National Center for Toxicological Research

	FY 2000 Actual	FY 2001 Appropriation	FY 2001 Current Estimate [1/]	FY 2002 Estimate [3/]	FY 2002 +/- FY 2001 Current Estimate
Total Program Level [2/]	**$36,522,000**	**$35,568,000**	**$35,490,000**	**$36,943,000**	**+ $1,453,000**
Center ($000)	$36,522,000	$35,568,000	$35,490,000	$36,943,000	+ $1,453,000
FTE	217	230	230	232	+ 2
Budget Authority [2/]	**$36,522,000**	**$35,568,000**	**$35,490,000**	**$36,943,000**	**+ $1,453,000**
Pay Increases					+1,094,000
Food Safety			$2,354,000	$2,754,000	+400,000

[1/] Reflects enacted levels adjusted for the 0.22 percent rescission, accounting for $78,000 in the NCTR program.
[2/] Reflects decrease in base funding from FY 2001 of $41,000, for Human Subject Protection & Bioterrorism.
[3/] Pay increases shown on separate line, and not reflected in individual program areas.

Historical Funding and FTE Levels

Fiscal Year	Program Level	Budget Authority	User Fees	Program Level FTE
1998 Actuals	$32,189,000	$32,189,000	0	218
1999 Actuals	$32,109,000	$32,109,000	0	223
2000 Actuals	$36,522,000	$36,522,000	0	217
2001 Current Estimate	$35,490,000	$35,490,000	0	230
2002 Estimate	$36,943,000	$36,943,000	0	232

MISSION

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

REQUESTED INCREASES

Pay Increase + $1,094,000

FDA's request for funds to cover pay cost increases is vital to the Agency 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 other government agencies. Payroll accounts for over 60 percent of the total FDA budget. This has a significant impact on all activities in FDA. The costs of the pay increases are necessary to ensure the integrity of the Agency's work at the NCTR for research functions.

In order to maintain the level of activities carried out in FY 2001, FDA is requesting $40,000,000 to cover the cost of the FY 2002 pay raise, annualization of the FY 2001 pay raise, anticipated within grade increases, and one extra day of pay. The NCTR program portion of this increase is $1,094,000.

Food Safety + $400,000 and 2 FTE

An effective food safety system must be based on sound science and be capable of dealing quickly and effectively with current and emerging public health concerns on the basis of the risk they present to the consumer. Risk analyses, including an assessment of food safety and public health risks and benefits, are helpful in defining the extent of scientific certainty and in helping decision-makers make the difficult decisions a science-based food safety system requires. In order to protect health and manage risk, effective production, marketplace and disease surveillance monitoring and other basic public health functions are essential. FDA must identify, contain and respond to foodborne outbreaks, assess antimicrobial resistance, and manage the array of animal drugs used in feed domestically and in foreign countries, thus reducing the exposure to dangerous drug residues. Information and education play a critical role in ensuring that everyone involved fulfills their responsibilities for food safety. Creating effective food safety policies and programs and building public confidence in the food safety system requires open, transparent decision making and accurate, timely exchange of information and ideas among government and other stakeholders.

As part of the national food safety initiative to improve and protect our nation's food supply, NCTR has taken full advantage of its multi-disciplinary, intra-center research capabilities and continues to focus resources on developing new scientific techniques and risk assessment models in support of the Food Safety Initiative. NCTR will:

- 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 resulting from identification of the human genome. These methods involve combining information on genes and proteins with computer technology to understand what causes specific biological events; and,

- Develop new risk assessment methods. A new approach will be validated for incorporating model uncertainties into microbial risk assessment.

JUSTIFICATION OF BASE

Activities Related to Increases for FY 2002

Payroll

- FDA's National Center for Toxicological Research conducts fundamental and applied research aimed at understanding critical biological events, such as adverse drug reactions and/or antibiotic resistance, to determine how people are adversely affected by exposure to products regulated by FDA. The center provides the scientific findings used by the FDA product centers for pre-market application review and product safety assurance to the scientific community for the betterment of public health. NCTR develops methods to measure human exposure to products that have been adulterated or to assess effectiveness and/or safety of a product.

Food Safety

- Develop new methods to assess antibiotic resistance on the farm and in processed food, as part of the Food Safety Initiative.

