological products intended to detect exposure to or infection with terrorist threat agents;

- Collaborates with CDC and DOD to develop a method to identify biomarkers of toxicity by using a mass spectrometry-based method for rapid detection of microorganisms and with other government agencies on counter terrorism research activities;

- Makes use of every available means to quickly hire applicants and begin training;

- Maintains a 24-hour notification system for counter terrorism incidents, including hoaxes, in cooperation with the Federal Bureau of Investigations (FBI); and,

- Coordinates with the DHHS Office of Emergency Preparedness (OEP) and has developed a draft protocol for response to a terrorist incident.

In FY 2003, FDA anticipates it will expend $159.048 million on counter terrorism activities.

Employee Pay Raises

Desired Outcome

Maintain the Agency's ability to fulfill its mission of protecting the public health through its focus on counter-terrorism efforts, improving patient safety, and improving patient access to safe and effective medical products.

Program Objectives

The public trusts FDA to ensure that food on the family table will be safe and wholesome; new medical products, drugs, biological products, medical devices, and radiological products are available in a timely manner with demonstrated benefits that outweigh risks; and, product information is useful and understandable.

How Will Built-in Increases Affect FDA's Mission?

- More than 60 percent of FDA's expenditures are pay related. Pay increases have a major impact on FDA because the Agency is more people-intensive than many government agencies. For FY 2002, Congress provided funds to cover pay raises which will allow FDA to more efficiently and effectively carry out its mission. Personnel are essential to accomplishing its regulatory mission because:

- The Agency's regulatory mandate is to protect the public health;

- Interpretation and enforcement of regulations is an inherently governmental function that must be performed by people;

- FDA's product review function requires numerous interdependent specialists in each of the Agency product areas who interact with industry on a regular basis;

- FDA's inspectional responsibilities require coverage of not only the entire country, but also around the world; and,

- FDA responsibilities require staff to monitor the entire life cycle of all products under the Agency's purview (e.g., from drug trials to drug application review to approved advertising to a product's effect on patient health).

Requested Increases for FY 2003

(Dollars in 000s)

	Center	Field	Total
Foods	$3,119	$4,776	$7,895
Human Drugs	$4,873	$2,315	$7,188
Biologics	$2,372	$730	$3,102
Animal Drugs and Feeds	$1,186	$767	$1,953
Medical Devices	$3,726	$1,447	$5,173
NCTR	$945	-0-	$945
Other Activities	$2,296	-0-	$2,296
Total	$18,517	$10,035	$28,552

This budget request includes $28.552 million in pay costs. Without pay raises, the Agency may reduce its personnel levels, directly reducing its ability to assure the safety and efficacy of the medical products

under its purview, protecting the food supply, and diminishing our capacity to support counter-terrorism activities. Specifically, pay increases allow FDA to:

- Continue the counter terrorism activities begun with FY 2002 supplemental funding;

- Support the increase examination of food imports. By the end of FY 2003, FDA estimates an increase of 100 percent over FY 2002 food field examinations;

- Support the development of new bioterrorism tools to accelerate the availability of medical products (i.e., drugs, devices, vaccines) necessary to protect the public health, and provide support to the CDC in managing the quantity and quality of stockpiled drugs and vaccines;

- Improve the drug review process. Payroll increases are needed to cover about half of the staff involved in the drug application review process not supported by Prescription Drug User Fee Act (PDUFA) fees; and,

- Improve FDA's ability to assure the safety of regulated products, inspect and investigate domestic and foreign manufacturers, and participate in Mutual Recognition Agreements (MRAs) with countries to establish global standards for foods and pharmaceuticals.

Consequences of Not Receiving Pay Increases

Without these pay increases, the Agency anticipates reductions in staffing levels that would severely impact day-to-day operations of FDA. The impact would be across all products areas and would greatly undermine our recent gains, particularly in counter terrorism. In FY 2003, without pay increases, the following scenarios could occur:

- Reverse the recent gains in combating foodborne illnesses;

- Reduce the testing and inspection of foods, medical devices, and radiological products;

- No improvement of blood and human tissue safety; and,

- Inability to strengthen the Agency's radiological health program that already fails to routinely inspect 95 percent of x-ray, sunlamp and laser products, and is unable to test 99 percent of all other radiation products.

How are we doing?

The Agency is showing great progress in program areas that continue to receive adequate funding. The American public benefits from a strong FDA performing efficiently and effectively.

Patient Safety/Medical Errors

Desired Outcome

Reduce preventable deaths and injuries associated with the use of medical products.

Program Objectives

Develop and enhance surveillance of FDA-regulated products to identify harm resulting from use, understand harm through expert analysis, and prevent harm to other patients by taking corrective action.

Why is FDA's Contribution so Important?

Approximately 1.3 million people are accidentally injured by medical therapy in the U.S. annually. Many errors are associated with the misuse of drugs, biologics, and medical devices regulated by FDA. Costs from these medical errors range from $20 to $75 billion annually. The Institute of Medicine estimates that as many as 100,000 Americans die annually as a result of ***preventable*** medical errors and the proliferation of new products may increase this number.

Requested Increases for FY 2003

(Dollars in 000s)

Program	Center	Field	Total
Human Drugs	$1,700	$500	$2,200
Biologics	$1,300	-0-	$1,300
Medical Devices	$1,500	-0-	$1,500
Total	$4,500	$500	$5,000

With increased funding of $5 million FDA will:

- Support the Department's Patient Safety Task Force to improve existing systems to collect data on patient safety. Specifically, the task force coordinates the collection and analysis of data from existing federal agency systems; develops efforts to help avert risks to patient safety;

- Continue enhancement to the Adverse Event Reporting System (AERS), to include electronic data entry initiatives. This will bring about harmonization with manufacturers and encourage more reporting by making it easier for drug manufacturers to enter reports;

- Continue developing the Medical Device Surveillance Network (MedSuN). When fully implemented, MedSuN will reduce the occurrence of medical device related events, serve as an advanced warning system, and greatly improve real-time public health communication among FDA and user facilities. The program significantly enhances postmarketing surveillance of medical products as they are used in medical practice and rapidly identifies critical health hazards associated with these products. With the additional resources, FDA expects to recruit 100 more hospitals and other health care facilities;

- Expand surveillance to identify potential patient safety risks from gene therapy, vaccines and other biological products;

- Enhance capability to assist with identifying potential tampering events by terrorists;

- communicates with other entities regarding reporting systems and safe practices;

- Continue participation on the International Conference on Harmonization (ICH), global pharmacovigilance (analysis and evaluation of adverse event reports and assessment of a product's risk versus benefits profile) initiatives; and,

- Conduct human factors research that is needed to identify and prevent user errors with medical device use.

Consequences of Not Achieving the Objectives

FDA believes that roughly half of the deaths and injuries associated with medical errors can be avoided by fully implementing its strategies. Thousands of lives and billions of dollars can be saved.

How Are We Doing?

Within the past few years, FDA has made progress in strengthening its internal systems for automating the collection of reports on these adverse events, and in pilot testing "smart" collection systems that look for patterns in adverse events. In FY 2001, FDA became part of a coordinated HHS-wide effort to establish common reporting criteria that will simplify the task for those who are submitting adverse events information, and for the federal agencies that are collecting it. We do not know how many adverse events there really are because adverse events are greatly under-reported. FDA lacks the data to fully assess the nature of the problem and sources of risk.

In FY 2002, FDA received an increase of $10 million to fund a portion of its systems approach to identifying and responding to adverse events reported in the U.S. An important aspect of this approach is the expansion of the MedSuN system to additional hospitals and user facilities for the reporting of adverse event reports, as well as enhancing and linking other existing databases. Additionally, FDA is expanding associated medical errors consumer and health care professional education programs, and increasing the number of analyses and reports evaluated.

The $5 million requested in FY 2003 will continue to build on collaborative efforts with other Federal and State governmental agencies, regulated industry and the American public, to ensure that the safest and most effective products possible are made available in a timely manner, and that critical product safety information is relayed to the American public and health care professionals quickly.

In FY 2003, FDA anticipates it will expend $22 million in support of the Department wide patient safety initiative. This is in addition to $41 million in base operational costs for adverse event reporting for a total of $63 million.

Generic Drugs

Desired Outcome

Reduce the total approval time for new generic drug applications.

Program Objective

Assure that only safe, effective, high-quality, and equivalent generic products are approved for use by consumers and health care professionals.

Why is FDA's Contribution so Important

The Generic Drugs Program has the primary responsibility for approving new generic drug applications. A generic drug is identical, or bioequivalent to a brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use. Although generic drugs are chemically identical to their branded counterparts, they are typically sold at substantial discounts from the branded price. According to the Congressional Budget Office, generic drugs save consumers an estimated $8 to $10 billion a year at retail pharmacies. Even more billions are saved when hospitals use generic drugs.

Through review of data on proposed products that must meet exacting specifications, FDA assures that generic products will perform the same as their respective brand name reference products. In the same manner, generic manufacturing and packaging sites must pass all of the same quality standards as those of brand name drugs.

Requested Increases for FY 2003

(Dollars in 000s)

Program	Center	Field	Total
Human Drugs	$3,436	$1,146	$4,582

FDA will use the $4,582,000 increase to:

- Hire additional reviewers and staff to accelerate the review and approval of Abbreviated New Drug Applications (ANDAs);
- Improve the review of ANDAs without sacrificing product quality. This will allow the Agency to set a more challenging goal of reviewing 75 percent of ANDAs within six months after submission;
- Hire additional inspectors to increase inspections of domestic and foreign firms, an activity critical to reducing total approval times; and,
- Increase coverage of imported generic drugs to better monitor the quality of finished drug products and bulk drug substances from overseas.

Consequences of Not Achieving the Objectives

The cost of prescription drugs has risen dramatically over the last decade. Many retired Americans, living on fixed incomes, can no longer afford the cost of the medications they depend on. For all Americans, the cost of prescription drugs today can have a significant effect on families' abilities to meet all expenses.

Generic drugs provide Americans with safe and effective lower-cost alternatives to the escalating costs of brand name prescription drugs.

How are we doing?

The American public can be confident that when a generic drug product is approved, it has met the rigorous standards established by FDA with respect to identity, strength, quality, purity, and potency.

Congressional interest in this program has been strong. Past increases have been instrumental in improving efficiency within the Generic Drugs Program. In FY 2001, increased staffing helped FDA review and act upon 55.6 percent of original generic drug applications within six months after the submission date, representing an increase of more than 27 percent over FY 1999. The Agency believes that future increases will further improve review and approval times.

Over the years, FDA has approved several thousand generic drugs that have been used successfully by millions of patients. The use of these products has resulted in substantial savings.
The most recently approved generic drugs were for anxiety, heartburn, depression, and pain management.

In FY 2003, FDA anticipates it will expend approximately $45.8 million on the generic drug program.

Generic Approvals by Fiscal Year

Fiscal Year	Number of Approvals	Median Approval Time (months)
1993	170	39.7
1994	168	24.4
1995	201	28.2
1996	214	24.7
1997	256	19.6
1998	230	18.7
1999	198	17.3
2000	232	18.9
2001	241	18.4

President's Management Agenda

Workforce Planning and Restructuring

FDA is responding to the President's Management Agenda by realigning functions to reduce organizational layers and achieve efficiencies. During FY 2003, 25 administrative/ management positions will be eliminated and $2.578 million in cost savings will be achieved. The Agency also plans to consolidate staff associated with the public affairs and legislative affairs functions at the Department.

The Agency also plans to study in FY 2002 the current organizational structure to identify opportunities to consolidate and streamline other administrative functions.

Organizational structures will be designed that most effectively serve internal and external constituencies. This includes a flattened hierarchical structure, cost-effective processes and knowledge management to support Agency decisions. FDA will also do more contracting with States to conduct domestic inspections of FDA regulated products and foods.

Consolidations of headquarters and field offices are underway at White Oak and other regional locations. Processes that directly support the mission of the Agency will be reviewed and redesigned, such as product review management, inspections and enforcement responsibilities. More knowledge management initiatives such as SCIENCE FIRSt and the FDA University will be planned for the future.

Initiatives such as the above will enable the FDA to more effectively carry out its mission of protecting the health and safety of the U.S. citizen.

Financial Management

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

The HHS long-term strategic vision is to optimize resources for the management of financial operations and systems across the Department. FDA is scheduled to be one of the first agencies to benefit from this planned system. This new system will provide FDA with the means to continue its considerable efforts to retain a clean audit opinion and meet accelerated timeframes for the Reports Consolidation Act. In FY 2002, Congress provided $3.1 million for FDA to improve financial management systems and processes related to its legacy systems. The request includes an additional $5.2 million in FY 2003.

Information Technology

FDA is ever more reliant upon the use of information technology in promoting

public health and preventing injury or death. The Agency has strategically organized and integrated its Information Technology (IT) resources into four strategic categories: electronic regulation, science, management, and IT infrastructure and security.

Electronic regulation can best be described as the electronic handling and manipulation of regulatory information toward improving public health. To the fullest extent practical, FDA is committed to providing and receiving regulatory information in an electronic format for both premarket review and postmarket safety activities.

