Food and Drug Administration
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ORGANIZATION CHART (EXHIBIT B)

Producing Public Health Through Regulatory Science

Agency Mission/Overview

The United States Food and Drug Administration (FDA) is charged with assuring the safety of a vast array of consumer products. FDA monitors the manufacture, import, transport, and storage of one trillion dollars' worth of goods annually. In this capacity, the Agency manages and monitors performance in each of the following program areas to:

- Ensure that the nation's food supply is safe and wholesome, that the cosmetics are not harmful, and that medicines, medical devices, and radiation-emitting consumer products are safe and effective;
- Oversee feeds and drugs for pets and food-producing animals;
- Ensure that products developed utilizing newly discovered research and technology meet high safety and performance standards when they reach the market. It is estimated that the public and private sector invest $50 billion in biomedical research and technology for products that FDA regulates;
- Conduct inspections for an inventory of over 100,000 U.S. firms that manufacture or process FDA regulated products; and,
- Monitor the safety of imported products. FDA is responsible for tracking over six million import line entries that enter the U.S. annually to prevent violative products from reaching U.S. consumers.

Program Objectives

With the FY 2002 increases, FDA expects to accomplish the following:

- Use increased base funding to meet inflationary payroll costs to achieve performance goals as specified in the FDA Performance Plan;
- Assure 100 percent compliance with the BSE ("Mad cow disease") regulation through inspection and compliance actions;
- Through guidances and rulemaking, establish processes to help prevent exposure by American citizens and pets to the agent of BSE through products FDA regulates, such as, biologics, pet foods, food additives, and dietary supplements;
- Increase the number of domestic and foreign inspections, including those for protecting volunteers in clinical trials, and expand import coverage in all product areas;
- Increase the number of analyses and adverse event reports evaluated to determine appropriate responses;
- Extend the MeDSuN adverse event reporting system to more hospital and user facilities for the reporting of adverse events associated with, medical devices, drugs and biologics;

- Review and follow-up on virtually 100 percent of complaints concerning clinical trials within 30 days of receipt;
- Monitor pesticide residues and environmental contaminants through analysis of an additional 360 food samples;
- Move the Center for Drug Evaluation and Research laboratory into the new White Oak location;
- Complete construction of the new Los Angeles field laboratory; and,
- Begin acquisition of a new integrated financial system to further improve financial management and maintain FDA's clean audit opinion.

Why is FDA's Contribution so Important?

FDA is a scientific regulatory agency that touches the lives of virtually every American every day. FDA protects all consumers in the U.S. with a broad umbrella of safeguards that enable them to go about their daily life without worries concerning the safety of the myriad of products that FDA regulates. FDA shields Americans against public health hazards that range from debilitating to deadly. The Agency creates this safety net day in and day out by ensuring the safety–and in most cases the quality and effectiveness–of a trillion dollars worth of products that constitute more than 20 percent of the total consumer expenditures of U.S. citizens.

FDA FY 2002 Budget Increases

(Dollars in 000s)

Program	*Center*	*Field*	*Total*
Foods	$10,772	$25,916	$36,688
Budget Authority	*9,372*	*13,916*	*23,288*
User Fees	*1,400*	*12,000*	*13,400*
Human Drugs	$18,671	$12,341	$31,012
Budget Authority	*12,948*	*9,674*	*22,622*
User Fees	*5,723*	*2,667*	*8,390*
Biologics	$10,261	$5,119	$15,380
Budget Authority	*7,279*	*4,211*	*11,490*
User Fees	*2,982*	*908*	*3,890*
Animal Drugs and Feeds	$5,462	$12,492	$17,954
Budget Authority	*5,462*	*11,792*	*17,254*
User Fees	*0*	*700*	*700*
Devices and Radiological Health	$8,591	$9,483	$18,074
Budget Authority	*8,450*	*5,467*	*13,917*
User Fees	*141*	*4,016*	*4,157*
NCTR	$1,494	$0	$1,494
Budget Authority	*1,494*		*1,494*
Other Activities 1/	$14,923		$14,923
Budget Authority	*12,935*		*12,935*
User Fees	*1,988*		*1,988*
Other Rent & Rent Related Activities	$6,000		$6,000
Budget Authority	*6,000*		*6,000*
GSA Rent	$380		$380
User Fees	*380*		*380*
Buildings & Facilities	$3,000		$3,000
Certification Fund	$189		$189
User Fees	*189*		*189*
Total Program Level*	$78,243	$65,351	$143,594
*Budget Authority**	*65,440*	*45,060*	*110,500*
User Fees	*12,803*	*20,291*	*33,094*
*Program Level w/ Contingent Funds***			*$146,544*

*PL & BA totals include a $1,497,000 reduction in the Foods program for a Congressional earmark provided in FDA's FY 2001 appropriation.

** Includes $2,950,000 in Contingent Budget Authority related to Medicine Equity and Safety Act (MEDSA).

1/ Includes $83 million for a new accounting system.

The FDA's total program level in FY 2002 is $1,414,391,000, a net increase of $123,594,000 above the FY 2001 total program level of $1,290,797,000. This net increase is offset by a reduction of $20,000,000 in contingent budget authority related to a potential funding increase of the Medicine Equity and Drug Safety Act (MEDSA) in FY 2001. Without the MEDSA offset, there is an increase of $143,594,000 in activities funded by regular budget authority and user fees. Of the $143,594,000 in total increases, $110,500,000 is funded through regular budget authority, $13,094,000 through current law user fees, and $20,000,000 through proposed user fees.

Congress passed the MEDSA in 2000 in an attempt to allow drug wholesalers and pharmacists in the U.S. to import FDA-approved pharmaceuticals produced outside the U.S. at, theoretically, lower prices. Congress authorized FDA a contingent appropriation of $23,000,000 in FY 2001 to carry out this Act if the Secretary could demonstrate that the Act would reduce the cost of pharmaceuticals without increasing health risks to the American consumer. Because the Secretary's review of this issue is ongoing, the Act has not yet been implemented. The contingent budget authority for MEDSA in both FY 2001 and FY 2002 will be available if the Secretary makes the required demonstrations.

FDA FY 2002 Budget Resources

FDA's FY 2002 non-contingent program level budget represents an 10 percent increase over the FY 2001 current estimate.