Other Activities Related to High Priority Areas

Premarket Activities

- Create databases used to predict adverse impact of estrogenic or hormonal compounds in humans. This work is being conducted in conjunction with the American Chemistry Council and scientists at the Environmental Protection Agency.

- Assess individual susceptibility to toxicants using advanced technology tools such as DNA microchip arrays and bioinformatics to more rapidly interpret the data generated by microarray and proteomic technology. Scientists are studying the effects of toxicants on gene expression profiles and are developing techniques to predict individual susceptibility to disease/drugs. Several of these efforts are collaborative between the NCTR, industry and academia.

- Geneticists are developing and validating sensitive and predictive transgenic systems which cross species boundaries to identify, quantify and understand how chemicals damage human genes.

Postmarket Activities

- Develop, patent and market products to detect food decomposition, such as Fresh Tag ™, a product selected by Popular Science as the "Best of What's New" Award for 1999.

- Provide data to set new standards of assessment and improve risk decisions for FDA-regulated compounds such as corn contaminants, pediatric sedatives, and aquaculture therapeutics.

- Conduct carcinogenicity studies on the combined effect of exposure to sunlight and the use of cosmetic products containing alpha-and beta-hydroxy acids. This is a joint effort with the National Institute of Environmental Health Sciences.

Selected FY 2000 Accomplishments

Developed new strategies and methods to predict toxicity and assess/detect risk for FDA regulated products (new and on the market)

- Used a multi disciplinary approach to predict human toxicity and to evaluate human risk using appropriate animal and non-animal models.

- Predicted human toxicity using transgenic rodents carrying critical reporter genes and human cell lines. Researchers continued to develop laboratory methods that closely mimic human genetic response and predict human genetic damage due to drug and/or product interactions.

- Developed a new biological assay to measure genetic changes and validated two existing models that predict human genetic damage. These systems are capable of simulating human exposure, increasing the ability to detect weak carcinogens, and decreasing the time required for determining mutation induction in the human genome.

- Established a Collaborative Research and Development Agreement with private industry to develop gene chip and gene array technology. The importance of risk chip technology is that it allows researchers to screen large numbers of people simultaneously for different types of biological indicators of effect. Each person has a different genetic profile. By looking at an individual's enzyme profile or the proteins in their blood, scientists can identify specific markers that allow the identification of individuals at risk for adverse drug reactions. This facilitates FDA review of individual susceptibility using profiles of agents with known toxicities and allows selection of a diverse group of individuals for clinical trials.

- Research includes thirteen major studies to identify ten bio-markers of the most frequently occurring cancers (pancreatic, colorectal, breast, larynx, ovary, lung, urinary bladder, bone marrow, esophagus, and prostate) in highly susceptible subpopulations. Scientists have

focused their research on the foodborne carcinogens, drugs, and natural occurring chemicals that have hormonal activity.

- The results to-date have proven that the DNA microarray chip has a 99 percent agreement rate with traditional genotyping but is much faster. This work provides assessment of the relative risks of dietary and environmental carcinogens in human cancer so critical to risk decision making.

Developed computer-based systems (knowledge bases) that predict human toxicity to enhance the efficiency and effectiveness of pre-market product reviews

Estrogenic activity is found in FDA regulated products as well as environmental chemicals, such as plastics and pesticides. Thus, it is important to understand the varying toxicological and pharmacological properties and the mechanisms of action of these regulated compounds.

- Partnered with private industry, NCTR scientists developed a knowledge base for the binding of chemicals to the estrogen and androgen receptor. This knowledge base addresses FDA's needs for a better, more rapid, and cheaper method for evaluating chemicals for potential estrogenic activity. Over 230 chemicals have estrogenic activity that may be used to predict whether these compounds are hazardous to females at risk for breast or uterine cancer. Studies on androgen receptor binding involving prostate cancer are continuing.

- Made NCTR's knowledge base available for use by the Center for Food Safety and Applied Nutrition (CFSAN) and the Center for Drug Evaluation and Research (CDER) to model estrogenic activity of products being reviewed.

- Incorporated these models into the NCTR Endocrine Disruptor Knowledge Base (EDKB). The development of the computer-based estrogen models done in conjunction with industry via a cooperative research and development agreement (CRADA) has provided a prototype and framework for developing models for predicting other types of chemically induced toxic responses. These chemical classes include androgens (male hormones) and compounds toxic to nerve cells.