IT projects in the science category provide FDA scientists with the ability to make regulatory decisions based on access to state-of-the-art science resources such as databases containing information on the latest discoveries. Rapid validation of data allows application decisions to meet statutory requirements.

Management functions provide structure and consistency for routine tasks and core operations. The Agency has facilitated major changes in the way it performs its administrative functions to achieve effectiveness. Automated systems have been planned or developed to support key areas such as: Time and Attendance, Personnel, Financial Management, and the Federal Register. The Agency is exploring the integration of these systems with other Department agencies with similar systems at the Department level.

The focal point of FDA's strategic application of IT infrastructure will be the continuation and expansion of its Information Systems Architecture (ISA) and Critical Infrastructure Protection (CIP) programs as participants in the DHHS Five Year Information Technology Plan. FDA's request includes funding to participate in Department wide efforts to improve the Information Technology Enterprise Infrastructure.

The request includes funds to participate in an enterprise approach to investing in key information technology infrastructure such as security and network modernization. These investments will enable FDA programs to carry out their missions more securely and at a lower cost. Agency funds will be co-administered with resources in the Information Technology Security and Innovation Fund to promote collaboration in planning and project management and to achieve common goals such as secure and reliable communication and lower costs for the purchase and maintenance of hardware and software. FDA will participate in these activities with an estimated $5.665 million in FY 2002, and an estimated $8.945 million in FY 2003.

E-Government

It is the goal of FDA to leverage information technology to make FDA a results-oriented and customer-focused government organization. FDA is developing and using electronic information and transactions that allow for more efficient and cost effective access to government for citizens, industry and other branches of the government without compromising privacy and information security. FDA's approach to expanding E-government includes: making the Agency more

citizen-centered by increasing the availability of information on the Internet; enhancing electronic communication with industry by increasing collaboration and retooling processes and the workforce; expanding long-term IT capital planning, and, leveraging greater efficiencies in E-procurement.

Competitive Sourcing

To achieve consistency in our inventory, FDA developed a matrix describing FDA's major activities and correlated each activity with the OMB function codes. The group determined whether the work performed was inherently governmental or commercial in nature, and applied these standards consistently across FDA's Centers and Offices. FDA continues to perform ongoing evaluation of other commercial activities for competition outsourcing, with the goal of studying 50 percent of our commercial FTE under the A-76 process. In FY 2002, FDA is studying commercial activities including web design and development, graphic arts and visual information services, medical/scientific librarian services, and television studio service. These activities represent approximately 76 staff. In FY 2003, the Agency expects to study real property management, personnel management and support, and administrative support -- activities representing approximately 171 staff. FDA already contracts for over 1,800 staff, representing over 16 percent of the workforce, under various types of service contracts. The Agency will explore ways of expanding existing contracts as well as developing new approaches.

Non-PDUFA User Fees

User Fee Overview

The budget includes inflationary increases for currently authorized user fees totally $1,355,000, plus $636,000 for retirement accruals associated with these fees.

Mammography Quality Standards Act (MQSA)

MQSA was reauthorized in 1998 for a five years. The current MQSA legislation expires October 28, 2002 and will need to be reauthorized. The Administration will be sending a bill to Congress in the coming months.

MQSA requires that mammography facilities be certified to remain in operation, and inspected annually to ensure compliance with national quality and safety standards. An increase of $837,000 will provide for inflationary costs for this program. The fees collected pay for the costs of these annual inspections to ensure compliance with national quality and safety standards. Funding of $315,000 is included for retirement accruals.

Color Certification

The FFD&C Act requires the certification of color additives. This function, which is administered by FDA's Center for Food Safety and Applied Nutrition (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. An increase of $436,000 will cover inflationary costs. Funding of $239,000 is also included for retirement accruals.

Requested Increases for FY 2003

(Dollars in $000s)

Program	Center	Field	Total
MQSA			
Medical Devices	$360	$458	$818
Other Activities	$19	-0-	$19
MQSA Total	**$379**	**$458**	**$837**
Color Certification	$436	-0-	$436
Export Certification	$82	-0-	$82
Total	**$897**	**$458**	**$1,355**

Note: Includes retirement accruals.

Export Certification

FDA is required to issue certificates to any person wishing to export a drug, animal drug, or device, that the product to be exported meets certain requirements of the law. This applies to products approved for sale in the U.S. as well as to unapproved products. The purpose of these certificates is to promote the export of products made in the U.S. The requirements for these certificates were amended by the FDA Export Reform and Enhancement Act of 1996, which also established user fees for this service.

Fees are set by regulation, up to a statutory maximum of $175. Estimated revenue is expected to be about $1,500,000 from certificates issued for drugs, animal drugs, and medical devices. FDA issues export certificates for foods, animal foods, and cosmetics, but these certificates are not covered under the statute. Export Certification fees are credited to FDA's Salaries and Expenses Appropriation, and must be authorized through the annual appropriations act. Funding of $82,000 is also included for retirement accruals.

Proposed PDUFA User Fee

User Fee Overview

The budget request includes $272.038 million in user fees from reauthorization of the Prescription Drug User Fee Act (PDUFA).

The FDA Modernization Act of 1997 reauthorized, through FY 2002, the collection of user fees to enhance the review process of new human drugs and biological products and established fees for applications, establishments, and approved products. FDA strongly believes in the success of PDUFA and that it represents a model for reinventing government with Congress, the Agency, industry and the consumer groups all working together providing necessary resources, setting performance goals, and holding the Agency responsible. The Act must be reauthorized before September 30, 2002, and FDA is working with industry on a proposal to reauthorize and enhance PDUFA for FY 2003 and beyond. Several public meetings have also been held so that all stakeholders have the opportunity to voice their opinions.

Effect on Program Objectives

These user fees have enabled FDA to improve its performance for drug review and approval times. Total approval time – the time from the initial submission of a marketing application to the issuance of the final approval letter – has dropped from a pre-PDUFA median of 23 months to 12 months. Total approval time for priority applications, those for products providing significant therapeutic gains, has dropped from a median of over 12 months in the early PDUFA years to 6 months. Before PDUFA, only about 60 percent of the applications submitted were ultimately approved. Now, about 80 percent are approved. For the consumer, this means more safe and effective products getting to market more quickly.

PDUFA III

As stated, FDA strongly believes in the success of PDUFA. The budget includes proposed increases in user fees of $272.038 million for activities related to assuring the safety of, and continue earlier patient access to, new drug and biological products, and improved risk management. The American public would continue to have improved access to new therapies, which results in reduced morbidity, mortality, disability days, and hospitalization, as well as improved quality of life issues.

PDUFA Resources

(Dollars in $000s)

PDUFA	FY 2002	FY 2003
Human Drugs		
W/accruals	$110,929	$185,830
W/o accruals	$106,188	$180,662
Biologics		
W/accruals	$37,006	$64,324
W/o accruals	$35,344	$62,474
Other Activities		
W/accruals	$14,778	$14,744
W/o accruals	$13,944	$13,944
GSA Rent		
W/accruals	$6,240	$7,140
W/o accruals	$6,240	$7,140
Total		
W/ accruals	**$168,953**	**$272,038**
W/o accruals	**$161,716**	**$264,220**

Overview
FY 2003 Annual Performance Plan

Our Mission and Scope of Responsibilities

FDA has broad responsibilities for protecting the health of American consumers. Although FDA's mission statement clearly outlines these general responsibilities, it does not convey the tremendous scope of activity that we oversee. Decisions made by FDA affect every American every day.
To illustrate:

- Last year consumers spent $1 trillion – more than 20% of their money – on products that we regulate.

- We judge the safety of an expanding scientific revolution. Public and private entities invest an estimated $50 billion annually in biomedical research and technology.

- We assure the safety of the Nation's manufacturing and processing: FDA is a 10,000 person agency, but it is responsible for monitoring over 100,000 U.S. firms that manufacture or process products.

- We also monitor the safety of almost 8 million import shipments that enter this country each year.

FDA: An Overview

The public trusts FDA to ensure that:

1. Foods are safe, wholesome, and properly labeled
2. Drugs for both humans and animals, and vaccines for humans, are safe and effective
3. Blood used for transfusions is safe and in adequate supply
4. Medical devices, from scalpels to CAT scans, are safe and effective
5. Transplanted tissues are safe and effective
6. Equipment that uses radiant energy, such as X-ray machines and microwave ovens, is safe

Prevention -- The Cornerstone of FDA Strategic Goals

To successfully accomplish its mission, FDA leadership has identified four strategic goals. Each goal reinforces the importance of ***prevention*** as the Agency's primary line of attack on the Nation's health and safety concerns.

Prevention, to FDA, means that we use all means available to minimize health or safety risks facing the American people by correctly assessing the risks and effectively managing them.

Our Strategic Goals:

- **Counter the Terrorist Threat** - FDA will prepare for the possibility of terrorist attacks on the U.S. population, and respond rapidly and appropriately in the event of an actual attack. This will require: developing a preventive capability for detection, deterrence and interdiction; having adequate supplies of safe and effective medical products to treat victims of an attack; and having in place an emergency preparedness and response plan that will protect U.S. citizens and maintain the internal security of FDA

- **Maintain a Strong and Effective FDA** - FDA will maximize return on its human capital by recruiting and adequately compensating the highest caliber scientists and health professionals to carry out its mission. It will also support the President's management objectives to create a streamlined, citizen-centered government agency. Key strategies to achieve this goal include: de-layering the bureaucracy; restructuring Agency functions so that they are more supportive of mission-critical activities; outsourcing traditional government functions where cost efficiencies can be realized; capitalizing on e-government efficiencies; strengthening financial management systems; establishing accountability to the U.S. taxpayer by linking Agency resources to performance; and reconfiguring information technology systems to more effectively support decision making at all levels in the Agency.

- **Assure Medical Product Safety** - FDA will assure that products are safe by conducting plant and product inspections to ensure that products are manufactured and distributed under safe conditions, and by developing surveillance systems to monitor the safety of the products themselves, their use and consumption.

- **Bring New Technologies to a World-Wide Market -**

  FDA will assure that the products of new technologies are available to U.S. consumers. Because of the Agency's timely science-based decisions, millions of Americans can get the medicines and medical devices they need and be assured of safe and effective products.

To effectively carry out these priorities the Agency will adhere to fundamental principles that frame all of its actions and which will lead to more effective public health results. These principles support:

- **using state-of-the-art science** to make accurate and timely decisions regarding the safety of products and processes;

- **thinking and acting in a global context –** Since the products we regulate are produced and marketed worldwide, our risk management strategies must also be approached from a global perspective.

- **making decisions that consider the total product life cycle –** We must use both premarket and postmarket product experience/data in making regulatory decisions. Our practices and regulations must be focused on keeping products safe and effective throughout their entire life cycle.

- **working with partners in all sectors** to strengthen the Agency's prevention efforts. We cannot accomplish our public health mission unless we collaborate with our stakeholders.

The table below summarizes FDA's strategic goals, the desired outcomes of these goals, and key performance targets for FY 2003.

FDA Strategic Goals	Desired Outcomes	Key FY 2003 Performance Goals
Counter the Terrorist Threat.	• Risks to U.S. citizens posed by potential or real terrorist attacks are minimized.	• Increase the number of physical exams of import entries by 100%; focus laboratory analysis on products with suspect histories or origins • Cover an additional 45 ports of entry where there are significant shipments of FDA-regulated products.
Maintain a Strong and Effective FDA	• State-of-the-art scientists and health professionals in position to make critical risk management decisions • Streamlined Agency optimally organized to support mission-critical activities • Cost-effective performance of functions • Citizen-centered agency accountable for results	• Develop and implement a plan to delayer all FDA components • Increase the percentage of electronically purchased transactions to 91%. • Increase the percentage of commercial FTEs that will be reviewed for outsourcing to a total of 15%.
Assure Medical Product Safety	• Significant reduction in the annual 100,000 deaths, injuries and illnesses is achieved because an effective safety net has been established which monitors medical products at all stages in the life cycle – from production through consumption.	• Meet statutory requirement by inspecting 50% of registered blood banks, source plasma operations and biologics manufacturing establishments. • Conduct targeted BSE inspections of 100% of all known renderers and feed mills handling prohibited material. • Ensure at least 97% of mammography facilities meet inspection standards, with less than 3% with Level I (serious) problems in FY 2002. • Ensure that all international standards and negotiations are based on good science and protect the public health.

FDA Strategic Goals	Desired Outcomes	Key FY 2003 Performance Goals
Bring New Technologies to a World-Wide Market	• Because of the Agency's timely science-based decisions, millions of Americans can get the medicines and medical devices they need and be assured of safe and effective products.	• Review and act on 90% of standard original new drug, product licensing and blood licensing (NDA/PLA/BLA) submissions within 10 months of receipt and 90% of priority original NDA/PLA/BLA submissions within 6 months. (PDUFA goal) • Review and act upon 75% of fileable original generic drug applications within 6 months of submission date. • Complete 95% of Premarket Approval Application (PMA) first actions within 180 days.