FDA FY 2002 Budget Resources

(Dollars in 000s)

	FY 2001	*FY 2002*	*% Change*
S&E Budget Authority (Non-Contingent)	$1,066,173	$1,173,673	+10.1%
PDUFA	149,273	161,716	+ 8.3%
Subtotal Non-Contingent S&E Direct Appropriation	1,215,446	1,335,389	+ 9.9%
Buildings & Facilities	31,281	34,281	+ 9.6%
Current Law Indefinite User Fees	21,120	21,771	+ 3.1 %
Proposed User Fees	0	20,000	
Program Level	$1,267,847	$1,411,441	+ 9.7%
FTE Level	9,150	9,519	+ 4.0%
Contingent BA (Drug Importation)	$22,950	$2,950	
Total Program Level	$1,290,797	$1,414,391	+9.6 %
Total FTE	9,174	9,526	+ 3.8%

The FY 2002 Budget also proposes to include FDA in the DHHS Departmental Transfer Authority. This transfer authority will allow DHHS to assist the FDA in responding to emerging public health issues. Language authorizing this transfer is proposed for inclusion in the Labor, Health and Human Services, Education, and Related Agencies Appropriation Act general provisions.

Consequences of Not Achieving the Objectives

To continue to meet the public's high expectations, the FDA must be equipped to make the correct judgements. To make these critical decisions, FDA requires that its scientists remain on the leading edge in their specific scientific disciplines.

FDA must keep up with the quickening pace of scientific discoveries that are propelling the development of a potential tidal wave of novel and extremely complex products and processes.

For example, the Agency will have to acquire scientific expertise in new informatics, artificial intelligence, and new knowledge development; develop better tools for quantitative risk assessment, modeling, clinical trial design and analysis; design better predictive tests involving transgenics, biomarkers, alternatives to test animals, and computational science; and find better methods for rapid product testing, and for easier identification of food borne, waterborne and other natural toxins, allergens, and transmissible spongiform encephalopathies.

Research expenditures by the pharmaceutical industry alone have more than tripled since 1990. More and more products that require FDA's preclinical and clinical design consultations; marketing application reviews; and post approval reassessment are products of growing research budgets. Francis Collins, Director of the National Human Genome Research Institute at NIH recently forecast that the next ten years would bring an immense amount of new genetic information. There are already hundreds of genetic tests in development, and this is only the tip of the iceberg of what will be submitted to FDA. Delays in product reviews will occur, keeping consumers from benefitting from this explosion of health care innovations. Furthermore, FDA's job does not end with premarket approvals, but continues throughout the entire life cycle of the products that are regulated. New product approvals lead to another set of challenges – monitoring products once they are on the market for any adverse event reports that may occur and taking appropriate action when necessary.

Through this budget request, FDA will be able to move quickly and decisively if regulated products do not fulfil their intended purposes. Failure to respond could have serious consequences for consumers.

As the world becomes more globalized and the U.S. is more actively engaged in international trade agreements, FDA needs additional resources to monitor and influence regulatory actions in the international arena. Insufficient resources will hamper FDA's capacity to evaluate foreign activities related to products exported to the U.S. and to inspect foreign establishments.

How are we doing?

Consumers trust FDA. According to a recent survey by the PEW Research Center in cooperation with Princeton Survey Research, FDA received an overall favorable rating of 80 percent, more than double the approval rate of the entire Federal government. The resulting peace of mind is an important contribution to the special quality of life, confidence, and vitality that is characteristic of the U.S.

Summary of Base Resources by Activity for Requested Budget Authority Increases in FY 2002

Requested Increases in FY 2002 by Activity	FY 2001 Base Resources by Activity	FY 2002 Increases by Activity	FY 2002 Request Level
Pay Increase		+ $40,000,000	
BSE	$3,800,000	+ $15,000,000	$18,800,000
Imports and Inspections	$341,762,000	+ $10,297,000	$352,059,000
Patient Safety/AERS	$48,035,000	+ $10,000,000	$58,035,000
Human Subject Protection	$25,997,000	+ $10,000,000	$35,997,000
Food Safety	$335,328,000	+ $9,400,000	$344,728,000
Management Priorities	$400,000	+ $8,300,000	$8,700,000
LA lab/CDER Lab Move	$20,000,000	+ $9,000,000	$29,000,000
Total [1/]		+ $110,500,000	

[1/] Total includes $1,497,000 reduction to a Congressional earmark in FY 2001.

Paying Our People – Our Most Valuable Resource

Desired Outcome

Maintain the Agency's staffing levels and scientific capabilities that meet the demands of an increasing workload and new challenges.

Program Objectives

Maintain current levels of performance, by funding the costs of payroll inflation.

How Will Pay Increases Affect FDA's Mission?

FDA's request for resources focuses on pay adjustments, because personnel are so essential to accomplishing its mission. Pay increases have a major impact on FDA, because the Agency is more people-intensive than many government agencies. Payroll accounts for over 60 percent of FDA's budget.

The link between FDA's relatively high labor percentage and its mission can be attributed to:

- The Agency's regulatory mandate to protect the public health;
- The fact that interpretation and enforcement of regulations is an inherently governmental function that must be performed by people;
- The fact that FDA's product review function requires numerous interdependent specialists in each of the Agency product areas who interact with industry on a regular basis;
- The Agency's inspectional responsibilities require coverage of not only the entire country, but also around the world; and,
- The fact that 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 product advertising to a product's effect on patients health).

Requested Increases for FY 2002
(Dollars in 000s)

Program	*Center*	*Field*	*Total*
Foods	$4,572	$6,916	$11,488
Human Drugs	$6,848	$3,374	$10,222
Biologics	$3,279	$1,011	$ 4,290
Animal Drugs & Feeds	$1,662	$692	$ 2,354
Medical Devices	$5,250	$2,067	$ 7,317
NCTR	$1,094	N.A.	$ 1,094
Other Activities	$3,235	N.A.	$ 3,235
Total	$25,940	$14,060	$40,000

In FY 2002, FDA requests $40,000,000 to cover pay-related increases. This increase will enable FDA to maintain current levels of performance, and:

- Continue to 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 PDUFA user fees; and,

- Improve the 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

From FY 1993 to FY 2001, the Agency absorbed a total of $284,000,000 to cover mandatory employee pay raises, increased costs of employee benefits, inflationary costs for supplies and equipment, and contractual services. FDA has reprioritized program priorities, streamlined and reengineered processes, reduced staff and operating expenses and otherwise attempted to absorb these unfunded increases.