- Developed computer models by working with other scientists in the agency that use measurable chemical properties (nuclear magnetic resonance and mass spectrometry spectra) of FDA regulated products to predict human risk. These techniques will help industry predict the safety of developed products and are a part of an FDA submitted patent. These models will continue to be applied to specific regulatory issues across a number of FDA product centers, and will aid in the making of regulatory decisions.

Conducted fundamental research to understand mechanisms of toxicity, assess new product technology and provide methods for use in FDA standards development and product risk surveillance

Research supported through an interagency agreement with the National Institutes for Environmental Health Sciences/National Toxicology Program (NIEHS/NTP) permits the NCTR to modify the rodent bioassay by including protocols to study mechanisms of toxic action that improve interpretation of data. As a result, time for product review is decreased resulting in a reduction in the cost of pre-clinical trials. Studies of malachite green (used in aquaculture) and endocrine-disrupting compounds (naturally-occurring and synthetic estrogens that effect reproduction) are in process.

- Conducting long-term, multi-generation studies of compounds that disrupt normal endocrine function, such as genistein (found in soybeans) and nonylphenol (found in food packaging). These studies are providing data on how estrogens and anti-estrogens may affect human development and may contribute to increasing cancer rates.

- Utilized the newly designed Phototoxicity Facility at NCTR to evaluate the harmful effects of skin exfoliants, such as alpha-hydroxy acids. Use of alpha-hydroxy acid containing cosmetics is increasing as the beauty-conscious public seeks drugs or cosmetic preparations that will give a more youthful appearance. The impact of continuous use of this type of treatment on the incidence of sunlight-induced skin cancer is not known. The Phototoxicity Facility allows the research subjects (i.e., mice) to be exposed to either simulated solar light or ultra-violet (UV) light. This research addresses the Agency's need to evaluate compounds of regulatory concern, such as alpha-hydroxy acids, found in many over-the-counter cosmetics.

- Developing methods to identify markers of food borne pathogens and to assess whether these microorganisms are undergoing change, thus becoming more virulent. This effort is in collaboration with the FDA's CFSAN, Center for Veterinary Medicine (CVM), and as part of the Food Safety Initiative. This research capitalizes on partnerships with other agencies such as the United States Department of Agriculture (USDA). The Agency needs state-of-the-art measurement of toxicity to strengthen its risk assessment of products on the market.

- Developed a project with the CVM for isolation and identification of the bacteria in competitive exclusion cultures, using the most reliable genetic microbial identification techniques available. Preliminary results have alerted CVM to the possibility that competitive exclusion products can introduce bacteria with undesirable antibiotic-resistance into the human food supply. Scientists have also been evaluating a cell culture module that can determine more quickly and accurately whether a competitive exclusion product can effectively exclude *Salmonella* sp., *Shigella* spp., and *Campylobacter* spp from intestinal cells. This assay will be available to producers and the FDA to evaluate the efficacy of competitive exclusion products.

National Center for Toxicological Research
Program Activity Data

Program Output	FY 2000 Actual	FY 2001 Estimate	FY 2002 Estimate
Research Publications (Academia)	225	235	245
Scientific Presentations (Academia)	450	500	425
Patents (Industry)	4	5	6
Interagency Agreements (IAG) (Government Agencies)*	5	9	10
Cooperative Research & Development Agreements (CRADA) (Industry)	4	3	4
Ongoing Projects Under Strategic Goal:			
Develop new strategies and methods to test or predict toxicity and assess/detect risk for FDA regulated products (new and on the market)	55	60	98
Develop computer-based systems (knowledge bases) that predict human toxicity to enhance the efficiency and effectiveness of pre-market product reviews	5	9	25
Conduct fundamental research to understand mechanisms of toxicity, assess new product technology and provide methods for use in FDA standards development and product risk surveillance	133	143	80
Total Ongoing Research Projects	193	212	203

* One IAG includes 22 separate projects.

Note: The decrease in program activity within the strategic goals from FY 2000 to FY 2001 is due to shifting the focus of NCTR's research to toxicity predictionm an area critical to FDA's pre-market review.