TITLE VI
RELATED AGENCIES AND FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

SALARIES AND EXPENSES

For necessary expenses of the Food and Drug Administration, including hire and purchase of passenger motor vehicles; for payment of space rental and related costs pursuant to Public Law 92-313 for programs and activities of the Food and Drug Administration which are included in this Act; for rental of special purpose space in the District of Columbia or elsewhere; and for miscellaneous and emergency expenses of enforcement activities, authorized and approved by the Secretary and to be accounted for solely on the Secretary's certificate, not to exceed $25,000; [$1,345,386,000, of which not to exceed $161,716,000 to be derived from prescription drug user fees authorized by 21 U.S.C. 379(h), including any such fees assessed prior to the current fiscal year but credited during the current year, in accordance with section 736(g)(4), shall be credited to this appropriation and remain available until expended: Provided, That fees derived from applications received during fiscal year 2002 shall be subject to the fiscal year 2002 limitation: Provided further, That none of these funds shall be used to develop, establish, or operate any program of user fees authorized by 31 U.S.C. 9701: Provided further, That of the total amount appropriated: (1) $312,049,000 shall be for the Center for Food Safety and Applied Nutrition and related field activities in the Office of Regulatory Affairs; (2) $352,647,000 shall be for the Center for Drug Evaluation and Research and related field activities in the Office of Regulatory Affairs, of which no less than $13,207,000 shall be available for grants and contracts awarded under section 5 of the Orphan Drug Act (21 U.S.C. 360ee); (3) $155,875,000 shall be for the Center for Biologics Evaluation and Research and for related field activities in the Office of Regulatory Affairs; (4) $82,967,000 shall be for the Center for Veterinary Medicine and for related field activities in the Office of Regulatory Affairs; (5) $179,521,000 shall be for the Center for Devices and Radiological Health and for related field activities in the Office of Regulatory Affairs; (6) $37,082,000 shall be for the National Center for Toxicological Research; (7) $29,798,000 shall be for Rent and Related activities, other than the amounts paid to the General Services Administration, of which $4,000,000 for costs related to occupancy of new facilities at White Oak, Maryland, shall remain available until September 30, 2003; (8) $105,116,000 shall be for payments to the General Services Administration for rent and related costs; and (9) $90,331,000 shall be for other activities, including the Office of the Commissioner; the Office of Management and Systems; the Office of the Senior Associate Commissioner; the Office of International and Constituent Relations; the Office of Policy, Legislation, and Planning; and central services for these offices: Provided further, That funds may be transferred from one specified activity to another with the prior approval of the Committees on Appropriations of both Houses of Congress] *$1,424,136,000.*

In addition, mammography user fees authorized by 42 U.S.C. 263(b) may be credited to this account, to remain available until expended.

In addition, export certification user fees authorized by 21 U.S.C. 381 may be credited to this account, to remain available until expended. *(Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2002; additional authorizing legislation required.)*

BUILDINGS AND FACILITIES

For plans, construction, repair, improvement, extension, alteration, and purchase of fixed equipment or facilities of or used by the Food and Drug Administration, where not otherwise provided, [$34,281,000] *$8,000,000*, to remain available until expended (7 U.S.C. 2209b). *(Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2002.)*

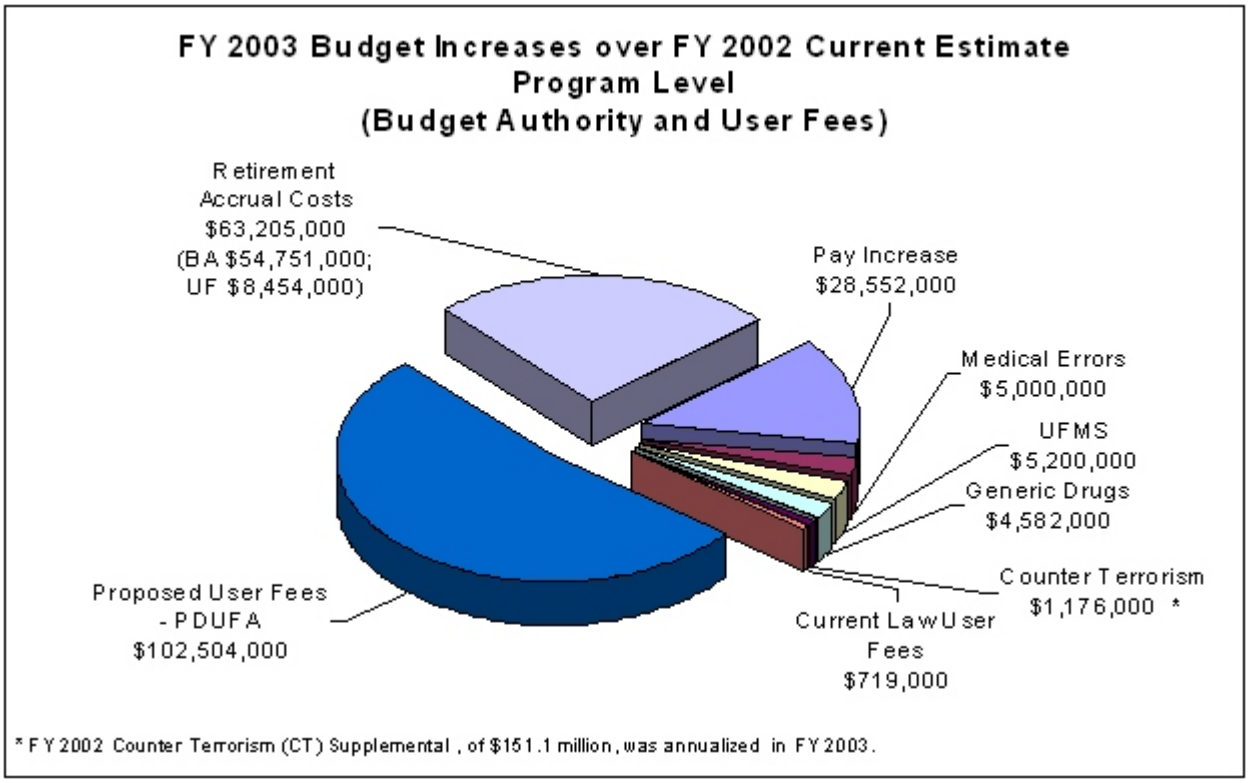
[For emergency expenses to respond to the September 11, 2001, terrorist attacks on the United Staes, for "Salaries and Expenses", $151,100,000 to remain available until expended, to be obligated from amounts made available in Public Law 107-38.] *(Emergency Supplemental Act, 2002.)*

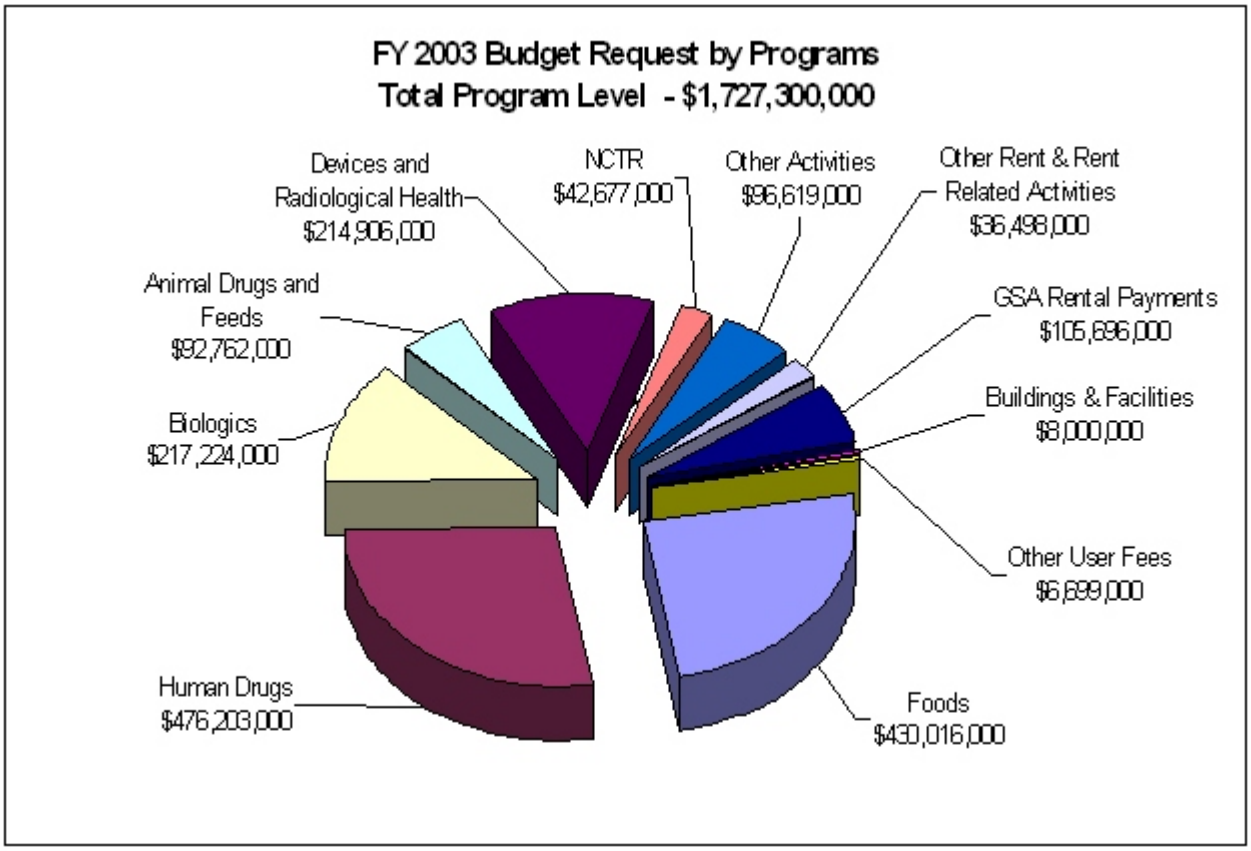
The Food and Drug Administration assures the safety of the nation's foods, medicines, medical devices and other products through regulations, pre-market product and manufacturer reviews and post-market inspections. The budget includes funding for counter terrorism activities that specifically deal with the protection of products regulated by the FDA (such as drugs, vaccines, foods, and animal feed), and the availability of medical products for public health preparedness in the event of an attack. The budget also requests funding for food safety, blood safety and patient safety.

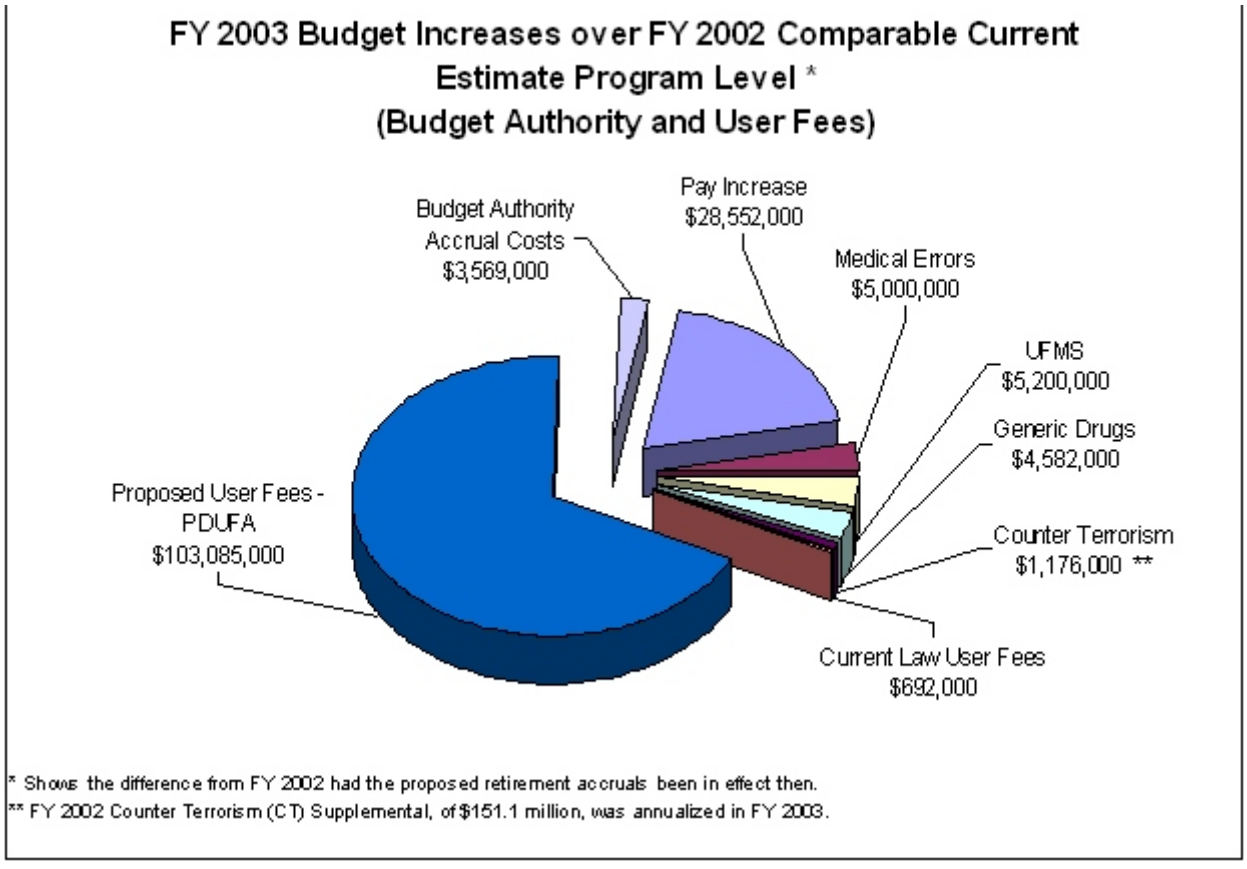
Salaries and Expenses
(Legislative Proposal not subject to PAYGO)

The budget includes a total of $272,038,000 in prescription drug user fees. Authorizing language for these fees will be proposed to authorize the collection and spending of the fees subject to appropriations language.