Payroll shortfalls erode FDA's ability to protect the public health in all product areas. In FY 2002, without pay increases, FDA predicts the following scenarios may occur:

- Reversal of recent gains in combating foodborne illnesses;
- Reduced pediatric drug development program;
- No improvement of blood and human tissue safety;
- 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;
- Inability to physically evaluate FDA-regulated imports at the border;
- Further reduction in our ability to meet biennial statutory requirements for inspections of human drug firms and medical device firms; and,
- Even more infrequent inspections of facilities not required by statute.

Additionally, if FDA continues to absorb pay increases, the Agency will be forced to further reduce investments in training and research that are essential for science-based decision making, resulting in delays for non-user fee supported product approvals and risk-based decisions (e.g., determining a course of action in cases of adverse event reports).

How are we doing?

The Agency is showing great progress in program areas that continue to receive adequate funding. The review of drug applications supported by user fees demonstrates that FDA can perform efficiently and effectively when provided with adequate resources.

Prevent Outbreak of Bovine Spongiform Encephalopathy (BSE)

Desired Outcomes

The continued absence of BSE, commonly known as "Mad Cow Disease," in the United States.

Prevent exposure by American citizens and pets to the agent of BSE through products regulated by FDA.

Program Objectives

Assure 100 percent compliance with the BSE regulation through inspection and compliance actions.

Through guidances and rulemaking, establish processes to help prevent exposure by American citizens and pets to the agent of BSE through products FDA regulates, such as biologics, pet foods, food additives, and dietary supplements.

Why is FDA's Contribution so Important?

BSE belongs to a group of progressive degenerative neurological diseases known as transmissible spongiform encephalopathies (TSEs). BSE is a TSE of cattle. TSE diseases are always fatal. There are six TSE diseases that affect humans, of which Creutzfeldt-Jakob disease (CJD) and variant Creutzfeldt-Jakob disease (vCJD) are best known. vCJD is believed to be transmitted to humans by the consumption of food products contaminated with the agent of BSE.

To protect consumers, it is essential that a multi-layered safeguard system be implemented and monitored to ensure that

BSE regulations and guidance principles are followed. A final rule (Title 21 Part 589.2000 of the Code of Federal Regulations) implemented by FDA in August 1997, prohibits the feeding of mammalian protein to ruminant animals.

The Animal and Plant Health Inspection Service (APHIS), of the United States Department of Agriculture, has also placed restrictions banning the importation of live ruminants and certain ruminant products from thirty-one countries to prevent BSE from entering the United States. FDA, in conjunction and cooperation with APHIS, has issued a series of import alerts and bulletins regarding products which FDA regulates.

Many products regulated by FDA contain these banned substances and it is important to enhance and make as comprehensive as possible our BSE monitoring system to identify products that may pose a health risk and ensure they do not enter the U.S.

The United States has the safest blood supply in the world. FDA continues to strengthen its efforts to protect the nation's blood supply and to minimize the risks from BSE. FDA will continue to conduct research of blood and blood products and develop regulations to minimize the risk of infectious disease.

Requested Increases for FY 2002

(Dollars in 000s)

Program	*Center*	*Field*	*Total*
Foods	$1,100		$1,100
Biologics	$500		$500
Animal Drugs and Feeds	$2,200	$10,900	$13,100
Other Activities	$300		$300
Total	$4,100	$10,900	$15,000

At the start of FY 2001, FDA had planned to spend base resources of about $3,800,000 for BSE-related activities. Given the recent events related to BSE in Europe, FDA has had to readjust its plan. By the end of FY 2001, FDA has committed to inspecting 100 percent of all feed mills, plus reinspection of those establishments not in compliance. Within the planned resource allocation, this would not have been possible. The Animal Drugs and Feeds program has reprioritized its inspection activities to focus on this issue in FY 2001. To maintain this effort, the Agency is requesting $15,000,000 in FY 2002 for needed BSE activities. With this funding, FDA will:

- Increase monitoring of imports to ensure prohibited materials do not enter the United States;
- Finalize initial inspections and conduct biennial and follow-up inspections of licensed feed mills;
- Provide training to federal and state inspectors on the current BSE situation;
- Conduct market studies to identify food, dietary supplements, and cosmetic products containing spinal cord and other at risk products;
- Conduct research on Chronic Wasting Disease, which affects elk, deer, and other domestic game and pen-reared animals in the United States; and,
- Conduct follow-up education on for-cause inspections of biological products, blood, and vaccines.

Consequences of Not Achieving the Objectives

Active surveillance efforts have yet to identify BSE in the US. If BSE emerged in the United States, it could pose a serious health risk to humans, and be financially devastating to the US beef industry. In a recent survey in Germany, more than 50 percent of those polled said they had little or no confidence in the safety of their beef products. So far, the BSE crisis in the farm industry has cost British taxpayers more than $6 billion. In the U.S. the cost of lost revenue to the beef industry alone could be over $15 billion, if a similar outbreak were to occur here.

Monitoring imports for bovine products has proven to be a challenge because banned animal proteins are often diverted from the originating country. Then, it is hard to determine the origin of the imported product, and it is difficult for inspectors monitoring imports to verify the presence of high-risk tissues in finished dietary supplements, drugs, vaccines, or cosmetics.

How are we doing?

The Agency has developed an enforcement plan with the goal of 100 percent compliance with the BSE feed regulations through education, inspections, and compliance actions for egregious actions or repeated noncompliance. In 1998, FDA was assigned to conduct inspections of all renderers and feed mills to determine compliance. We estimate that there are approximately 9,500 renderers and feed mills (licensed and un-licensed). To date, FDA has conducted initial inspections of approximately 87 percent of renderers, 86 percent of licensed feed mills, that produce medicated animal feeds, and at least 63 percent of the known unlicenced feed mills. Of these inspections, 78 percent were conducted by the States.

Percentage of Firms Handling Prohibited Material that are Out of Compliance

	Commingling	Labeling	Records
Renderers	14%	4%	3%
FDA Licensed Feed Mills	13%	15%	1%
Non-FDA Licensed Feed Mills	18%	33%	.4%
Other*	12%	18%	3%

Note: As more inspections are completed the information in this table will change. This data is as of 2/27/01.
* Examples include ruminant feeders, on-farm mixers, haulers, and distributors.