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Tobacco Enforcement and Evaluation

	(Budget Authority in Millions)			
	FY 2000 Enacted	FY2000 Actual	FY 2001 Appropriation	FY 2002 Request
Total	**$34.000**	**$5.701**	**$ 0**	**$ 0**
Total FTE	**25**	**21**	**0**	**0**

On August 23, 1996, FDA issued its final regulation restricting the sale and marketing of nicotine-containing cigarettes and smokeless tobacco products. The rule contained a comprehensive set of provisions that limit young people's access to tobacco products, as well as restrictions on the marketing of these products to minors. The rule was the culmination of an intense multi-year investigation that sought to determine if FDA had jurisdiction over these products, and if so, what form regulation should take.

The cigarette, smokeless tobacco, advertising and retail industries, and others brought suit in the United States District Court for the Middle District of North Carolina (Greensboro Division) to invalidate FDA's assertion of jurisdiction and enjoin its regulations. Argument was heard on February 10, 1997 and the Court issued its decision on April 25, 1997 upholding FDA's jurisdiction and its access and labeling regulations. The Court held that the statutory provision relied on by FDA did not provide FDA with authority to regulate advertising and promotion of tobacco products. Furthermore, the court delayed implementation of all remaining provisions, pending appeal, except those for age and photo identification that had gone into effect on February 28, 1997.

Both the government and plaintiffs appealed to the United States Court of Appeals for the Fourth Circuit. On August 13, 1998, the Fourth Circuit issued its decision finding the FDA's assertion of jurisdiction and issuance of regulations invalid. On April 26, 1999, the U.S. Supreme Court granted the Petition for a Writ of Certiorari filed by the Solicitor General. The granting of the petition continued a stay of the issuance of the Fourth Circuit's mandate while the Supreme Court considered the case. The age and identification provisions of FDA's tobacco rule in effect since February 1997 therefore remained in effect pending the Supreme Court's final decision.

On March 21, 2000, the Supreme Court, in a 5-4 decision, affirmed the decision of the U.S. Court of Appeals for the Fourth Circuit that FDA lacks jurisdiction under the Federal Food, Drug, and Cosmetic Act to regulate cigarettes as they are customarily marketed. FDA immediately began the process of an orderly shutdown. This following information summarizes FDA's shutdown activities for FY 2000.

Enforcement

Within several hours of the Supreme Court's ruling, FDA issued termination notices via e-mail to the States and Territories under contract with FDA to enforce the Age and ID restrictions. FDA informed its contractors of the Supreme Court's decision, terminated their contracts for the convenience of the government, and directed them to stop conducting FDA compliance checks at tobacco retail establishments.

On April 7, 2000, in consultation with FDA's Contracts Office, FDA issued interim guidance via e-mail to States regarding termination activities, including invoicing, settlement proposals and inventory. On April 14, 2000, FDA's Contracts Office authorized States to continue doing specified work-in-progress in order to prevent undue loss to the government. This work included returning all compliance check forms to FDA, resolving questions concerning completed compliance checks, submitting a final quarterly report, and storing evidence. Under Federal Acquisition Regulations (48 CFR Part 52), the FDA Contracts Office issued deadlines for specific termination activities:

- July 19, 2000 – States and Territories submit their final inventories of Federally owned equipment and furniture

- September 30, 2000 – States and Territories submit all vouchers seeking reimbursement for work under their contracts

- March 21, 2001 – States and Territories submit settlement proposals for closing out their contracts with FDA

Currently, FDA is evaluating invoices and settlement proposals, and making final payments to settle contracts with its State and Territory contractors.

Compliance-Based Outreach

On March 21, 2000, FDA issued a stop work order to Arnold Communications, the national advertising firm under contract to conduct a multimedia ad campaign targeted to retailers and consumers. Currently, FDA is evaluating Arnold's invoices and settlement proposal in order to make a final payment and close out their contract.

Regulation

In FY 2000, FDA had planned on exploring questions associated with product regulation, including classification and quality system regulations to ensure that the health consequences of tobacco products or their ingredients, additives or constituents are made less harmful. No funds were expended as of March 21, 2000, so the associated funding for this activity was included as a part of FDA's FY 2000 tobacco reprogramming requests approved by the House and Senate.