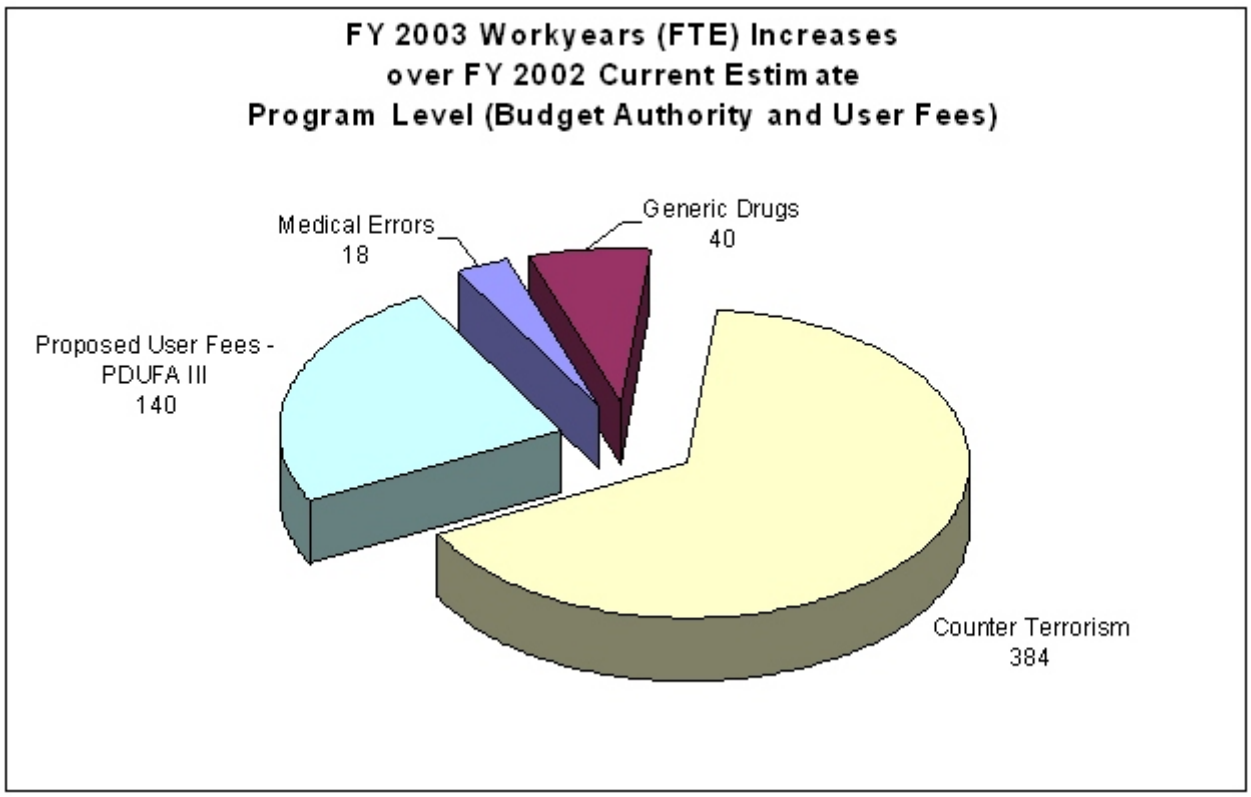
Explanation:
1/ Brackets remove Appropriation language that sets forth specific amounts by program and other areas, and therefore provides some flexibility for FDA resource allocation. Reprogramming language as contained in the General Provisions, section 720 would still apply.

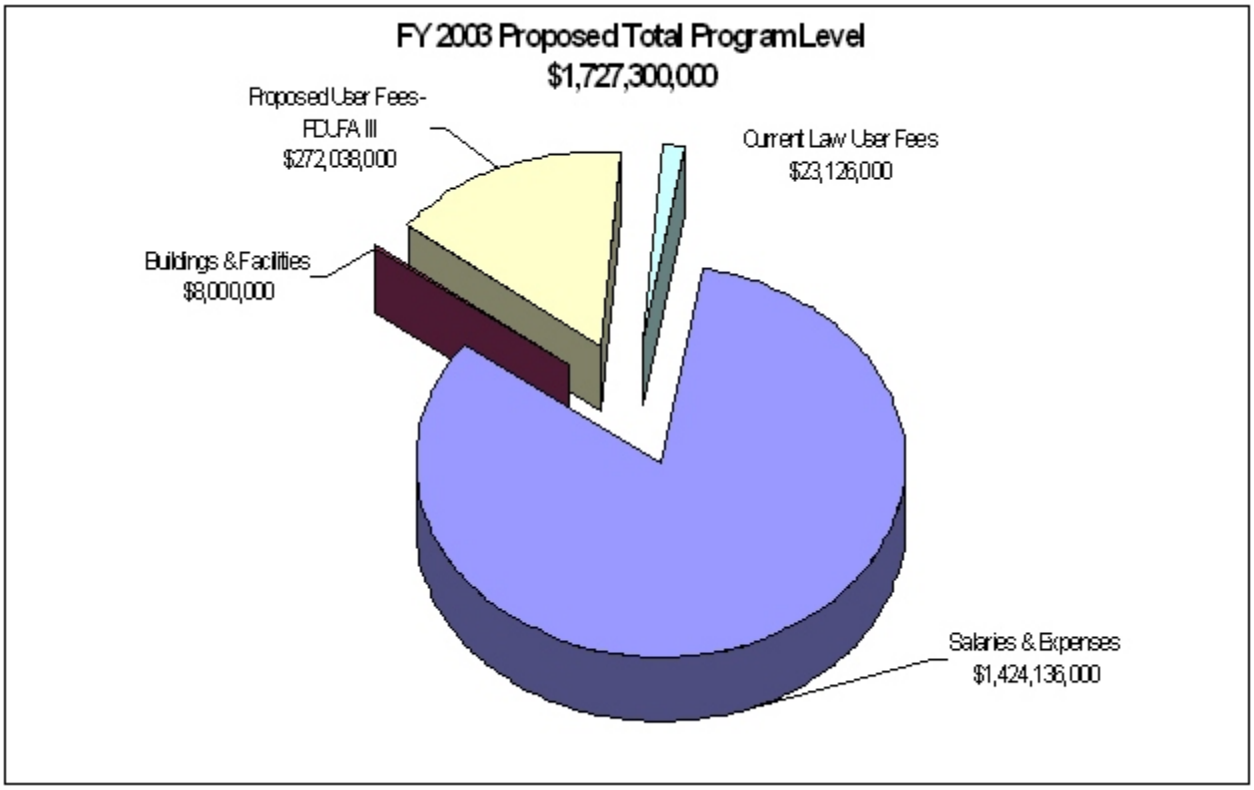

FY 2003 Budget Increases over FY 2002 Current Estimate
Program Level
(Budget Authority and User Fees)
Retirement Accrual Costs $63,205,000 (BA $54,751,000; UF $8,454,000)
Pay Increase $28,552,000
Medical Errors $5,000,000
UFMS $5,200,000
Generic Drugs $4,582,000
Counter Terrorism $1,176,000 *
Current Law User Fees $719,000
Proposed User Fees - PDUFA $102,504,000
* FY 2002 Counter Terrorism (CT) Supplemental , of $151.1 million, was annualized in FY 2003.

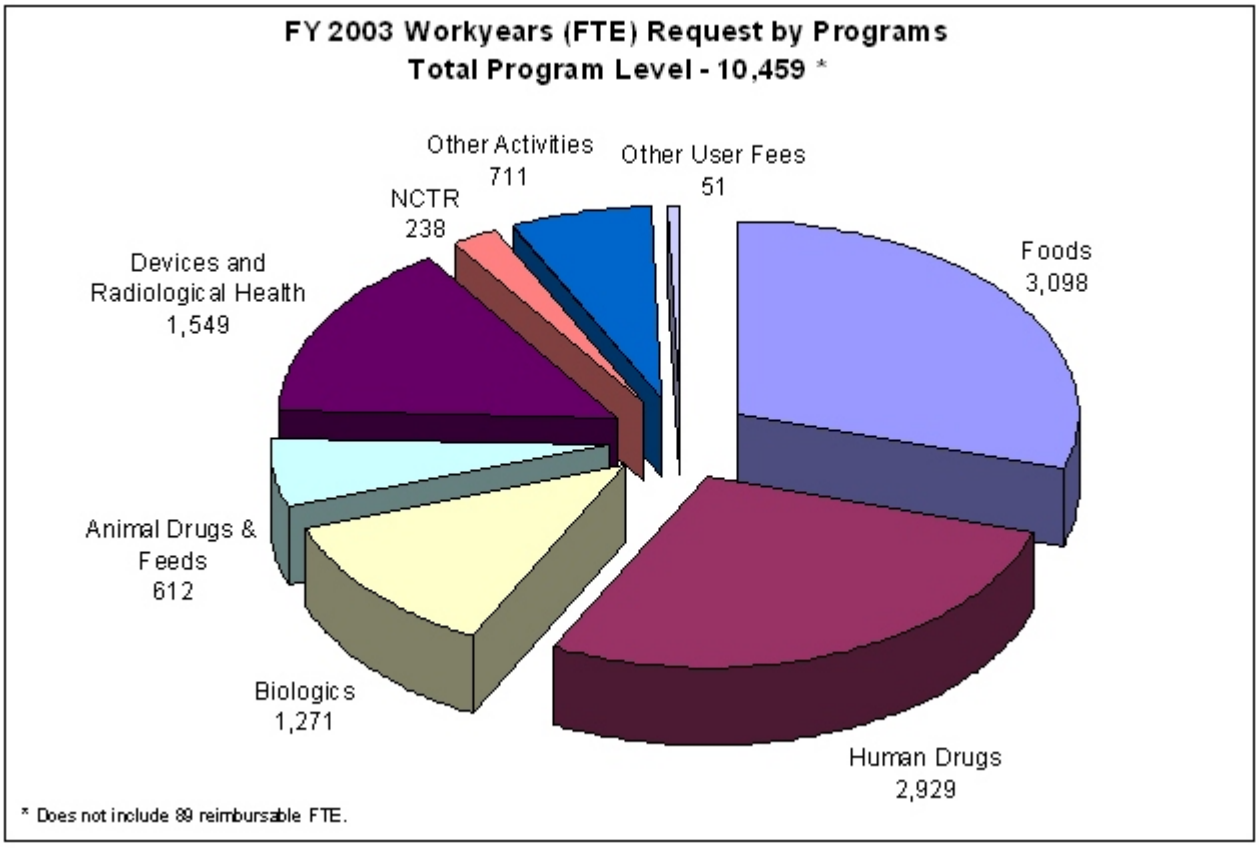




* Shows the difference from FY 2002 had the proposed retirement accruals been in effect then.
** FY 2002 Counter Terrorism (CT) Supplemental, of $151.1 million, was annualized in FY 2003.


FY 2003 Workyears (FTE) Increases
over FY 2002 Current Estimate
Program Level (Budget Authority and User Fees)
Medical Errors
18
Generic Drugs
40
Proposed User Fees -
PDUFA III
140
Counter Terrorism
384


FY 2003 Proposed Total Program Level
$1,727,300,000
Proposed User Fees-
PDUFA III
$272,038,000
Current Law User Fees
$23,126,000
Buildings & Facilities
$8,000,000
Salaries & Expenses
$1,424,136,000


FY 2003 Workyears (FTE) Request by Programs
Total Program Level - 10,459 *
Other Activities
711
Other User Fees
51
NCTR
238
Devices and
Radiological Health
1,549
Foods
3,098
Animal Drugs &
Feeds
612
Biologics
1,271
Human Drugs
2,929
* Does not include 89 reimbursable FTE.