FDA is seeking assistance from state feed control officials to conduct additional inspections and identify non-FDA licensed feed mills. Field offices have been assigned to re-inspect over 800 firms that were not in compliance with the rule. FDA will also continue to develop and implement an import monitoring program that will help identify all products containing high risk products. In January and March 2001, FDA issued an import alert and import bulletin, respectively, to facilitate the detention of high risk products.

FDA has also been working to protect the nation's blood supply from the BSE threat, by publishing guidance recommending the deferral of potential blood donors who resided in Britain from 1980 through 1996, for a cumulative six month period. Continued evaluation and research is needed to further assess the threat of BSE to the blood supply.

FDA has asked all licensed vaccine manufacturers

to evaluate all bovine derived material used at any stage in vaccine production. FDA has asked manufacturers to identify the country from which the animals originated, the date the material was obtained, and the date the material was used in the production of vaccines.

FDA continues to chair the Interdepartmental Steering Committee for BSE/TSE Affairs. This group includes representatives of CDC, FDA, NIH, USDA, the United States Trade Representative, the Office of Management and Budget, the Customs Service, the Department of State, the Department of Defense, the State Association of Feed Control Officials, the National Association of State Departments of Agriculture, and the White House Office of Science and Technology Policy. The functions of this committee are to assure ongoing coordination between agencies, integrate contingency planning for the possibility that a case of BSE or of vCJD might be found in the United States, identify and address potential vulnerabilities in the United States to BSE and vCJD, and coordinate development and implementation of risk communication plans by the various agencies.

Finally, FDA has worked closely with the CDC, NIH, and the Office of the Secretary to produce a departmental TSE Action Plan that has recently been submitted to the Secretary for his consideration. This Action Plan outlines further expansion of these activities to continue to improve the BSE/TSE safety net.

Imports and Inspection Activities

Desired Outcome

Increased safety of marketed products used by Americans every day.

Program Objectives

Increase the number of domestic and foreign inspections, and expand import coverage in all product areas.

Why is FDA's Contribution so Important?

FDA is responsible for ensuring the safety of products produced and distributed by more than 100,000 domestic establishments. The Agency uses its inspectional authority, as directed by statute, to provide this assurance. For many establishments, the law requires FDA to conduct inspections at specified time intervals, such as once every two years.

In FY 2002, FDA will also be responsible for ensuring the safety of almost 7 million line entries of imported products that cross our borders annually. The sources of many of these entries are diversified and include an increasing number of products from countries that are typically categorized as emerging economies, with developing regulatory infrastructures. FDA conducts sampling and end point product testing as a means of determining that imports have been properly produced.

Sampling and testing of imported products cannot be relied on as the only method of confirming that the products were manufactured in conformance with Good Manufacturing Practices (GMPs). The Agency's foreign inspection program is an important part of attaining confidence that all imported products meet the same standards as domestic goods.

Requested Increases for FY 2002

Additional funding of $25,000,000 is requested for imports and inspections. This includes $10,300,000 in budget authority and $14,700,000 in new import user fees. If the new user fees are not implemented, a larger portion of the budget authority may need to be used to support the import program. By program, increases will be used as follows:

(Dollars in 000s)

Program	*Center*	*Field*	*Total*
Foods	$700	$9,697	$10,397
Budget Authority	*700*	*1,597*	*2,297*
User Fees	*0*	*8,100*	*8,100*
Human Drugs	$1,000	$4,500	$5,500
Budget Authority	*1,000*	*3,000*	*4,000*
User Fees	*0*	*1,500*	*1,500*
Biologics	$200	$1,100	$1,300
Budget Authority	*200*	*400*	*600*
User Fees	*0*	*700*	*700*
Animal Drugs and Feeds	$100	$900	$1,000
Budget Authority	*100*	*200*	*300*
User Fees	*0*	*700*	*700*
Devices/Rad Health	$700	$5,800	$6,500
Budget Authority	*700*	*2,100*	*2,800*
User Fees	*0*	*3,700*	*3,700*
Other Activities			
Budget Authority	$300	$0	$300
Total	$3,000	$22,000	$24,997
Budget Authority	*3,000*	*7,300*	*10,297*
User Fees	*0*	*14,700*	*14,700*

This funding will allow FDA to:

- Increase inspections of domestic medical device manufacturers;
- Increase surveillance of imported tissues and other imported biological products;
- Increase sample analyses of domestic and imported drug products;
- Increase criminal investigation of fraudulent drug imports; and,
- Increase sample collection, analysis, and field exams of imported foods and dietary supplements.
- Improve public confidence in the standards of drugs, biological, and device products imported from the European Union by working towards implementation of the European Mutual Recognition Agreement, and by intensifying drug inspections in developing countries;
- Expand import entry review resources to keep pace with the increase in line entries; and,
- Modernize the OASIS import data processing system to provide import reviewers with more rapid and direct access to information necessary for entry decisions.

Consequences of Not Achieving the Objectives

Inspections and import surveillance are the primary means of assuring the safety of marketed products. Consumers rely on the FDA to prevent dangerous and unreliable products from entering into commerce. Public safety and confidence could be jeopardized by a failure to increase surveillance activities.

Products may enter the U.S. through one of approximately 300 U.S. Customs ports located throughout the country. While the FDA continues to undertake activities to improve the safety of imported products, there is often no substitute for physically examining these products.

FDA is monitoring regulated products in an environment that has become significantly more complex over the past several years. Contributing to this change is the growth in international trade leading to a tripling of imports during the past 10 years; much more technologically complex and diverse products, both domestically and internationally; and increasing use of the internet by industry to develop, distribute and market their products. While the regulatory challenges have grown more complex, the size of the FDA field force has declined during the same 10-year period, falling from 2,702 FTE in 1990 to 2,635 FTE in 2000.

How are we doing?

The law requires that FDA inspect certain biologic, human and animal drugs, and medical device manufacturers at least once every 2 years. In recent years, coverage has fallen short of meeting these statutory requirements.