Office of Regulatory Affairs

(For Information Only, Field Request is Included with Programs)

	FY 2000 Actual		FY 2001 Appropriation		FY 2001 Current Estimate		FY 2002 Estimate		FY 2002 +/- FY 2001 Current Estimate	
	FTE	**$(000)**	**FTE**	**$(000)**	**FTE**	**$(000)**	**FTE**	**$(000)**	**FTE**	**$(000)**
Program Level Total	**3,093**	**308,280**	**3,283**	**324,046**	**3,204**	**323,372**	**3,467**	**386,875**	**263**	**63,503**
By Program:										
Foods	1,556	155,115	1,580	160,151	1,542	159,799	1,620	184,034	78	24,235
Human Drugs	737	70,853	819	73,336	799	73,189	836	85,454	37	12,265
Biologics	211	19,426	238	22,474	232	22,426	250	27,520	18	5,094
Animal Drugs & Feeds	135	13,122	158	15,044	154	15,011	255	27,486	101	12,475
Devices	454	49,764	488	53,041	477	52,947	506	62,381	29	9,434
Total Budget Authority	**3,003**	**291,814**	**3,193**	**306,373**	**3,114**	**305,699**	**3,313**	**348,911**	**199**	**43,560**
Total User Fees	**90**	**16,466**	**90**	**17,673**	**90**	**17,673**	**154**	**37,964**	**64**	**20,291**

Historical Funding and FTE Levels

Fiscal Year	Program Level	Budget Authority	User Fees	Program Level FTE
1998 Actuals	$262,079,000	$246,918,000	$15,161,000	3,129
1999 Actuals	$280,719,000	$266,038,000	$14,681,000	3,153
2000 Actuals	$308,280,000	$291,814,000	$16,466,000	3,093
2001 Current Estimate	$323,372,000	$305,699,000	$17,673,000	3,204
2002 Estimate	$386,875,000	$348,911,000	$37,964,000	3,467

MISSION

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

The Office of Regulatory Affairs (ORA) field staff support Agency premarket activities by conducting preapproval inspections and laboratory methods validations when requested by program managers responsible for premarket application decisions. These inspections, which can be of either foreign or domestic establishments, include bioresearch monitoring inspections of clinical research that is part of premarket applications. Other premarket inspections are conducted in manufacturing facilities to determine if the facility is able to manufacture the product to the specifications stated in the application. Inspections are generally performed by consumer safety officers who may be accompanied by a laboratory analyst if review of manufacturing information in the application suggests that additional laboratory expertise is appropriate to assess the facility. Laboratory method validations are conducted to confirm that the methods described in the premarket application work as described in FDA laboratories.

Field investigators and laboratory analysts conduct foreign inspections for both premarket approval and postmarket compliance purposes. FDA product center managers select most establishments for inspection. Postmarket foreign inspections in the drug, biologic, animal drug, and device programs are conducted to assess Good Manufacturing Practices (GMP). This is consistent with the biennial inspection requirement that Congress requires of domestic manufacturers in these programs. While Congress mandated that domestic manufacturers be inspected every two years, foreign manufacturers are not included in this requirement. Beginning in FY 1999, the Foods program, which has historically supported fewer than 100 foreign inspections, began to expand the number of foreign inspections. About 250 foods foreign inspections are planned for FY 2001.

In addition to conducting regular surveillance over regulated products, the field workforce also serves a critical function when the Agency must respond to emergencies. The field work force is able to by immediately mobilize to investigate reports of product problems including tampering incidents and those due to natural disasters such as hurricanes, floods and earthquakes. The field workforce is also involved in informing businesses and consumers about FDA-related topics, and

in working with state and local agencies to develop programs that make the best use of Federal, State, and local resources in protecting the public health.

To complement the regular field force, the Office of Criminal Investigations (OCI) was established in FY 1992 as part of FDA's efforts to more effectively investigate instances of criminal activity in the regulated industries. Agents are given intensive training at the Federal Law Enforcement Training Center in Glencoe, Georgia, and are assigned to offices throughout the country.

Field facilities include Regional Offices, District Offices, laboratories, OCI field offices, and resident posts. The five Regional Offices are staff offices which coordinate FDA activities and also coordinate with state authorities. The 19 District Offices serve as offices for investigators and compliance action staff, and are the main control points for day-to-day operations in their assigned areas. The current inventory of 13 laboratories provide FDA's basic field product testing capability. A number of these laboratories serve as specialized facilities for certain types of testing and new regulatory methods development.