FOOD AND DRUG ADMINISTRATION
Summary of Changes

	Budget Authority	User Fees	Program Level	Program Level FTE [1]
FY 2002 Appropriation	**1,217,951,000**	**183,487,000**	**1,401,438,000**	**9,472**
FY 2002 Counter-Terrorism Supplemental	**151,100,000**	**0**	**151,100,000**	**510**
FY 2002 Total	**1,369,051,000**	**183,487,000**	**1,552,538,000**	**9,982**
Comparability Adjustments				
Consolidation of Legislation and Public Affairs [2]	(6,975,000)	0	(6,975,000)	(82)
Retirement Accruals [3]	51,182,000	7,900,000	59,082,000	0
FY 2002 Comparable Total	**1,413,258,000**	**191,387,000**	**1,604,645,000**	**9,900**
Net Change from FY 2002 Comparable Total	**18,878,000**	**103,777,000**	**122,655,000**	**559**
FY 2003 Budget Estimate	**1,432,136,000**	**295,164,000**	**1,727,300,000**	**10,459**
Non-Pay Increases (1.8%)	**6,459,000**	**0**	**6,459,000**	**0**
Absorption of Non-Pay Increases (1.8%)	**(6,459,000)**	**0**	**(6,459,000)**	**0**
Commissioned Corps Retiree Health Benefits	**3,029,000**	**0**	**3,029,000**	**0**
Absorption of Commissioned Corps Retiree Health Benefits	**(3,029,000)**	**0**	**(3,029,000)**	**0**
Management Efficiencies	**(2,578,000)**	**0**	**(2,578,000)**	**(25)**
Built-in Increases				
Pay-Related Inflationary Increases, before consolidation	28,552,000	0	28,552,000	0
Effect of consolidation	(342,000)	0	(342,000)	0
Subtotal, Pay Related Inflationary Increases	*28,210,000*	*0*	*28,210,000*	0
Retirement Accruals (Other than User Fees)	3,569,000	0	3,569,000	0
Program Increases:				
Budget Authority:				
Counter Terrorism, other than Security	7,426,000	0	7,426,000	384
Patient Safety/Medical Errors	5,000,000	0	5,000,000	18
Generic Drugs	4,582,000	0	4,582,000	40
UFMS	5,200,000	0	5,200,000	0
User Fees:				
Non-PDUFA User Fee Changes				
MQSA	0	522,000	522,000	0
Color Certification	0	197,000	197,000	0
Retirement Accruals (change from FY 2002)	0	(27,000)	(27,000)	0
Total Non-PDUFA User Fee Increases	***0***	***692,000***	***692,000***	***0***
PDUFA User Fees				
PDUFA II (other than retirement accrual)	0	(161,716,000)	(161,716,000)	(1,102)
PDUFA II (retirement accrual)	0	(7,237,000)	(7,237,000)	0
PDUFA II Total	**0**	**(168,953,000)**	**(168,953,000)**	**(1,102)**
PDUFA III (retirement accrual)	0	264,220,000	264,220,000	1,242
PDUFA III (other than retirement accrual)	0	7,818,000	7,818,000	0
PDUFA III Total	**0**	**272,038,000**	**272,038,000**	**1,242**
Total PDUFA Increases	***0***	***103,085,000***	***103,085,000***	***140***
Total, User Fee Increases	**0**	**103,777,000**	***103,777,000***	**140**
Total Increases	**51,409,000**	**103,777,000**	***155,186,000***	**559**
Reduction due to non-recurring costs				
Buildings and Facilities - Net Change	(26,281,000)	0	(26,281,000)	0
Counterterrorism Physical Security Enhancements	(6,250,000)	0	(6,250,000)	0
Total Non-recurring Funds from FY 2002	**(32,531,000)**	**0**	**(32,531,000)**	0
Net Change from FY 2002 Comparable Total	**18,878,000**	**103,777,000**	**122,655,000**	**559**
Total FY 2003 Budget Request	**1,432,136,000**	**295,164,000**	**1,727,300,000**	**10,459**

[1] Does not include 89 reimbursable FTE, and does not reflect comparable adjustment as a result of the FY 2003 Legislation and Public Affairs Transfer to DHHS.
[2] The reduction in budget for Public Affairs and Legislation is not a true decrease in budgetary resources, but only a proposed transfer of functions from FDA to HHS/OS for these activities.
[3] The budget authority accrued retirement costs of $54,751,000, proposed for FY 2003, are fully funded in this budget request.

Food and Drug Administration
Crosswalk to Summary of Change - Budget Authority
Dollars in Thousands

Budget Authority FY 2003 Changes	Counter Terrorism												President's Management Plan									
	Food Safety		Safe and Effective Medical Products		Physical Security		Pay	Patient Safety/ Medical Errors		Generic Drugs		UFMS	Legislation and Public Affairs Consolidation [1]		Management Efficiencies		B&F Consoli-dation	Sub-Totals		Proposed Retirement Accruals	Grand Totals w/ Accruals	
	FTE	$000	FTE	$000	FTE	$000	$000	FTE	$000	FTE	$000	$000	FTE	$000	FTE	$000	$000	FTE	$000	$000	FTE	$000
Foods	**251**	**$0**	**0**	**$0**	**0**	**$0**	**$7,895**								**(4)**	**($397)**		**247**	**$7,498**	**$17,919**	**247**	**$25,417**
CFSAN	*16*	*0*					*3,119*								*(3)*	*(300)*		*13*	*2,819*	*5,333*	*13*	*8,152*
Field Activities	*235*	*0*					*4,776*								*(1)*	*(97)*		*234*	*4,679*	*12,586*	*234*	*17,265*
Human Drugs	**0**	**0**	**42**	**3,034**	**0**	**0**	**7,188**	**11**	**2,200**	**40**	**4,582**				**(4)**	**(396)**		**89**	**16,608**	**13,056**	**89**	**29,664**
CDER	*0*	*0*	*9*	*(2,712)*			*4,873*	*5*	*1,700*	*30*	*3,436*				*(3)*	*(300)*		*41*	*6,997*	*8,002*	*41*	*14,999*
Field Activities	*0*	*0*	*33*	*5,746*			*2,315*	*6*	*500*	*10*	*1,146*				*(1)*	*(96)*		*48*	*9,611*	*5,054*	*48*	*14,665*
Biologics	**0**	**0**	**38**	**2,512**	**0**	**0**	**3,102**	**6**	**1,300**						**(4)**	**(396)**		**40**	**6,518**	**6,051**	**40**	**12,569**
CBER			*35*	*2,586*			*2,372*	*6*	*1,300*						*(3)*	*(300)*		*38*	*5,958*	*4,503*	*38*	*10,461*
Field Activities			*3*	*(74)*			*730*	*0*	*0*						*(1)*	*(96)*		*2*	*560*	*1,548*	*2*	*2,108*
Animal Drugs & Feeds	**22**	**948**	**0**	**0**	**0**	**0**	**1,953**	**0**	**0**						**(4)**	**(396)**		**18**	**2,505**	**3,790**	**18**	**6,295**
CVM	*8*	*948*					*1,186*	*0*	*0*						*(3)*	*(300)*		*5*	*1,834*	*2,013*	*5*	*3,847*
Field Activities	*14*	*0*					*767*	*0*	*0*						*(1)*	*(96)*		*13*	*671*	*1,777*	*13*	*2,448*
Device & Radiological Products	**0**	**0**	**27**	**3,422**	**0**	**0**	**5,173**	**1**	**1,500**						**(4)**	**(396)**		**24**	**9,699**	**7,964**	**24**	**17,663**
CDRH			*6*	*284*			*3,726*	*1*	*1,500*						*(3)*	*(300)*		*4*	*5,210*	*5,306*	*4*	*10,516*
Field Activities			*21*	*3,138*			*1,447*	*0*	*0*						*(1)*	*(96)*		*20*	*4,489*	*2,658*	*20*	*7,147*
NCTR	**0**	**(775)**	**3**	**(2,067)**			**945**								**(2)**	**(297)**		**1**	**(2,194)**	**1,989**	**1**	**(205)**
Other Activities	**0**	**(50)**	**1**	**402**	**0**	**0**	**2,296**					**5,200**	**(80)**	**(6,997)**	**(3)**	**(300)**		**(82)**	**551**	**3,982**	**(82)**	**4,533**
Office of the Commissioner		*(50)*	*1*	*402*	*0*	*0*	*385*											*1*	*737*	*717*	*1*	*1,454*
Office of Management & Systems		*0*					*1,151*					*5,200*			*(1)*	*(100)*		*(1)*	*6,251*	*2,349*	*(1)*	*8,600*
Office of Senior Assoc. Commisioner							*266*						*(47)*	*(4,214)*	*(1)*	*(100)*		*(48)*	*(4,048)*	*199*	*(48)*	*(3,849)*
Office of International Constituent Relations							*203*											*0*	*203*	*398*	*0*	*601*
Office of Planning, Policy and Legislation							*291*						*(33)*	*(2,438)*	*(1)*	*(100)*		*(34)*	*(2,247)*	*319*	*(34)*	*(1,928)*
Central Services							*0*							*(345)*				*0*	*(345)*	*0*	*0*	*(345)*
Other Rent & Rent-Related					**0**	**(6,250)**												**0**	**(6,250)**	**0**	**0**	**(6,250)**
GSA Rent					**0**	**0**								**(320)**				**0**	**(320)**	**0**	**0**	**(320)**
Salaries & Expenses Increases	**273**	**123**	**111**	**7,303**	**0**	**(6,250)**	**28,552**	**18**	**5,000**	**40**	**4,582**	**5,200**	**(80)**	**(7,317)**	**(25)**	**(2,578)**		**337**	**34,615**	**54,751**	**337**	**89,366**
Non-Field	*24*	*123*	*54*	*(1,507)*	*0*	*0*	*18,517*	*12*	*4,500*	*30*	*3,436*	*5,200*	*(80)*	*(6,997)*	*(20)*	*(2,097)*		*20*	*21,175*	*31,128*	*20*	*52,303*
Field	*249*	*0*	*57*	*8,810*	*0*	*0*	*10,035*	*6*	*500*	*10*	*1,146*		*0*	*0*	*(5)*	*(481)*		*317*	*20,010*	*23,623*	*317*	*43,633*
Rents				*0*		*(6,250)*								*(320)*		*0*			*(6,570)*	*0*		*(6,570)*
Buildings and Facilities																	**(26,281)**		**(26,281)**	**0**		**(26,281)**
Total Budget Authority	**273**	**$ 123**	**111**	**$ 7,303**	**0**	**$ (6,250)**	**$ 28,552**	**18**	**$ 5,000**	**40**	**$ 4,582**	**$ 5,200**	**(80)**	**$ (7,317)**	**(25)**	**$ (2,578)**	**$ (26,281)**	**337**	**$ 8,334**	**$ 54,751**	**337**	**$ 63,085**

[1] The reduction in budget for Public Affairs and Legislation is not a true decrease in budgetary resources, but only a proposed transfer of functions from FDA to HHS/OS for these activities.

Food and Drug Administration
Crosswalk to Summary of Change -- User Fees
(dollars in thousands)

User Fee FY 2003 Increases	PDUFA [1/]		MQSA	Color Certification Fund	Sub-Total User Fees		Proposed Retirement Accruals	Grand Total User Fees w/ Accruals	
	FTE	*$000*	*$000*	*$000*	*FTE*	*$000*	*$000*	*FTE*	*$000*
Foods					**0**	**$0**	**$0**	**0**	**$0**
CFSAN					*0*	*0*	*0*	*0*	*0*
Field Activities					*0*	*0*	*0*	*0*	*0*
Human Drugs	**99**	**74,474**			**99**	**74,474**	**5,168**	**99**	**79,642**
CDER	*87*	*67,074*			*87*	*67,074*	*4,671*	*87*	*71,745*
Field Activities	*12*	*7,400*			*12*	*7,400*	*497*	*12*	*7,897*
Biologics	**41**	**27,130**			**41**	**27,130**	**1,850**	**41**	**28,980**
CBER	*37*	*26,030*			*37*	*26,030*	*1,781*	*37*	*27,811*
Field Activities	*4*	*1,100*			*4*	*1,100*	*69*	*4*	*1,169*
Animal Drugs & Feeds					**0**	**0**	**0**	**0**	**0**
CVM					*0*	*0*	*0*	*0*	*0*
Field Activities					*0*	*0*	*0*	*0*	*0*
Device & Radiological Products			**516**		**0**	**516**	**302**	**0**	**818**
CDRH			159		*0*	*159*	*201*	*0*	*360*
Field Activities			357		*0*	*357*	*101*	*0*	*458*
NCTR					**0**	**0**	**0**	**0**	**0**
Other Activities	**0**	**0**	**6**		**0**	**6**	**813**	**0**	**819**
Other Rent & Rent-Related					**0**	**0**	**0**	**0**	**0**
Buildings and Facilities					**0**	**0**	**0**	**0**	**0**
GSA Rent	**0**	**900**			**0**	**900**	**0**	**0**	**900**
Color Certification Fund				**197**	**0**	**197**	**239**	**0**	**436**
Export Certification							**82**	**0**	**82**
TOTALS	**140**	**$102,504**	**$522**	**$197**	**140**	**$103,223**	**$8,454**	**140**	**$111,677**
Non-Field	*124*	*93,104*	*165*	*197*	*124*	*93,466*	*7,787*	*124*	*101,253*
Field	*16*	*8,500*	*357*	*0*	*16*	*8,857*	*667*	*16*	*9,524*
Rent	*0*	*900*	*0*	*0*	*0*	*900*	*0*	*0*	*900*

[1/] The increase for PDUFA in this table is over the FY 2002 Current Estimate. Reauthorization of PDUFA is required in FY 2002. Total PDUFA estimate in FY 2003 is $264,220,000.