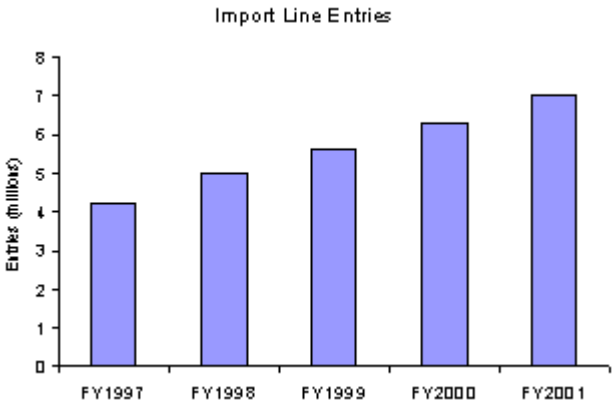
Although at least 50 percent of statutory establishments should be inspected annually, only 22 percent of human drug, 39 percent of animal drug, and 13 percent of high risk medical device statutory establishments were inspected in FY 2000. The Agency did inspect 57 percent of the biologics statutory establishments in FY 2000.

The total number of FDA establishment inspections, including foreign and domestic, has decreased by 12 percent in the last few years. FDA conducted 17,275 inspections in FY 1998, and 15,146 inspections in FY 2000. The number of FDA State contract inspections has also decreased during the same period, dropping from 13,877 inspections in FY 1998 to 13,553 inspections in FY 2000.

Despite a decrease in the overall number of inspections, FDA's foreign inspection program continues to be one of the Agency's top priorities, as FDA regulated products originating from foreign sources continues to increase. FDA conducted 880 foreign inspections in FY 2000, which represented a 12 percent increase over FY 1999. For FY 2001, approximately 1,300 foreign inspections are planned.

Imports of all FDA-regulated products have been increasing over the last several years. In FY 2000 alone, there were over 6,300,000 line entries of items including food products that have been implicated in prior disease outbreaks; food products that could pose a health threat if not processed and handled properly; over the counter drugs that do not require a new drug application; and approved drugs, biologics, and medical devices. By the end of 2001, it is expected that over 7 million import line entries will be received.

FDA has only about 150 field investigators and inspectors assigned to import operations to review entry documents, determine product admissibility, collect samples, and conduct investigations. In FY 2000, FDA physically examined less than one percent of all entries offered for import into the United States.



[Note for Line Entries (above): A line is each portion of an entry which is listed as a separate item on the entry document.]

FDA continues to pursue the International Trade Data System (ITDS) project, which is intended to create an important electronic link to U.S. Customs to enable FDA to effectively and efficiently decide which import entries can proceed and which require sampling or administrative actions. When implemented, ITDS will establish a standard data set and a "single window" clearance mechanism for cargo, conveyance, and crew. ITDS will improve compliance with regulatory requirements, reduce the cost and burden of processing international trade transactions, and provide access to accurate and timely statistical international trade data and information. Innovations such as ITDS help target FDA activities, thereby saving resources for other important regulatory responsibilities.

FDA will expend $341,762,000 base resources on inspections in FY 2001.

Reduced Adverse Events Related to Medical Products

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 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 and medical devices regulated by FDA. Costs from these medical errors may be as high as $75 billion annually. The Institute of Medicine, in their report, "To Err is Human," estimated that as many as 98,000 Americans die annually as a result of preventable medical errors.

Most injuries and deaths associated with medical products result from known side effects, however, some side effects are unavoidable, and others can be prevented or minimized by careful product choice and use. The greatest need is to identify potential threats and then educate patients and health care professionals on how to avoid them.

FDA is adopting a systems approach, of which the most significant component is the identification, of and response, to adverse events that are reported in the U.S. FDA is planning to expand its knowledge of adverse events and medical errors by linking with new sources of data.

Requested Increases for FY 2002

(Dollars in 000s)

Program	*Center*	*Field*	*Total*
Foods	$1,000	$0	$1,000
Human Drugs	$3,600	$500	$4,100
Biologics	$2,000	$200	$2,200
Medical Devices	$2,000	$300	$2,300
Other Activities	$400		$400
Total	$9,000	$1,000	$10,000

With an increase in funding of $10,000,000 FDA will:

- Increase the number of analyzes done and adverse event reports evaluated to determine appropriate responses;
- Increase education programs for dietary supplements;
- Speed the identification and reporting of adverse events by enhancing existing data systems and linking them with other health care databases;
- Educate consumers and health care professionals on the importance of preventing and reporting medical errors; and,
- Extend the system to additional hospitals and user facilities for the reporting of adverse event reports involving not only medical devices, but also drugs and biologics.

Consequences of Not Achieving the Objectives

Many patient deaths and injuries are associated with the use of FDA-regulated medical products. The Agency needs a comprehensive safety evaluation system for medical products. This requires strengthening existing systems as well as implementing new ones. The Agency also requires additional expertise in medical epidemiology and statistical analysis to conduct the safety evaluations. The FDA believes that roughly half of these deaths and injuries can be avoided by fully implementing its strategies. Thousands of lives and billions of dollars can be saved.

How are we doing?

FDA worked with other agencies in DHHS, through the interagency Patient Safety Task Force, to evaluate the feasibility of sharing existing data resources. The Agency also participated in national meetings related to improving patient safety, including attention to reducing drug, biologic and medical device errors. FDA published a regulation that requires the reporting of any event associated with biologics, including blood and blood components and source plasma that represents a deviation in manufacturing.

A new program was initiated for the review and risk-analysis of proprietary names for drug products. FDA also initiated development of packaging standards to prevent dosing and drug mix-ups.

The Agency implemented a MeDSuN system, which is a pilot program designed to educate and encourage hospital personnel to accurately identify and report injuries and deaths associated with medical products; and upgraded the Adverse Event Reporting System (AERS) for drugs to allow electronic submission of adverse event reports.

FDA will expend $48,035,000 in bases resources on Patient Safety/AERS in FY 2001.

Protecting Volunteers and the Integrity of Data in Clinical Trials

Desired Outcome

Better protection of the rights and welfare of volunteers who participate in clinical research studies. Verification of the quality and integrity of data submitted to the Agency in a greater number of applications, with an increased focus on high-risk trials that involve vulnerable populations, including children.

Program Objectives

Increase the number of annual inspections of clinical trials by more than 20 percent (from 1,200 to 1,475), with an emphasis on high-risk trials, such as those enrolling vulnerable populations (mentally impaired, pediatric, etc.) and sponsor-investigators who have a proprietary interest in the product under study.

Review and provide initial follow-up on virtually all complaints concerning clinical trials within 30 days of receipt.

Why is FDA's Contribution so Important?

Prior to marketing their products, manufacturers of drugs, biologics, medical devices, and animal drugs must show FDA that their medical products are safe and effective for their intended use. Manufacturers generate, collect, and report data from clinical studies (involving human subjects) in support of their applications.