FDA also maintains more than 120 resident posts distributed widely across the country. These are smaller offices which serve primarily as a base for investigators so that FDA can have investigative staff widely dispersed to respond to emergencies whenever they occur, as quickly as possible to minimize any potential harm. With all of these Field facilities combined, FDA maintains offices and staff in 49 of the States, and in the District of Columbia and Puerto Rico.

In 1994, the Field Laboratory Consolidation Plan was approved calling for the number of field laboratories to be reduced from 18 to 9 over 20 years. Under the plan, outdated facilities would be closed and other laboratories would be renovated or relocated. The plan specified five large total capacity/multipurpose regulatory laboratories and four specialty laboratories. The five multi purpose laboratories would be located in Atlanta, GA; Seattle, WA; Jamaica/Queens, NY; Jefferson, AR; and Irvine, CA. Currently, the Jamaica/Queens construction and Atlanta and Seattle expansions are complete. The Jefferson, AR, construction is nearing completion, and the second phase of the Irvine, CA, construction is slated for completion in 2003.

REQUESTED INCREASES
(For Information Only, Field Request is Included with Programs)

Pay Increase + $14,060,000

FDA's request for funds to cover pay cost increases is vital to the Agency 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 other government agencies. Payroll accounts for over 60 percent of the total FDA budget. This has a significant impact on all activities in FDA, particularly the field. The costs of the pay increases are necessary to ensure the integrity of the Agency's field labor force for inspections, compliance, and investigational functions.

In order to maintain the level of activities carried out in FY 2001, FDA is requesting $40,000,000 million to cover the cost of the FY 2002 pay raise, annualization of the FY 2001 pay raise, anticipated within grade increases, and one extra day of pay. ORA's portion of this increase is $14,060,000.

This increase will enable the field force to keep pace with a growing and more technologically complex and diverse regulatory environment. The field force has been unable to grow to meet the new challenges because the Agency had to absorb the costs of pay increases.

Bovine Spongiform Encephalopathy (BSE) + $10,900,000 and 98 FTE

- Conduct additional training for Federal and State inspectors on the BSE feed regulation, update them on the current European Union situation, Animal Plant and Health Inspection Service (APHIS) authority and approach, and what to look for and how and when to sample.

- Increase domestic protection by conducting 1,000 more domestic inspections.

- Increase leveraging with State agencies by funding approximately 4,000 contract inspections of feed mills and renderers, and conduct compliance, follow-up, and audit inspections to state contracts.

- Collect and analyze 600 new domestic and 600 new import feed and feed component samples for BSE related contaminants to ensure proper labeling of animal feeds and feed components.

- Provide intensive line entry and label review of an anticipated 175,000 import line entries for use in domestic commerce for the Animal Drugs and Feeds program by expanding import staff by 17 FTE.

Imports and Inspections + $22,000,000 and 83 FTE (Budget Authority + $7,300,000 and 36 FTE; User Fees + $14,700,000 and 47 FTE)

Budget Authority

- Increase monitoring of fraudulent drug import activities by increasing criminal investigations and conducting 96 more authenticity analyses of imported drug products.

- Improve safety of domestic drug products by increasing sample analyses of domestic products.

- Improve the safety of imported biological products by increasing the surveillance of imported human tissues and other imported biological products.

- Increase coverage of domestic biological products by conducting 18 more tissue bank inspections.

- Consult with the Center for Veterinary Medicine on developing compliance guidance and revising the electronic review criteria, (i.e. may proceed criteria) based on current risk assessments and risk based decision making of imported products.

- Conduct 30 additional inspections for illegal drug residue and chemical contaminants in animal feed and increase sampling.

- Assure current information is available to import examiners to make well founded regulatory decisions.

- Improve imported medical device compliance by increasing surveillance and product testing of these products.

- Increase domestic medical device surveillance by conducting 150 additional inspections of manufacturers.

- Improve the confidence that FDA has in the safety of foreign drugs, biological and device products by working towards implementation of the European Mutual Recognition Agreement and by intensifying drug inspections in developing countries.

User Fees

- Improve the effectiveness of cargo control activities at Ports, and the monitoring of products that have been refused entry pending exportation or destruction, by working with the U.S. Customs Service to increase coordination of import activities.