Food and Drug Administration
Crosswalk to Summary of Change -- Program Level
Dollars in Thousands

Program Level Increases FY 2003	Counter Terrorism						Budget Authority										Inflationary Costs		Proposed User Fees		Sub-Totals		Proposed Retirement Accruals	Grand Totals w/ Accruals	
	Food Safety		Safe and Effective Medical Products		Physical Security		Pay	Patient Safety/ Medical Errors		Generic Drugs		UFMS	Legislation and Public Affairs Consolidation[1/]		Management Efficiencies		B&F Consoli-dation	MQSA	Color Cert. Fund	PDUFA [2/]						
	FTE	$000	FTE	$000	FTE	$000	$000	FTE	$000	FTE	$000	$000	FTE	$000	FTE	$000	$000	$000	$000	FTE	$000	FTE	$000	$000	FTE	$000
Foods	**251**	**$0**					**$7,895**								**(4)**	**($397)**						**247**	**$7,498**	**$17,919**	**247**	**$25,417**
CFSAN (BA)	*16*	-					*3,119*								*(3)*	*(300)*						*13*	*2,819*	*5,333*	*13*	*8,152*
Field Activities (BA)	*235*	-					*4,776*								*(1)*	*(97)*						*234*	*4,679*	*12,586*	*234*	*17,265*
User Fees																						-	-	-	-	-
CFSAN																						-	-	-	-	-
Field Activities																						-	-	-	-	-
Human Drugs			**42**	**3,034**			**7,188**	**11**	**2,200**	**40**	**4,582**				**(4)**	**(396)**						**89**	**16,608**	**13,056**	**89**	**29,664**
CDER (BA)			*9*	*(2,712)*			*4,873*	*5*	*1,700*	*30*	*3,436*				*(3)*	*(300)*						*41*	*6,997*	*8,002*	*41*	*14,999*
Field Activities (BA)			*33*	*5,746*			*2,315*	*6*	*500*	*10*	*1,146*				*(1)*	*(96)*						*48*	*9,611*	*5,054*	*48*	*14,665*
User Fees																				**99**	**74,474**	*99*	*74,474*	*5,168*	*99*	*79,642*
Human Drugs																				*87*	*67,074*	*87*	*67,074*	*4,671*	*87*	*71,745*
Field Activities																				*12*	*7,400*	*12*	*7,400*	*497*	*12*	*7,897*
Biologics			**38**	**2,512**			**3,102**	**6**	**1,300**						**(4)**	**(396)**						**40**	**6,518**	**6,051**	**40**	**12,569**
CBER (BA)			*35*	*2,586*			*2,372*	*6*	*1,300*						*(3)*	*(300)*						*38*	*5,958*	*4,503*	*38*	*10,461*
Field Activities (BA)			*3*	*(74)*			*730*								*(1)*	*(96)*						*2*	*560*	*1,548*	*2*	*2,108*
User Fees																				**41**	**27,130**	*41*	*27,130*	*1,850*	*41*	*28,980*
Biologics																				*37*	*26,030*	*37*	*26,030*	*1,781*	*37*	*27,811*
Field Activities																				*4*	*1,100*	*4*	*1,100*	*69*	*4*	*1,169*
Animal Drugs & Feeds	**22**	**948**					**1,953**								**(4)**	**(396)**						**18**	**2,505**	**3,790**	**18**	**6,295**
CVM (BA)	*8*	*948*					*1,186*								*(3)*	*(300)*						*5*	*1,834*	*2,013*	*5*	*3,847*
Field Activities (BA)	*14*	-					*767*								*(1)*	*(96)*						*13*	*671*	*1,777*	*13*	*2,448*
User Fees																						-	-	-	-	-
Animal Drugs and Feeds																						-	-	-	-	-
Field Activities																						-	-	-	-	-
Device & Radiological Products			**27**	**3,422**			**5,173**	**1**	**1,500**						**(4)**	**(396)**						**24**	**9,699**	**7,964**	**24**	**17,663**
CDRH (BA)			*6*	*284*			*3,726*	*1*	*1,500*						*(3)*	*(300)*						*4*	*5,210*	*5,306*	*4*	*10,516*
Field Activities (BA)			*21*	*3,138*			*1,447*								*(1)*	*(96)*						*20*	*4,489*	*2,658*	*20*	*7,147*
User Fees																		**516**				-	*516*	*302*	-	*818*
Devices and Rad. Products																		*159*				-	*159*	*201*	-	*360*
Field Activities																		*357*				-	*357*	*101*	-	*458*
NCTR (BA)	-	**(775)**	**3**	**(2,067)**			**945**								**(2)**	**(297)**						**1**	**(2,194)**	**1,989**	**1**	**(205)**
Other Activities	-	**(50)**	**1**	**402**	-	-	**2,296**					**5,200**	**(80)**	**(7,317)**	**(3)**	**(300)**		**6**		-	-	**(82)**	**237**	**4,795**	**(82)**	**5,032**
Budget Authority	-	*(50)*	*1*	*402*	-	-	*2,296*					*5,200*	*(80)*	*(7,317)*	*(3)*	*(300)*						*(82)*	*231*	*3,982*	*(82)*	*4,213*
User Fee																		*6*				-	*6*	*813*	-	*819*
Other Rent & Rent-Related					-	*(6,250)*																-	*(6,250)*	-	-	*(6,250)*
Buildings and Facilities																	*(26,281)*					-	*(26,281)*	-	-	*(26,281)*
GSA Rent Budget Authority																						-	-	-	-	-
GSA Rent User Fees																					*900*	-	*900*	-	-	*900*
Color Certification Fund																			*197*			-	*197*	*239*	-	*436*
Export Certification																						-	-	*82*	-	*82*
Total BA	**273**	**$123**	**111**	**$7,303**	-	**($6,250)**	**$28,552**	**18**	**$5,000**	**40**	**$4,582**	**$5,200**	**(80)**	**($7,317)**	**(25)**	**($2,578)**	**($26,281)**	**$0**	**$0**	-	**$0**	**337**	**$8,334**	**$54,751**	**337**	**$63,167**
Non-Field	*24*	*123*	*54*	*(1,507)*	-	-	*18,517*	*12*	*4,500*	*30*	*3,436*	*5,200*	*(80)*	*(7,317)*	*(20)*	*(2,097)*		-		-	-	*20*	*20,855*	*31,128*	*20*	*51,983*
Field	*249*	-	*57*	*8,810*	-	-	*10,035*	*6*	*500*	*10*	*1,146*	-	-	-	*(5)*	*(481)*		-		-	-	*317*	*20,010*	*23,623*	*317*	*43,633*
Rent/B&F	-	-	-	-	-	*(6,250)*	-	-	-	-	-	-	-	-	-	-	*(26,281)*	-		-	-	-	*(32,531)*	-	-	*(32,531)*
Total User Fees	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		*522*	*197*	*140*	*102,504*	*140*	*103,223*	*8,454*	*140*	*111,595*
Non-Field	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		*165*	*197*	*124*	*93,104*	*124*	*93,466*	*7,787*	*124*	*101,171*
Field	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		*357*		*16*	*8,500*	*16*	*8,857*	*667*	*16*	*9,524*
Rent/B&F	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		-		-	*900*	-	*900*	-	-	*900*
Total Increase	**273**	**$123**	**111**	**$7,303**	-	**($6,250)**	**$28,552**	**18**	**$5,000**	**40**	**$4,582**	**$5,200**	**(80)**	**($7,317)**	**(25)**	**($2,578)**	**($26,281)**	**$522**	**$197**	**140**	**$102,504**	**477**	**$111,557**	**$63,205**	**477**	**$174,762**

[1/] The reduction in budget for Public Affairs and Legislation is not a true decrease in budgetary resources, but only a proposed transfer of functions from FDA to HHS/OS for these activities.

[2/] The increase for PDUFA in this table is over the FY 2002 Current Estimate. Reauthorization of PDUFA is required in FY 2002. Total PDUFA estimate in FY 2003 is $264,220,000.

Food and Drug Administration
ALL PURPOSE TABLE - Current Law Budget Authority [5/]
(Dollars in thousands)

PROGRAM	FY 2001 [1/] Current Estimate		FY 2001 [2/] Actual Obligations		FY 2002 [3/] Current Estimate		Change +/- FY 2002 Current Estimate		FY 2003 Budget Estimate [1/]	
	FTE	$	FTE	$	FTE	$	FTE	$	FTE	$
Salaries and Expenses:										
Foods	2,389	$287,530	2,445	$287,504	2,851	$404,599	247	$7,498	3,098	$412,097
Center	865	125,729	879	125,888	909	145,293	13	2,819	922	148,112
Field	1,524	161,801	1,566	161,616	1,942	259,306	234	4,679	2,176	263,985
Human Drugs	1,921	218,527	1,824	218,515	2,019	260,709	89	16,608	2,108	277,317
Center	1,197	151,089	1,140	151,468	1,251	183,531	41	6,997	1,292	190,528
Field	724	67,438	684	67,047	768	77,178	48	9,611	816	86,789
Biologics	826	108,310	786	108,303	937	140,331	40	6,518	977	146,849
Center	604	86,242	561	86,215	689	112,456	38	5,958	727	118,414
Field	222	22,068	225	22,088	248	27,875	2	560	250	28,435
Animal Drugs and Feeds	454	64,075	442	64,070	594	86,467	18	2,505	612	88,972
Center	302	48,861	290	48,440	320	56,041	5	1,834	325	57,875
Field	152	15,214	152	15,630	274	30,426	13	671	287	31,097
Devices and Radiological Health	1,423	165,316	1,428	165,306	1,477	181,021	24	9,699	1,501	190,720
Center	966	122,077	986	121,972	996	132,210	4	5,210	1,000	137,420
Field	457	43,239	442	43,334	481	48,811	20	4,489	501	53,300
National Center for Toxicological Research	227	36,249	206	35,248	237	42,882	1	(2,194)	238	40,688
Other Activities	638	67,992	674	67,985	664	77,137	(82)	551	582	77,688
Office of the Commissioner	87	10,009	97	10,147	101	12,429	1	737	102	13,166
Office of Management & Systems	339	29,551	343	29,292	350	34,670	(1)	6,251	349	40,921
Office of Senior Associate Commissioner	76	7,772	87	8,032	75	8,088	(48)	(4,048)	27	4,040
Office of International & Constituent Relations	56	6,370	63	6,268	57	7,207	0	203	57	7,410
Office of Policy, Planning, & Legislation	80	7,453	84	7,533	81	7,906	(34)	(2,247)	47	5,659
Central Services	0	6,837		6,713	0	6,837	0	(345)	0	6,492
Other Rent and Rent Related Activities	0	30,898	0	30,897	0	42,748	0	(6,250)	0	36,498
GSA Rental Payments	0	87,276	0	87,276	0	98,876	0	(320)	0	98,556
SUBTOTAL, Salaries & Expenses 4/	7,878	$ 1,066,173	7,805	$ 1,066,104	8,779	$ 1,334,770	337	$ 34,615	9,116	$ 1,369,385
Center Activities	4,799	638,239	4,736	638,216	5,066	749,550	20	21,175	5,086	770,725
Field Activities	3,079	309,760	3,069	309,715	3,713	443,596	317	20,010	4,030	463,606
Rent Activities	0	118,174	0	118,173	0	141,624	0	(6,570)	0	135,054
Buildings and Facilities		$31,281	0	$33,207	0	$34,281	0	($26,281)	0	$8,000
TOTAL Budget Authority	7,878	$1,097,454	7,805	$1,099,311	8,779	$1,369,051	337	$8,334	9,116	$1,377,385
Emergency Relief Fund (Total BA)										
Amount ERF (non-add)	0	$1,750	0	$1,750	0	$151,100	0	$0	0	$0
Amount non-ERF (non-add)	0	$1,097,454	0	$1,099,311	0	$1,217,951	0	$0	0	$0

[1/] Excludes $1.75 million and $4.75 million and 15 FTE received from DHHS for Counterrorism needs.
[2/] Includes $1.88 million from the Contingency Fund for BSE related extraordinary expenses.
[3/] Includes FY 2002 Appropriation plus $151.1 million from the Counter Terrorism Supplemental.
[4/] Does not include Reimbursable FTE of 89 in each year.
[5/] Please see Exhibit S for the crosswalk from current law to proposed law to reflect the Administration's proposal for full accrual retirement and health benefits.