FDA oversees a system of safeguards for all trial participants. Without studies of new drugs and devices in clinical trials, the development of new health-care products could not be possible; and without voluntary participants, clinical trials would grind to a halt. The protection of human subjects in product studies is highly important for both the health and safety of the study participants and for the integrity of the drug development process.

The primary responsibility for the subjects' rights and welfare belongs to the clinical investigator. That investigator must be sure that participants understand the potential risks of the experiment. Sponsors of the trials are responsible for selecting qualified investigators, providing them with adequate information to conduct the studies, and monitoring the progress and safety of the clinical investigations. The next layer of protection is provided by physicians, scientists, and other members of the Institutional Review Boards (IRBs) who must approve the trials and continually review their integrity.

FDA, whose product reviews depend on the validity of clinical trial data, monitors the entire system. The Agency conducts about 1,200 trial-associated inspections per year (1,100 domestic and 100 foreign). These inspections may involve extensive interviews with sponsors, monitors, investigators, site staff, and IRB administrators, and examination of their records, procedures, and responsiveness to participants' concerns.

In recent years, oversight of human subject protection has become more essential than ever because of the proliferation of multi-site clinical trials (including an increase in international sites), emergence of gene

therapy and other new technologies, and an increase in clinical studies involving vulnerable populations, such as pediatric patients.

FDA's efforts to protect human subjects generally emphasize education, outreach, and training programs for investigators and members of the IRBs.

Requested Increases for FY 2002

(Dollars in 000s)

Program	*Center*	*Field*	Total
Human Drugs	$1,500	$2,800	$4,300
Biologics	$1,300	$2,600	$3,900
Medical Devices	$500	$1,000	$1,500
Other Activities	$300		$ 300
Total	**$3,600**	**$6,400**	**$10,000**

With an increase in funding of $10,000,000, FDA will:

- Increase the number of inspections by about 23 percent, and in particular, target high risk clinical trials. Inspections will cover clinical investigators, IRBs, sponsors, monitors, and contract research organizations;
- Increase scientific and regulatory training for FDA investigators to make them more efficient and effective;
- Coordinate bioresearch monitoring activities with other Federal agencies;
- Improve the inspection process for IRBs by establishing consistent operational standards, strengthening compliance with greater outreach, and developing preventative/ corrective action plans where necessary; and,
- Enhance follow-up compliance activities.

Consequences of Not Achieving the Objectives

Failure to achieve the goals may result in needless suffering and/or deaths of participants in clinical trials.

Without an effective independent oversight body, participation in clinical trials may be adversely affected by fewer volunteers, thus stunting new product development and depriving consumers of medical advances.

Recent press reports, such as the February 2001 USA Today article, or the March 2001 Seattle Times article, have highlighted resource problems with FDA's domestic oversight of clinical trials. The Washington Post's December 2000 six-part series emphasized inadequacies on the foreign front: [FDA] "has limited authority and few resources to police experiments overseas..." This resource shortage will continue without increased funding.

How are we doing?

FDA performed 735 clinical investigator inspections of the 1,200 trial-based inspections in FY 2000. This figure represents only two percent of the 35,000 clinical sites conducting FDA-regulated research. The remaining inspections include Institutional Review Boards (240), sponsors and/or contract research organizations (105), in-vivo

bioequivalence studies (45), and laboratories conducting supportive toxicology studies in animals (75). While the Agency understands it cannot inspect every clinical study, added funds will enable FDA to increase its inspections and lower the risks to volunteers in clinical studies.

FDA will expend $25,997,000 in base resources on Human Subject Protection in FY
2001.

Provide a Safe Food Supply

Desired Outcome

Ensure safety of FDA regulated food products (representing 80 percent all food consumed in the United States) by minimizing contamination of food by pathogens, unlawful animal drug and pesticide residues, and environmental contaminants.

Authorize the Secretary to recover costs of food export certificate-related activities through user fees to free up critical resources to devote to other food safety activities, while continuing to provide a service to the export industry.

Program Objectives

Expand the scope of the highly successful multi-agency Food Safety Initiative beyond microbiological contamination of foods to cover a much broader spectrum of potential hazards, including chemical and physical hazards. Expansion of the initiative will improve control and reduce food borne pathogens and toxicants in the American food supply.

Monitor pesticide residues and environmental contaminants through analysis of an additional 360 food samples.

Develop inspection and testing programs for shell eggs to reduce the risk of *Salmonella enteriditis* illness and expand HACCP programs.

Reduce the number of illnesses caused by *Listeria monocytogenes* contamination through implementation of the joint DHHS and USDA Listeria Risk Assessment and Action Plan.

Conduct annual inspections of domestic establishments that produce high-risk food products.

Implement an imported food safety program that emphasizes the highest risk food products through inspection of foreign manufacturers and increased border surveillance of products.

Why is FDA's Contribution so Important?

For almost a century, the Federal government has assumed the responsibility to protect the food supply from such threats as microbial contamination, unlawful animal drug and pesticide residues, and environmental contaminants such as dioxin.

Recent statistical estimates show that each year in the U.S., microbial food borne disease causes approximately 76 million illnesses, 325,000 hospitalizations, and 5,000 deaths. Costs attributed to hospitalization and lost productivity amount to well over 3 billion dollars a year. Most food borne illness is preventable, and FDA's food safety activities have played a crucial part in significantly reducing the enormous societal costs related to these illnesses.

The nature of food and food borne illness has changed dramatically, and FDA's role to ensure a safe food supply has become increasingly difficult. For example, the number of food borne pathogens has increased five-fold in the last 50 years; consumers are eating different foods–more

seafood, fresh produce, imported produce, and "convenience" ready-to-eat foods; we have an increasingly vulnerable at-risk population; and we are experiencing major changes within the arena of international trade negotiations.

Bioengineered foods are another important area of concern related to food safety. Although drugs produced using biotechnology have been widely accepted, the topic of bioengineered foods has generated much controversy, particularly about whether these foods should be labeled.

