FOOD AND DRUG ADMINISTRATION

(dollars in millions)

	2000 Actual	2001 Enacted	2002 Request	Request +/-Enacted
Program Level	$1,214	$1,291	$1,414	+$123
FTE	8,917	9,219	9,611	+392

SUMMARY

The FY 2002 budget request for the Food and Drug Administration (FDA) is $1,414 million, a net increase of $123 million over FY 2001. Within this total, there are program increases of $143 million, partially offset by a $20 million decrease in contingent appropriations related to drug re-importation. Of the funds requested, $204 million will be derived from industry-specific user fees, including $20 million in proposed fees for food export certificates, and fees to improve the import program. The increase over FY 2001 is targeted to program expansions including food safety, preventing the spread of mad cow disease to the U.S., protecting human research subjects, assuring the safety of FDA-regulated products, and improving infrastructure.

FDA protects the public health by preventing injury or illness due to unsafe or ineffective products. FDA actively identifies health problems associated with FDA-regulated products and assesses the origin and impact of these health problems. FDA makes every effort to prevent problems that would expose the public to hazards, and monitors the marketplace to ensure compliance with laws, regulations, and good manufacturing practices.

PROTECTING THE U.S. FOOD SUPPLY

The FY 2002 President's Budget includes a $15 million increase to enhance efforts to prevent the spread of mad cow disease to the U.S., and an additional $15 million to continue and expand successful food safety activities.

Preventing the Spread of Mad Cow Disease to the U.S: The budget requests an additional $15 million to enhance efforts to prevent the spread of mad cow disease to the United States. Bovine Spongiform Encephalopathy (BSE) has spread from the United Kingdom to continental Europe, and the European Union has ordered the destruction of up to two million cattle at-risk for the disease. It is feared that processed proteins from these cattle will make their way illegally into the U.S., labeled as fishmeal or some other legal product.

> ***Preventing the spread of mad cow disease: FDA will inspect all 9,500 U.S. feed mills to ensure that quality assurance practices are in place and being followed.***

FDA plans to strengthen its efforts to keep BSE out of the U.S. and ensure that proteins from infected animals are not being

fed to cattle. First, FDA will biennially inspect all FDA licenced feed mills (1,240) in order to ensure that quality assurance practices are in place and being followed, and that there is no co-mingling of processed animal proteins and cattle feed. In addition, training will be provided to better educate Federal and State inspectors on the regulations for production of cattle feeds and how to best prevent co-mingling. Finally, additional resources will be directed to tighten oversight and inspection of imported dietary supplements and cosmetics that include animal byproducts.

In the mid-1990s, BSE emerged in the United Kingdom, infecting cattle herds, and spreading to people who ate meat from infected animals. Consumption of infected meat has been linked to the development of variant Creutzfeldt-Jakob Disease (vCJD) in humans. Scientists concluded that BSE spread among cattle through processed cattle and sheep proteins used as feed.

The U.S. took two significant actions to prevent the spread of BSE. The Department of Agriculture (USDA) banned the importation of processed cattle and sheep proteins from countries that either experienced or are at risk of experiencing BSE cases. FDA banned feeding any processed cattle and sheep proteins to cattle.

Food Safety: A total of $124 million, an increase of $15 million, is requested to make food safer. While our Nation has one of the safest food supplies in the world, much work remains to be done. First, there is a need to continue efforts to reduce foodborne diseases. Every year an estimated 76,000,000 people get sick, 325,000 are hospitalized, and 5,000 die from foodborne illness. HHS and the Department of Agriculture have collaborated very successfully to ensure the continued safety of our Nation's food supply.

Investment in food safety has resulted in a 20 percent decrease in foodborne illnesses for the nine most common pathogens over the past three years, representing one million fewer cases. FDA scientists have also developed methods for detecting viral and microbial food contaminents more quickly. Additionally, FDA is completing the National Antibiotic Resistance Monitoring System (NARMS) that focuses on emerging antibiotic resistance in food animals.