- Increase import surveillance by expanding import entry review resources to keep pace with the increase in line entries.

- Improve import surveillance activities by increasing the frequency of on-screen entry review and updating on a risk basis the criterion that determines which import line entries are selected for on screen review.

- Modernize the Operational and Administrative System for Import Support (OASIS) import data processing system to allow import reviewers to have rapid and direct access to information necessary for entry decisions.

- Increase data audits, import filer training, and liaison activities to ensure the integrity of import data submitted by import filers.

Patient Safety/AERS + $1,000,000 and 6 FTE

- Increase patient safety by holding more public meetings to educate consumers and other stakeholders about the prevention and reporting of medical errors.

- Reduce medical errors by conducting more investigations of reported errors to collect information that program managers need to assess the error and develop error reduction strategies with manufacturers and the medical community.

- Accelerate the upgrade of field investigational data systems to complement Agency error tracking systems to provide better information on the incidence of medical errors.

Human Subject Protection + $6,400,000 and 32 FTE

- Increase direct FDA oversight of bioresearch through an increase of 205 BIMO inspections in the Human Drugs (80), Biologics (50), and Device (75) programs.

- Improve the quality, consistency, and effectiveness of bioresearch monitoring (BIMO) inspections by developing an investigators' certification program to provide training and practical experience and assure that investigators keep pace with emerging issues in clinical research.

- Improve compliance with the bioresearch regulations through a timely Clinical Investigator Disqualification Process and improve the consistency of these disciplinary actions among drugs, biologics, and device programs.

- Improve the safety and quality of foreign bioresearch activities by developing new relationships with foreign governments and participating in international regulatory standards organizations.

Food Safety + $9,300,000 and 44 FTE (Budget Authority + $5,400,000 and 27 FTE; User Fees + $3,900,000 and 17 FTE)

Budget Authority

- Increase the number of State contract inspections by 1,000 (to a total of 4,700) by expanding the funding and coordination of State contract inspections.

- Improve food safety activities by the States by expanding State audit inspections, enforcement, and data reporting for State inspectional and compliance activities.

- Increase the utilization of State inspectional data and findings by having more States enter inspection data directly into FDA field data systems.

- Improve the safety of the domestic food supply by conducting 400 more domestic sample analyses for foodborne pathogens and contaminants.

User Fees

Food Safety-Export Certification

- Facilitate international trade by preparing export certificates on a timely basis and in the languages required by current international agreements.
- Provide reimbursement of operating costs to allow existing food safety resources to be more effectively utilized for inspections and sample analyses.

Current Law User Fees + $1,380,000

Prescription Drug User Fee Act (PDUFA) + $1,375,000

The Food and Drug Administration 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. In FY 2002, based on the information currently available and the statutory PDUFA formulas, an increase of $1,375,000 is included for the field activities.

Mammography Quality Standards Act + $5,000

The Mammography Quality Standards Act (MQSA) of 1992 was reauthorized in 1998 for an additional five years (P.L. 105-298). FDA requests an increase of $5,000 in MQSA authorized inspection user fees to cover inflationary costs. The fees collected will pay for overhead costs related to inspections.

JUSTIFICATION OF BASE

Activities Related to Increases for FY 2002

Payroll

- ORA is primarily responsible for conducting inspections of regulated industry, and collecting and analyzing samples. Other activities that often arise are review and management of enforcement actions, consumer complaints, trace back efforts to determine the cause of food borne illness outbreaks, and review of import entries for admissibility decisions. These functions are inherently governmental and highly personnel intensive.

Bovine Spongiform Encephalopathy (BSE)

- Conduct inspections of licensed and unlicensed feed mills for compliance with BSE regulations.

- Coordinate with State agencies to enforce the BSE regulations.

Imports and Inspections

- Provide criminal investigation of reported product tampering, counterfeit products and other fraudulent criminal activities involving regulated products.

- Provide emergency operation, investigation and response for incidents involving regulated products.

- Develop laboratory analytical methods to permit the analyses of products for chemical and microbiological hazards.

- Inspect about 14,000 domestic and 900 foreign establishments.

- Fund about 13,600 State contract inspections.

- Review 6,300,000 import line entries for admissibility into domestic commerce.