Requested Increases for FY 2002

(Dollars in 000s)

Program	*Center*	*Field*	*Total*
Foods	$3,400	$9,300	$12,700
Budget Authority	*2,000*	*5,400*	*7,400*
User Fees	*1,400*	*3,900*	*5,300*
Animal Drugs and Feeds	$1,500	$0	$1,500
NCTR	$400	$0	$400
Other Activities	$100		$100
Totals	$5,400	$9,300	$14,700
Budget Authority	*4,000*	*5,400*	*9,400*
User Fees	*1,400*	*3,900*	*5,300*

In FY 2002, FDA requests a total increase of $14,700,000 for food safety activities, of which $9,400,000 is budget authority and $5,300,000 represents new fees for export certification. With the additional funding, FDA will:

- Develop inspection and testing programs for shell eggs to reduce the risk of *Salmonella enteriditis* illness;
- Expand HACCP inspection programs in additional areas;
- Reduce *Listeria monocytogenes* contamination;
- Conduct training for industry to promote good agricultural and manufacturing practices;
- Develop new methodologies to identify adverse effects of genetically modified foods, drug residues in foods and antibiotic-resistant strains of bacteria, using new molecular biomarkers and methods identified through genomic and proteomic technologies; and,
- Develop new risk assessment methods. New approaches will be validated for incorporating model uncertainties into microbial risk assessment.

Consequences of Not Achieving the Objectives

FDA needs to expand food safety efforts to chemical and pesticide contamination, expand HACCP inspection programs, implement new programs to reduce Listeria monocytogines contamination, and develop new methodologies to identify adverse effects in genetically modified foods.

Inspections are one of FDA's major sources of information, including the accurate assessment of the scope of activity at firms. Funding requests would allow for improvements in these activities.

Section 801 (e)(4)(B) of the Federal Food, Drug, and Cosmetic Act authorizes the recoupment of fees of up to $175 for export certificates for drugs, animal drugs, and devices. This section, however, does not cover collection of user fees for export certificates for foods.

FDA spends millions of dollars in food safety resources to support the specific needs of U.S. food exporters instead of supporting critical food safety activities that benefit the entire population. This will continue if FDA does not receive authority to collect the user fees for export certificates for foods.

How are we doing?

The Food Safety Initiative has been a highly successful multi-agency initiative to control and reduce food borne pathogens in the U.S. food supply. Faster outbreak response and stronger prevention programs have resulted in a 20 percent reduction in food borne illnesses for the nine most common pathogens, in just three years, based on CDC data from 1996 through 1999.

Through a combination of FDA and State contract inspections, domestic firms that produce high-risk food products have been inspected on the average once every three to four years. In FY 2000, FDA inspected over 90 percent of the 6,250 high-risk establishments. By FY 2001, the Agency expects to inspect 90 to 100 percent of high-risk establishments. Such establishments include high-acid canned foods, seafood, infant formula, and ready-to-eat. In FY 1999, about 90 percent of domestic seafood firms received a Hazard Analysis and Critical Control Point (HACCP) inspection. In January 2001, HACCP requirements were established for fruit and vegetable juice production.

FDA scientists have developed rapid methods for the detection of microbial and viral food contaminants. FDA has leveraged this expertise with public and private sector partners to operate national rapid identification systems used to control outbreaks of food borne diseases.

FDA will expend $335,32800 in base resources on Food Safety in FY 2001.

Modernize FDA's Financial System

Desired Outcome

Begin acquisition of a new integrated financial system to support FDA's needs.

Program Objective

Further improve Agency financial management and maintain FDA's clean audit opinion for its financial statements and related disclosures.

Why is this Action so Important to FDA?

The FDA Financial System supports all of the Agency's financial activities providing information and internal controls and is considered to be a mission critical system to support FDA's public health mission. This past year the DHHS Inspector General performed a management review of FDA's existing financial system during the annual CFO Audit, under OMB Circular A-127. OMB A-127 guidelines establish general requirements for Federal financial management systems and require an assessment to determine the degree of compliance or conformance with established system requirements. The review found several shortcomings in the existing system, some of which can only be corrected by an investment in a new financial system. The Accounting System operates using a third generation language, Common Business Oriented Language (COBOL), and the code is over 30 years old. Other major flaws with the current systems are lack of integration with the various financial systems and an absence of a managerial cost accounting module. A strong managerial cost accounting module is mandatory in order to meet the Federal financial requirement for the Government Performance and Results Act (GPRA).

Other DHHS agencies face similar difficulties and have begun efforts to modernize their financial systems. One of the DHHS priorities is to strengthen management by improving its financial systems in an effort to streamline operations and meet increasing demands.

Requested Increases for FY 2002

(Dollars in 000s)

Program	
Other Activities	$8,300

The FY 2002 request for $8,300,000 will begin initial acquisition and implementation of the new financial system. Funding to complete the project will be requested in subsequent fiscal years.

Proposed Outcome from Requested Resources

FDA intends to purchase an off-the-shelf, fully integrated financial system. A recent General Accounting Office (GAO) report, "Creating Value Through World Class Financial Management," cites the advantages of using commercial off-the-shelf (COTS) software. These advantages include: (1) COTS software is less costly than developing in-house applications; (2) software upgrades are affordable and are regularly available; and (3) COTS software is designed to include best practices and as a result would further improve operations by enabling FDA to take full advantage of

the best practices already built into the software.

FDA is working to minimize costs by taking advantage of work already performed by other HHS agencies that are similar to FDA in size, scope, and transaction volume. FDA is coordinating with CDC in their procurement and implementation of a new financial system. FDA has received CDC's accounting system requirements document and has modified it to meet FDA's specifications. In addition, FDA is participating with other DHHS agencies in a workgroup whose objective is to streamline accounting operations throughout DHHS in an effort to enhance coordination, eliminate duplication of effort and develop unified approaches to key management issues. This effort will allow maximum use of resources across agencies and the leveraging of lessons learned.

Consequences of Not Achieving the Goal

The existing FDA accounting system does not utilize the technology available today to meet increased demands. In addition, the expertise needed to maintain this large and complicated system is limited to a few individuals with knowledge of COBOL programming. Industry resources to maintain such a system are limited as well. FDA will continue to operate many different legacy systems which are not integrated, requiring additional resources to enter data and reconcile accounts to meet increasing audit requirements. FDA is in an environment where demands and requirements are continuing to grow. A new financial system is essential to meet these changing Federal Financial requirements, maintain a clean audit opinion and keep up with demands from OMB, DHHS and FDA Centers.