However, foodborne illness is not the only threat to consumers; chemical pesticides and other contaminants also pose potential health hazards. As a result, the FY 2002 budget will improve FDA's efforts to ensure foods are not contaminated by pesticides and other chemicals. FDA will also expand and improve coverage and inspection rates at import entry points, develop inspection and testing programs for shell eggs to reduce the risk of Salmonella enteriditis, and reduce listeria monocytogenes contamination.

PROTECTING HUMAN RESEARCH SUBJECTS

FDA currently performs about 1,100 inspections related to clinical trials each year, including 600 clinical research sites. FDA also conducts reviews of clinical investigators, investigational review boards (IRBs), sponsors, monitors, and contract research organizations.

The $10 million increase in FY 2002 will allow for a significant increase in inspection and oversight of clinical trials, by approximately 33 percent (375 inspections). Emphasis will be on high-risk trials involving vulnerable populations and sponsor-investigators who have a proprietary interest in the product under study. New funds will also allow for increased training of investigators and improvements in the

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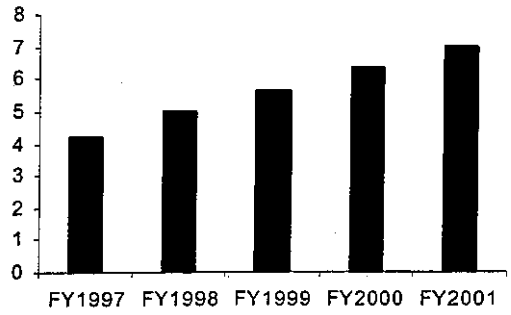
inspection process for IRBs. Finally, increased funds will allow FDA to follow-up on 100 percent of complaints concerning clinical trials within 30 days of receipt. Currently, response times range from a few days to several months to accomplish these complaint reviews.

ASSURING PRODUCT SAFETY

FDA has significantly accelerated approval of safe and effective products over the last several years. The budget includes an additional $35 million to make comparable improvements in 'post-market' safety assurance programs to maximize benefits and minimize injuries.

Increasing Inspection and Import Sampling Rates: The budget also includes an increase of $25 million to expand capacity to meet public and statutory expectations for inspections of production facilities and increase sampling of imported products. Current resources limit inspections to only about 18 percent of the approximately 129,000 production and storage facilities, and 0.7 percent of the 6.3 million import entries. This includes contracts carried out by State partnerships. Additionally, the number of import entries has increased by 75 percent since FY 1997, from roughly 4 million to an estimated 7 million in FY 2001.

IMPORT LINE ENTRIES
Entries (millions)



FY 2002 funds will allow for an increase in the number of domestic and foreign inspections it performs each year, in an effort to increase the safety of products on the market. An additional 1,800 inspections are anticipated in FY 2002, for a total of 24,500 inspections. Also planned are increased import analysis and sampling in all product areas. FDA will seek to enhance its import monitoring system (Operational and Administrative System for Import Support or OASIS) and link it to other databases. This expansion is linked to enacting and receiving user fees from importers for each import entry that they seek.

Reducing Adverse Events: An increase of $10 million will expand efforts to reduce adverse events from regulated medical products. FDA currently receives over 300,000 confidential adverse event reports each year. Reviews are conducted to detect potential patterns for follow-up. The most common outcome is improved information for medical providers on the safe use of regulated products. This information is also used to determine when unanticipated side effects or usage errors are sufficiently severe that a product should be removed from the market.

The additional funds requested will allow for improved computer systems to compile and analyze these reports, and added staff for follow-up. Improvements in the quality of information FDA receives is also needed. For medical devices, FDA and partner hospitals are testing an active surveillance system (MeDSun) to provide better statistical information for targeting follow-up efforts. Based on results to date, this approach will be expanded to human drugs and biologics. Simultaneously, collaborative work is underway with CDC (hospital acquired infections), AHRQ (health care quality and safety improvement), and HCFA (Medicare) to develop a common automated interface that would significantly reduce the reporting

burden for partnering providers, and provide this confidential information electronically.

DRUG RE-IMPORTATION

The FY 2001 appropriation includes $23 million that FDA can use for pre-implementation activities associated with an expanded authority under the Medicine Equity and Drug Safety Act of 2000, to allow retailers and wholesalers to import prescription drugs. This provision has not been implemented. The FY 2002 budget requests $3 million for continued pre-implementation activities that will be available if the Secretary concludes that the Act would reduce prices without increasing health risks.