Food and Drug Administration
ALL PURPOSE TABLE - Current Law User Fees [1/]
(Dollars in thousands)

PROGRAM	FY 2001 Current Estimate		FY 2001 Actual Obligations		FY 2002 Current Estimate		Change +/- FY 2002		FY 2003 Request	
	FTE	$	FTE	$	FTE	$	FTE	$	FTE	$
Salaries and Expenses, Definite Appropriations:										
Human Drugs (PDUFA)	702	$99,298	711	$103,965	722	$106,188	0	$0	0	$0
Center	635	92,615	644	96,995	655	98,338	0	0	0	0
Field	67	6,683	67	6,970	67	7,850	0	0	0	0
Biologics (PDUFA)	253	32,154	255	38,927	253	35,344	0	$0	0	0
Center	246	31,484	248	36,217	246	34,466	0	0	0	0
Field	7	670	7	2,710	7	878	0	0	0	0
Other Activities (PDUFA)	127	11,961	123	11,961	127	13,944	0	0	0	0
Office of the Commissioner	17	1,793	16	1,793	17	2,090	0	0	0	0
Office of Management & Systems	64	5,702	62	5,702	64	6,648	0	0	0	0
Office of Senior Associate Commissioner	21	1,932	20	1,932	21	2,252	0	0	0	0
Office of International & Constituent Relations	9	925	9	925	9	1,078	0	0	0	0
Office of Policy, Planning, & Legislation	16	1,609	16	1,609	16	1,876	0	0	0	0
GSA Rental Payments (PDUFA)	0	5,860	0	5,860	0	6,240	0	0	0	0
SUBTOTAL, Definite Appropriations	1,082	$149,273	1,089	$160,713	1,102	$161,716	0	$0	0	$0
Indefinite Appropriations:										
MQSA	50	$15,128	47	$12,439	50	$15,590	0	$522	50	$16,112
Devices & Radiological Health	48	14,947	45	12,259	48	15,404	0	516	48	15,920
Center	32	4,627	30	3,900	32	4,768	0	159	32	4,927
Field	16	10,320	15	8,359	16	10,636	0	357	16	10,993
Other Activities	2	181	2	180	2	186	0	6	2	192
Export Certification	13	1,500	13	1,479	13	1,500	0	0	13	1,500
Color Certification Fund	38	4,492	35	4,205	38	4,681	0	197	38	4,878
Subtotal, Indefinite Appropriations	101	$21,120	95	$18,123	101	$21,771	0	719	101	$22,490
Total, Current Law User Fees	1,183	$170,393	1,184	$178,836	1,203	$183,487	0	$719	101	$22,490
Center Activities	1,093	146,860	1,095	154,937	1,113	157,883	0	362	85	11,497
Field Activities	90	17,673	89	18,039	90	19,364	0	357	16	10,993
Rent Activities	0	5,860	0	5,860	0	6,240	0	0	0	0

[1/] Please see Exhibit S for the crosswalk from current law to proposed law to reflect the Administration's proposal for full accrual retirement and health benefits.

Food and Drug Administration
ALL PURPOSE TABLE - Proposed Law User Fees [2/]
(Dollars in thousands)

PROGRAM	Changes +/- FY 2002		FY 2003 1/ Request	
	FTE	$	FTE	$
PDUFA [1/]				
Human Drugs	**99**	**$74,474**	**821**	**$180,662**
Center	*87*	*67,074*	*742*	*165,412*
Field	*12*	*7,400*	*79*	*15,250*
Biologics	**41**	**27,130**	**294**	**62,474**
Center	*37*	*26,030*	*283*	*60,496*
Field	*4*	*1,100*	*11*	*1,978*
Other Activities	**0**	**0**	**127**	**13,944**
Office of the Commissioner	*0*	*0*	*17*	*2,090*
Office of Management & Systems	*0*	*0*	*64*	*6,648*
Office of Senior Associate Commissioner	*0*	*0*	*21*	*2,252*
Office of International & Constituent Relations	*0*	*0*	*9*	*1,078*
Office of Policy, Planning, & Legislation	*0*	*0*	*16*	*1,876*
GSA Rental Payments (PDUFA)	**0**	**900**	**0**	**7,140**
Total, Proposed Law User Fees	**140**	**$102,504**	**1,242**	**$264,220**
Center Activities	124	93,104	1,152	239,852
Field Activities	16	8,500	90	17,228
Rent Activities	0	900	0	7,140

[2/] Please see Exhibit S for the crosswalk from current law to proposed law to reflect the Administration's proposal for full accrual retirement and health benefits.

Food and Drug Administration
ALL PURPOSE TABLE - Total Program Level 5/
(Dollars in thousands)

PROGRAM	FY 2001 1/ Current Estimate		FY 2001 2/ Actual Obligations		FY 2002 3/ Current Estimate		Change +/- FY 2002 Current Estimate		FY 2003 Budget Request	
	FTE	$	FTE	$	FTE	$	FTE	$	FTE	$
Salaries and Expenses:										
Foods	2,389	$287,530	2,445	$287,504	2,851	$404,599	247	$7,498	3,098	$412,097
Center	865	125,729	879	125,888	909	145,293	13	2,819	922	148,112
Field	1,524	161,801	1,566	161,616	1,942	259,306	234	4,679	2,176	263,985
Human Drugs	2,623	317,825	2,535	322,480	2,741	366,897	188	91,082	2,929	457,979
Center	1,832	243,704	1,784	248,463	1,906	281,869	128	74,071	2,034	355,940
Field	791	74,121	751	74,017	835	85,028	60	17,011	895	102,039
Biologics	1,079	140,464	1,041	147,230	1,190	175,675	81	33,648	1,271	209,323
Center	850	117,726	809	122,432	935	146,922	75	31,988	1,010	178,910
Field	229	22,738	232	24,798	255	28,753	6	1,660	261	30,413
Animal Drugs and Feeds	454	64,075	442	64,070	594	86,467	18	2,505	612	88,972
Center	302	48,661	290	48,440	320	56,041	5	1,834	325	57,875
Field	152	15,214	152	15,630	274	30,426	13	671	287	31,097
Devices and Radiological Health	1,471	180,263	1,473	177,565	1,525	196,425	24	10,215	1,549	206,640
Center	998	126,704	1,016	125,872	1,028	136,978	4	5,369	1,032	142,347
Field	473	53,559	457	51,693	497	59,447	20	4,846	517	64,293
National Center for Toxicological Research	227	36,249	206	36,248	237	42,882	1	(2,194)	238	40,688
Other Activities	767	80,134	799	80,126	793	91,267	(82)	557	711	91,824
Office of the Commissioner	104	11,802	113	11,940	118	14,519	1	737	119	15,256
Office of Management & Systems	405	35,434	407	35,174	416	41,504	(1)	6,257	415	47,761
Office of Senior Associate Commissioner	97	9,704	107	9,964	96	10,340	(48)	(4,048)	48	6,292
Office of Intern'l & Constituent Relations	65	7,295	72	7,193	66	8,285	0	203	66	8,488
Office of Policy, Planning, & Legislation	96	9,062	100	9,142	97	9,782	(34)	(2,247)	63	7,535
Central Services	0	6,837	0	6,713	0	6,837	0	(345)	0	6,492
Other Rent and Rent Related Activities	0	30,898	0	30,897	0	42,748	0	(6,250)	0	36,498
GSA Rental Payments	0	93,136	0	93,136	0	105,116	0	580	0	105,696
SUBTOTAL, 4/,	9,010	1,230,574	8,941	1,239,256	9,931	1,512,076	477	137,641	10,408	1,649,717
Center Activities	5,841	779,107	5,783	787,469	6,128	901,252	144	114,444	6,272	1,015,696
Field Activities	3,169	327,433	3,158	327,754	3,803	462,960	333	28,867	4,136	491,827
Rent Activities	0	124,034	0	124,033	0	147,864	0	(5,670)	0	142,194
Export Certification	13	1,500	13	1,479	13	1,500	0	0	13	1,500
Certification Fund	38	4,492	35	4,205	38	4,681	0	197	38	4,878
SUBTOTAL, Salaries & Expenses Appropriation	9,061	$1,236,566	8,989	$1,244,940	9,982	$1,518,257	477	$137,838	10,459	$1,656,095
Buildings and Facilities:	0	31,281	0	33,207	0	34,281	0	(26,281)	0	8,000
Total Program Level	9,061	$ 1,267,847	8,989	$ 1,278,147	9,982	$ 1,552,538	477	$ 111,557	10,459	$ 1,664,095
Less User Fees:										
Current Law:										
Prescription Drug User Fee Act (PDUFA)	1,082	149,273	1,089	160,713	1,102	161,716	(1,102)	(161,716)	0	0
Mammography Quality Standards Act (MQSA)	50	15,128	47	12,439	50	15,590	0	522	50	16,112
Export Certification	13	1,500	13	1,479	13	1,500	0	0	13	1,500
Certification Fund	38	4,492	35	4,205	38	4,681	0	197	38	4,878
Proposed Law:										
PDUFA III 6/	0	0	0	0	0	0	1,242	264,220	1,242	264,220
SUBTOTAL User Fees	1,183	170,393	1,184	178,836	1,203	183,487	140	103,223	1,343	286,710
Total Budget Authority	7,878	$1,097,454	7,805	$1,099,311	8,779	$1,369,051	337	$8,334	9,116	$1,377,385
Emergency Relief Fund (Total Program Level)										
Amount ERF (non-add)	0	$1,750	0	$1,750	0	$151,100	0	$0	0	$0
Amount non-ERF (non-add)	0	$ 1,267,847	0	$ 1,278,147	0	$ 1,401,438	0	$0	0	$0

1/ Excludes $1.75 million and $4.75 million and 15 FTE received from DHHS for Counterterrism needs.
2/ Includes $1.88 million from the Contingency Fund for BSE related extraordinary expenses.
3/ Includes FY 2002 Appropriation plus $151.1 million from the Counter Terrorism Supplemental.
4/ Does not include Reimbursable FTE of 89 in each year.
5/ Please see Exhibit S for the crosswalk from current law to proposed law to reflect the Administration's proposal for full accrual retirement and health benefits.
6/ PDUFA is currently authorized through FY 2002. This proposes a new authorization in FY 2003.

Food and Drug Administration
Proposed Law Comparability Crosswalk to All Purpose Table - Budget Authority
(Dollars in thousands)

PROGRAM	FY 2001 Accrued Retirement	FY 2001 PA/LEG Transfer		FY 2002 Accrued Retirement	FY 2002 PA/LEG Transfer		FY 2003 Accrued Retirement	FY 2003 PA/LEG Transfer [1]	
	$	FTE	$	$	FTE	$	$	FTE	$
Salaries and Expenses:									
Foods	$14,078			$16,856			$17,919		
Center	5,097			5,374			5,333		
Field	8,981			11,482			12,586		
Human Drugs	11,466			11,841			13,056		
Center	7,145			7,337			8,002		
Field	4,321			4,504			5,054		
Biologics	4,930			5,496			6,051		
Center	3,605			4,041			4,503		
Field	1,325			1,455			1,548		
Animal Drugs and Feeds	2,710			3,484			3,790		
Center	1,803			1,877			2,013		
Field	907			1,607			1,777		
Devices and Radiological Health	8,045			7,932			7,964		
Center	5,461			5,349			5,306		
Field	2,584			2,583			2,658		
National Center for Toxicological Research	2,011			1,983			1,989		
Other Activities	3,637	(82)	(6,260)	3,590	(82)	(6,670)	3,982	(80)	(6,997)
Office of the Commissioner	563			595			717		
Office of Management & Systems	2,132			2,102			2,349		
Office of Senior Associate Commissioner	295	(48)	(3,749)	255	(48)	(3,995)	199	(47)	(4,214)
Office of International & Constituent Relations	322			357			398		
Office of Policy, Planning, & Legislation	325	(34)	(2,202)	281	(34)	(2,346)	319	(33)	(2,438)
Central Services	0		(309)	0		(329)	0		(345)
Other Rent and Rent Related Activities	0			0			0		
GSA Rental Payments	0		(286)	0		(305)	0		(320)
SUBTOTAL, Salaries & Expenses	$ 46,877	(82)	($6,546)	$ 51,182	(82)	($6,975)	$ 54,751	(80)	($7,317)
Center Activities	28,760	(82)	(6,260)	29,551	(82)	(6,670)	31,127	(80)	(6,997)
Field Activities	18,117	0	0	21,631	0	0	23,623	0	0
Rent Activities	0	0	(286)	0	0	(305)	0	0	(320)
Buildings and Facilities									
TOTAL Budget Authority	$46,877	(82)	($6,546)	$51,182	(82)	($6,975)	$54,751	(80)	($7,317)

[1] The Public Affairs/Legislation Transfer is already shown in non-comparable APT for FY 2003.

Food and Drug Administration
Proposed Law Comparability Crosswalk to All Purposed Table User Fees
(Dollars in thousands)

PROGRAM	FY 2001 Accrued Retirement	FY 2002 Accrued Retirement	FY 2003 Accrued Retirement [1]
	$	$	$
Salaries and Expenses:			
Human Drugs (PDUFA)	**$4,324**	**$4,741**	**$5,168**
Center	*3,911*	*4,301*	*4,671*
Field	*413*	*440*	*497*
Biologics (PDUFA)	**1,559**	**1,662**	**1,850**
Center	*1,516*	*1,616*	*1,781*
Field	*43*	*46*	*69*
Other Activities (PDUFA)	**782**	**834**	**800**
Office of the Commissioner	*105*	*112*	*107*
Office of Management & Systems	*394*	*420*	*403*
Office of Senior Associate Commissioner	*129*	*138*	*132*
Office of International & Constituent Relations	*55*	*59*	*57*
Office of Policy, Planning, & Legislation	*99*	*105*	*101*
GSA Rental Payments (PDUFA)			
SUBTOTAL, Definite Appropriations	**$6,665**	**$7,237**	**$7,818**
Indefinite Appropriations:			
MQSA	**$308**	**$328**	**$315**
Devices & Radiological Health	296	315	302
Center	*197*	*210*	*201*
Field	*99*	*105*	*101*
Other Activities	*12*	*13*	*13*
Export Certification	**80**	**85**	**82**
Color Certification Fund	**234**	**250**	**239**
Subtotal, Indefinite Appropriations	**$622**	**$663**	**$636**
Total, Current Law User Fees	**$7,287**	**$7,900**	**$8,454**
Center Activities	6,732	7,309	7,787
Field Activities	555	591	667
Rent Activities	0	0	0

[1] PDUFA fees in FY 2003 are proposed law user fees.