Improve FDA Facilities and Gain Operational Efficiencies

FDA has implemented several activities to improve the quality of the facilities occupied by the Agency. The most significant are plans for headquarters and field laboratory consolidations. The headquarters consolidation seeks to consolidate the FDA headquarters offices and laboratories, now located in multiple locations in the Washington, D.C. metropolitan area, on three campuses. The long standing field laboratory consolidation plan seeks to reduce the number of field laboratories from the original eighteen to nine regional and specialized facilities.

1. Headquarters Consolidation

Desired Outcome

To take occupancy of new, consolidated FDA Headquarters facilities.

Program Objective

Implement the Headquarters consolidation plan by moving the Center for Drug Evaluation and Research (CDER) laboratory into the new White Oak location.

Why is This So Important to FDA?

FDA is consolidating existing headquarters facilities at White Oak, in Adelphi, Maryland to make operations more effective and efficient. Phase I, the construction of the CDER laboratory portion, is scheduled to be completed in FY 2002. As other phases of the project are completed, FDA will be relocating the remaining Headquarters offices and laboratories.

Requested Increases for FY 2002

(Dollars in 000s)

Program	
Rent & Rent Related Facilities	$6,000

GSA is responsible for funding construction of the project, but FDA must fund the actual move of staff and equipment, as well as certain telecommunications and equipment costs. In FY 2002, FDA requests an increase of $6,000,000. FDA proposes to occupy its White Oak facility over a period of several years, and will require additional future funding to support the phased-in relocation strategy.

Proposed Outcome from Requested Resources

In FY 2002, FDA requests funds for one-time costs to equip and occupy the CDER laboratory portion of the facility located in Adelphi, Maryland. The FY 2002 funds will support telecommunications equipment and necessary connections, and moving costs. The funds will relocate the CDER laboratory functions to a state-of-the-art facility scheduled to open in 2002; and begin the consolidation of most FDA Headquarters activities in one location. FDA Headquarters currently occupies approximately 39 buildings in more than 16 locations. FDA expects to achieve considerable annual operating savings when the consolidation is complete.

Consequences of Not Achieving the Goal

Without these funds, the facility will not be fully operational and there will be unnecessary delays in occupying the facility due to start up costs needed to complete the move. If the funds are not provided, FDA may be forced to pay rent on both the old and new facilities.

2. Field Laboratory Consolidation

Desired Outcome

Replacement of the existing Los Angeles (LA) field laboratory.

Program Objective

Complete construction of the new state-of-the-art Los Angeles field laboratory.

Why is This so Important to FDA?

FDA's field laboratories provide critical laboratory and analytical support to the domestic and import inspection effort and are a key element in the science base of FDA. The existing LA laboratory is an outmoded facility in a high crime area. The LA District is responsible for entry decisions on nearly 1.6 million import line entries, almost 25 percent of the FDA total. In FY 2000, the LA laboratory analyzed 24.2 percent of the imported food samples analyzed by FDA. The capability to test imported products in southern California is a critical need since FDA does not have the advantage of direct observation of the growing or manufacture of imported products in other countries.

Requested Increases for FY 2002

(Dollars in 000s)

Program		
Buildings & Facilities	FY 2001	FY 2002
	$20,000	$23,000

In FY 2002, FDA requests an additional $3,000,000, for a total of $23,000,000, to complete construction of the Los Angeles replacement laboratory and office space project. The second phase of the project completes building construction and fit-out of laboratory and office spaces. Total construction costs are currently estimated at $43,000,000.

Proposed Outcome from Requested Resources

Upon completion of the LA project, FDA will consolidate the exisiting laboratory, current district office in Irvine, and the San Pedro Resident Post into one location. The new Irvine facility will be built in two phases. Phase II completes the mechanical and electrical infrastructure and completely fits-out both the laboratory and the office at an estimated cost of $23,000,000. In FY 2001, FDA received $20,000,000 for the construction of the first phase, the core and shell of the project. Construction costs may be revised as necessary to reflect increases in equipment costs or construction delays.

Consequences of Not Achieving the Goal

FDA cannot remain in the present Pico Boulevard facility. If funding is not provided, FDA will have to shift work to laboratories in other states, further from the point of entry. This will have a significant negative impact on FDA's import surveillance capability, and on the southern California food import industry. This would also remove FDA's laboratory presence from the area at a critical time when FDA and Congress are being pressured by the import community to become more responsive to the growing workload in regulated imported products entering the country.

How are we doing?

FDA awarded a contract to Hensel Phelps Construction Company on February 27, 2001. A ground-breaking ceremony was held on March 6, 2001.

Current Law User Fees

User Fee Overview

PDUFA
The FDA Modernization Act of 1997 reauthorized the collection of user fees to enhance the review process of new human drugs and biological products through FY 2002 and established fees for applications, establishments, and approved products.

MQSA
The Mammography Quality Standards Act of 1992 was reauthorized in 1998 for an additional five years (P.L. 105-298). MQSA required that mammography facilities be certified by October 1, 1994, to remain in operation and inspected annually to ensure compliance with national quality and safety standards. The fees collected will pay for the costs of the inspections.

Export Certification
FDA is required to issue certificates to any person wishing to export a drug, animal drug, or device, and ensure that the product to be exported meets certain requirements of the law. This applies to products approved for sale in the US 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 established by regulation, up to a statutory maximum of $175. Estimated revenue from these fees for FY 2001 is expected to be about $1.5 million. These fees are credited to FDA's Salaries and Expenses Appropriation, and must be authorized through the annual appropriations act.

Requested Increases for FY 2002

(Dollars in 000s)

Program	*Center*	*Field*	*Total*
PDUFA			
Human Drugs	$5,723	$1,167	$6,890
Biologics	$2,982	$208	$3,190
Other Activities	$1,983	$0	$1,983
Other Rent	$380	$0	$380
Total	$11,068	$1,375	$12,443
MQSA Total	$146	$316	$462
Export Certification Total			$189

Effect on Program Objectives

PDUFA
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 products getting to market more quickly.

MQSA
The fees collected pay for the costs of the annual inspections to ensure compliance with national quality and safety standards. FDA has performed 200 audit inspections

under the Inspector Quality Assurance program and trained 16 new inspectors on the requirements of the MQSA regulations.

Export Certification

The fees collected allow the Agency to assure the safety of regulated products, inspect and investigate domestic manufacturers whose products are destined for foreign markets that require certificates of compliance (Export Certificates), and participate in Mutual Recognition Agreements with foreign countries to establish global standards for foods and pharmaceuticals.

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