INVESTING IN INFRASTRUCTURE

In FY 2002, the budget proposes to invest an additional $17.3 million for infrastructure improvements.

Improving Scientific Infrastructure: Evaluating state-of-the-art medical and food products requires comparable scientific facilities. The budget includes a total of $23 million, an increase of $3 million, to finish replacing a dilapidated Los Angeles regional laboratory facility. The Los Angeles laboratory performs 24 percent of food import analyses conducted each year.

The budget also includes an increase of $6 million in one-time costs to enable the Center for Drug Evaluation and Research (CDER) to occupy a new laboratory that the General Services Administration (GSA) is constructing at White Oak, Maryland. This will cover costs associated with telecommunications and laboratory equipment, moving, and decommissioning of their current facility. In addition, the FY 2002 budget request for GSA includes $9 million for planning the next phase of developing a consolidated FDA headquarters at White Oak.

Improving Information Technology Infrastructure: The FY 2002 budget request includes $8.3 million to begin development of a replacement financial system. This is part of a Department-wide effort to replace antiquated and inflexible systems with modern enterprise support systems. The current system cannot integrate the numerous financial management systems within FDA, nor does it contain a managerial accounting module, which is mandated by the Chief Financial Officer Act.

USER FEES

The FY 2002 budget request includes $203 million in user fees. Of this amount $20 million are new fees for which authorizing legislation is needed. Of this requested increase, $15 million will support the cost of import activities, such as reviewing import entries through its Operational and Administrative System for Import Support (OASIS) import tracking system. A fee would be established per import entry to support the OASIS system in tracking shipments and targeting inspections. An import entry can be a single item or several shipping containers that are brought in together for import. This will enhance FDA's ability to ensure the safety and efficacy of products that are imported for use by American consumers. The remaining $5 million will allow FDA to recover the costs for providing certifications requested by food exporters. Drug and device exporters already cover such costs.

The budget includes $161 million in Prescription Drug User Fee Act (PDUFA) fees, an increase of $12 million. PDUFA authorizes the collection of user fees for reviewing drug applications and was reauthorized as part of the FDA Modernization Act of 1997. To date, the PDUFA program has been highly successful in achieving the objective of reducing the amount of time it takes FDA to review

applications for new drugs and biologics, while maintaining the objectivity and standards of safety that are essential in order to enhance and protect the public's health.

FDA has consistently met its statutory timeframes. The FY 2002 increase will allow FDA to keep up with the increasing number of products submitted for review.

FDA OVERVIEW

(dollars in millions)

	2000 Actual	2001 Enacted	2002 Request	Request +/-Enacted
Foods	$280	$285	$319	+$34
Drugs	313	317	348	+31
Biologics	138	140	155	+15
Animal Drugs and Feeds	50	64	82	+18
Medical Devices	172	180	198	+18
National Center for Toxicological Research	36	35	37	+2
Tobacco	6	0	0	0
Other Activities	78	79	95	+16
Other Rent & Rent Related Activities	32	26	32	+6
Subtotal	**$1,105**	**$1,126**	**$1,266**	**+$140**
GSA Rental Payments	93	105	105	0
Buildings and Facilities	11	31	34	+3
Certification Fund	4	5	5	0
Export Certification	1	1	1	0
Subtotal, Program Level	**$1,214**	**$1,268**	**$1,411**	**+$143**
Drug Re-importation (contingent funding)	0	23	3	-20
Total Program Level	**$1,214**	**$1,291**	**$1,414**	**+$123**
Less User Fees:				
Current Law:				
Prescription Drug User Fee Act (PDUFA)	145	149	161	+12
Mammography Quality Standards Act (MQSA)	15	15	16	+1
Certification Fund	4	5	5	0
Export Certification	1	1	1	0
Proposed Law:				
Foods	0	0	5	+5
Imports	0	0	15	+15
Subtotal, User Fees	**$165**	**$170**	**$203**	**+$33**
Total, Budget Authority	**$1,049**	**$1,120**	**$1,211**	**+$91**
FTE	8,917	9,219	9,611	+392