Food and Drug Administration
ALL PURPOSE TABLE - Proposed Law Budget Authority w/ Comparability [5/]
(Dollars in thousands)

PROGRAM	FY 2001 [1/] Current Estimate		FY 2001 [2/] Actual Obligations		FY 2002 [3/] Current Estimate		Change +/- FY 2002 Current Estimate		FY 2003 Budget Estimate [1/]	
	FTE	$	FTE	$	FTE	$	FTE	$	FTE	$
Salaries and Expenses:										
Foods	2,389	$301,608	2,445	$301,582	2,851	$421,455	247	$8,561	3,098	$430,016
Center	865	130,826	879	130,985	909	150,667	13	2,778	922	153,445
Field	1,524	170,782	1,566	170,597	1,942	270,788	234	5,783	2,176	276,571
Human Drugs	1,921	229,993	1,824	229,981	2,019	272,550	89	17,823	2,108	290,373
Center	1,197	158,234	1,140	158,613	1,251	190,868	41	7,662	1,292	198,530
Field	724	71,759	684	71,368	768	81,682	48	10,161	816	91,843
Biologics	826	113,240	786	113,233	937	145,827	40	7,073	977	152,900
Center	604	89,847	561	89,820	689	116,497	38	6,420	727	122,917
Field	222	23,393	225	23,413	248	29,330	2	653	250	29,983
Animal Drugs and Feeds	454	66,785	442	66,780	594	89,951	18	2,811	612	92,762
Center	302	50,664	290	50,243	320	57,918	5	1,970	325	59,888
Field	152	16,121	152	16,537	274	32,033	13	841	287	32,874
Devices and Radiological Health	1,423	173,361	1,428	173,351	1,477	188,953	24	9,731	1,501	198,684
Center	966	127,538	986	127,433	996	137,559	4	5,167	1,000	142,726
Field	457	45,823	442	45,918	481	51,394	20	4,564	501	55,958
National Center for Toxicological Research	227	38,260	206	38,259	237	44,865	1	(2,188)	238	42,677
Other Activities	556	65,369	592	65,362	582	74,057	0	7,613	582	81,670
Office of the Commissioner	87	10,572	97	10,710	101	13,024	1	859	102	13,883
Office of Management & Systems	339	31,683	343	31,424	350	36,772	(1)	6,498	349	43,270
Office of Senior Associate Commissioner	28	4,318	39	4,578	27	4,348	0	(109)	27	4,239
Office of International & Constituent Relations	56	6,692	63	6,590	57	7,564	0	244	57	7,808
Office of Policy, Planning, & Legislation	46	5,576	50	5,656	47	5,841	0	137	47	5,978
Central Services	0	6,528		6,404	0	6,508	0	(16)	0	6,492
Other Rent and Rent Related Activities	0	32,648	0	32,647	0	42,748	0	(6,250)	0	36,498
GSA Rental Payments	0	86,990	0	86,990	0	98,571	0	(15)	0	98,556
SUBTOTAL, Salaries & Expenses 4/	7,796	$ 1,108,254	7,723	$ 1,108,185	8,697	$ 1,378,977	419	$ 45,159	9,116	$ 1,424,136
Center Activities	4,717	660,738	4,654	660,715	4,984	772,431	102	29,422	5,086	801,853
Field Activities	3,079	327,878	3,069	327,833	3,713	465,227	317	22,002	4,030	487,229
Rent Activities	0	119,638	0	119,637	0	141,319	0	(6,265)	0	135,054
Buildings and Facilities		$31,281	0	$33,207	0	$34,281	0	(26,281)	0	$8,000
TOTAL Budget Authority	7,796	$1,139,535	7,723	$1,141,392	8,697	$1,413,258	419	$18,878	9,116	$1,432,136
Emergency Relief Fund (Total BA)										
Amount ERF (non-add)	0	$1,750	0	$1,750	0	$151,100	0	$0	0	$0
Amount non-ERF (non-add)	0	$1,137,785	0	$1,139,642	0	$1,262,158	0	$0	0	$0

[1/] Includes $1.75 million for allocated from PHSSEF for FDA physical security. Does not include $4.75 million and 15 FTE received from DHHS for Counterrorism needs.
[2/] Includes $1.88 million from the Contingency Fund for BSE related extraordinary expenses.
[3/] Includes FY 2002 Appropriation plus $151.1 million from the Counter Terrorism Supplemental.
[4/] Does not include Reimbursable FTE of 89 in each year.

Food and Drug Administration
ALL PURPOSE TABLE - Current Law User Fees w/ Comparability
(Dollars in thousands)

PROGRAM	FY 2001 Current Estimate		FY 2001 Actual Obligations		FY 2002 Current Estimate		Change +/- FY 2002		FY 2003 Request	
	FTE	$	FTE	$	FTE	$	FTE	$	FTE	$
Salaries and Expenses, Definite Appropriations:										
Human Drugs (PDUFA)	**702**	**$103,622**	**711**	**$108,289**	**722**	**$110,929**	**0**	**$0**	**0**	**$0**
Center	*635*	*96,526*	*644*	*100,906*	*655*	*102,639*	*0*	*0*	*0*	*0*
Field	*67*	*7,096*	*67*	*7,383*	*67*	*8,290*	*0*	*0*	*0*	*0*
Biologics (PDUFA)	**253**	**33,713**	**255**	**40,486**	**253**	**37,006**	**0**	**$0**	**0**	**0**
Center	*246*	*33,000*	*248*	*37,733*	*246*	*36,082*	*0*	*0*	*0*	*0*
Field	*7*	*713*	*7*	*2,753*	*7*	*924*	*0*	*0*	*0*	*0*
Other Activities (PDUFA)	**127**	**12,743**	**123**	**12,743**	**127**	**14,778**	**0**	**0**	**0**	**0**
Office of the Commissioner	*17*	*1,898*	*16*	*1,898*	*17*	*2,202*	*0*	*0*	*0*	*0*
Office of Management & Systems	*64*	*6,096*	*62*	*6,096*	*64*	*7,068*	*0*	*0*	*0*	*0*
Office of Senior Associate Commissioner	*21*	*2,061*	*20*	*2,061*	*21*	*2,390*	*0*	*0*	*0*	*0*
Office of International & Constituent Relations	*9*	*980*	*9*	*980*	*9*	*1,137*	*0*	*0*	*0*	*0*
Office of Policy, Planning, & Legislation	*16*	*1,708*	*16*	*1,708*	*16*	*1,981*	*0*	*0*	*0*	*0*
GSA Rental Payments (PDUFA)	**0**	**5,860**	**0**	**5,860**	**0**	**6,240**	**0**	**0**	**0**	**0**
SUBTOTAL, Definite Appropriations	**1,082**	**$155,938**	**1,089**	**$167,378**	**1,102**	**$168,953**	**0**	**$0**	**0**	**$0**
Indefinite Appropriations:										
MQSA	**50**	**$15,436**	**47**	**$12,747**	**50**	**$15,918**	**0**	**$509**	**50**	**$16,427**
Devices & Radiological Health	48	15,243	45	12,555	48	15,719	*0*	*503*	48	16,222
Center	*32*	*4,824*	*30*	*4,097*	*32*	*4,978*	*0*	*150*	*32*	*5,128*
Field	*16*	*10,419*	*15*	*8,458*	*16*	*10,741*	*0*	*353*	*16*	*11,094*
Other Activities	*2*	*193*	*2*	*192*	*2*	*199*	*0*	*6*	*2*	*205*
Export Certification	**13**	**1,580**	**13**	**1,559**	**13**	**1,585**	**0**	**(3)**	**13**	**1,582**
Color Certification Fund	**38**	**4,726**	**35**	**4,439**	**38**	**4,931**	**0**	**186**	**38**	**5,117**
Subtotal, Indefinite Appropriations	**101**	**$21,742**	**95**	**$18,745**	**101**	**$22,434**	**0**	**692**	**101**	**$23,126**
Total, Current Law User Fees	**1,183**	**$177,680**	**1,184**	**$186,123**	**1,203**	**$191,387**	**0**	**$692**	**101**	**$23,126**
Center Activities	1,093	153,592	1,095	161,669	1,113	165,192	0	339	85	12,032
Field Activities	90	18,228	89	18,594	90	19,955	0	353	16	11,094
Rent Activities	0	5,860	0	5,860	0	6,240	0	0	0	0

Food and Drug Administration
ALL PURPOSE TABLE - Proposed Law User Fees w/ Comparability [2/]
(Dollars in thousands)

PROGRAM	Changes +/- FY 2002		FY 2003 1/ Request	
	FTE	$	FTE	$
PDUFA [1/]				
Human Drugs	**99**	**$74,901**	**821**	**$185,830**
Center	*87*	*67,444*	*742*	*170,083*
Field	*12*	*7,457*	*79*	*15,747*
Biologics	**41**	**27,318**	**294**	**64,324**
Center	*37*	*26,195*	*283*	*62,277*
Field	*4*	*1,123*	*11*	*2,047*
Other Activities	**0**	**(34)**	**127**	**14,744**
Office of the Commissioner	*0*	*(5)*	*17*	*2,197*
Office of Management & Systems	*0*	*(17)*	*64*	*7,051*
Office of Senior Associate Commissioner	*0*	*(6)*	*21*	*2,384*
Office of International & Constituent Relations	*0*	*(2)*	*9*	*1,135*
Office of Policy, Planning, & Legislation	*0*	*(4)*	*16*	*1,977*
GSA Rental Payments (PDUFA)	**0**	**900**	**0**	**7,140**
Total, Proposed Law User Fees	**140**	**$103,085**	**1,242**	**$272,038**
Center Activities	124	93,605	1,152	247,104
Field Activities	16	8,580	90	17,794
Rent Activities	0	900	0	7,140

Food and Drug Administration
Proposed Law Comparability Crosswalk to All Purpose Table - Budget Authority
(Dollars in thousands)

PROGRAM	FY 2001 Accrued Retirement	FY 2001 PA/LEG Transfer		FY 2002 Accrued Retirement	FY 2002 PA/LEG Transfer		FY 2003 Accrued Retirement	FY 2003 PA/LEG Transfer [1]	
	$	FTE	$	$	FTE	$	$	FTE	$
Salaries and Expenses:									
Foods	**$14,078**			**$16,856**			**$17,919**		
Center	*5,097*			*5,374*			*5,333*		
Field	*8,981*			*11,482*			*12,586*		
Human Drugs	**11,466**			**11,841**			**13,056**		
Center	*7,145*			*7,337*			*8,002*		
Field	*4,321*			*4,504*			*5,054*		
Biologics	**4,930**			**5,496**			**6,051**		
Center	*3,605*			*4,041*			*4,503*		
Field	*1,325*			*1,455*			*1,548*		
Animal Drugs and Feeds	**2,710**			**3,484**			**3,790**		
Center	*1,803*			*1,877*			*2,013*		
Field	*907*			*1,607*			*1,777*		
Devices and Radiological Health	**8,045**			**7,932**			**7,964**		
Center	*5,461*			*5,349*			*5,306*		
Field	*2,584*			*2,583*			*2,658*		
National Center for Toxicological Research	**2,011**			**1,983**			**1,989**		
Other Activities	**3,637**	**(82)**	**(6,260)**	**3,590**	**(82)**	**(6,670)**	**3,982**	**(80)**	**(6,997)**
Office of the Commissioner	*563*			*595*			*717*		
Office of Management & Systems	*2,132*			*2,102*			*2,349*		
Office of Senior Associate Commissioner	*295*	*(48)*	*(3,749)*	*255*	*(48)*	*(3,995)*	*199*	*(47)*	*(4,214)*
Office of International & Constituent Relations	*322*			*357*			*398*		
Office of Policy, Planning, & Legislation	*325*	*(34)*	*(2,202)*	*281*	*(34)*	*(2,346)*	*319*	*(33)*	*(2,438)*
Central Services	*0*		*(309)*	*0*		*(329)*	*0*		*(345)*
Other Rent and Rent Related Activities	**0**			**0**			**0**		
GSA Rental Payments	**0**		**(286)**	**0**		**(305)**	**0**		**(320)**
SUBTOTAL, Salaries & Expenses	**$ 46,877**	**(82)**	**($6,546)**	**$ 51,182**	**(82)**	**($6,975)**	**$ 54,751**	**(80)**	**($7,317)**
Center Activities	*28,760*	*(82)*	*(6,260)*	*29,551*	*(82)*	*(6,670)*	*31,127*	*(80)*	*(6,997)*
Field Activities	*18,117*	*0*	*0*	*21,631*	*0*	*0*	*23,623*	*0*	*0*
Rent Activities	*0*	*0*	*(286)*	*0*	*0*	*(305)*	*0*	*0*	*(320)*
Buildings and Facilities									
TOTAL Budget Authority	**$46,877**	**(82)**	**($6,546)**	**$51,182**	**(82)**	**($6,975)**	**$54,751**	**(80)**	**($7,317)**

[1] The Public Affairs/Legislation Transfer is already shown in non-comparable APT for FY 2003.