Patient Safety/AERS

- Provide training for field staff to improve the information gathered through investigation of consumer complaints.

- Provide health education for U.S. consumers about FDA-regulated products, which may impact their health adversely.

Human Subject Protection

- Conduct Bioresearch Monitoring inspections and data audits in the human and animal drug, biologic, and medical device areas to monitor the methods and reporting of FDA regulated research.

- Inspect clinical investigators to protect the rights and welfare of human subjects involved in FDA regulated research, and to assure the quality and integrity of data submitted to the Agency in support of new product approvals.

Food Safety

- Conduct inspections of all high-risk domestic food establishments, currently identified at 6,250. Laboratory capabilities are being enhanced for the analytical support associated with the level of inspectional activity. High risk establishments include processors of infant formula; processors of ready to eat foods, or produce; seafood product processors; low-acid canned food processing plants and juice processors.

- Identify the food source and contaminant of foodborne illness outbreaks ranging from chemical, microbiological, and physical hazards.

- Continue State contract audit inspections to ensure consistent application of regulations nationwide by FDA and the States.

- Replace outdated field laboratory equipment to improve the accuracy and timeliness of food product analyses to determine compliance with safety requirements.

Activities Related to Other Priority Areas

Internet Drug Sales

- Continue the monitoring of potentially fraudulent Internet sites to identify targets for investigation and sampling of products.

- Conduct undercover online purchases of prescription drugs from Internet sites suspected of engaging in illicit drug sales, distribution, and/or marketing.

- Reduce the health risks to individuals ordering pharmaceuticals from foreign sources over the Internet by providing oversight of mail and courier packages entering from foreign sources and destined for individuals, e.g., personal importations. These personal importations are largely excluded from FDA's electronic import data system.

Premarket Activities

- Improve the quality and timeliness of product reviews through monitoring pre-approval inspections and by expanding inspectional expertise in emerging technologies and expanding quality assurance to monitor the inspection process.

- Recruit, hire and train new investigators and provide training, information technology and contract support to improve the scientific expertise of field investigators. This training enables the investigators to conduct the pre-market inspections that are essential to meet pre-market review time frames.

Countering Bioterrorism

- Participate in the planning for and coordination of exercises simulating responses to bioterrorist attacks.

- Develop a notification system for bioterrorism incidents (including hoaxes) with the Federal Bureau of Investigations (FBI) who will notify FDA through our 24- hour emergency number regarding any threat that may involve an FDA regulated product.

- Inspect of drug and vaccine manufacturers whose products may be stockpiled as part of the Government's bioterrorist efforts.

International Activities

- Plans for FDA's international inspection program continues to be one of the Agency's top priorities as more FDA regulated products originate from foreign sources. The Agency's international inspection program is paramount in attaining confidence that all imported FDA regulated products meet the same standards as domestic goods. While FDA is working to foster effective international inspection cooperation agreements, the primary tool for this assurance is for FDA to conduct international inspections.

Selected FY 2000 Accomplishments

Science

- **Implementation of Pulsed Field Gel Electrophoresis (PFGE)**. DNA finger printing by PFGE is one of the most important tools to combat foodborne outbreaks. ORA established PFGE capability in five field laboratories. This method can provide timely identification of the source of contamination. This technique has been successfully used in several outbreak situations involving Salmonella and *Listeria monocytogenes*.

- **Development of Antibiotics Sensitivity Screening of Salmonella.** The emergence of antibiotics resistance has become a major public health concern. Of particular interest is the emergence of Salmonella with resistant genes to multiple antibiotics. FDA needs data on the extent of antibiotic-resistant Salmonella in our food supply. ORA has established a program of screening Salmonella isolates from foods in our Denver laboratory. In FY 2000, about 250 Salmonella isolates were screened and several multiple-antibiotic resistant strains were found.

- **Imported Produce Analyzed for Pathogens.** ORA analyzed 1,000 fresh imported produce samples for microbiological pathogens. This first systematic look at this dietary significant group of foods for pathogens found approximately 5 percent of the samples contained pathogens. Pathogens detected were *Shigella* and *Salmonella spp*. Commodities found positive included: cantaloupe, celery, cilantro, green onions, lettuce and parsley.

Investigations

- ORA conducts inspections to evaluate regulated establishment operations against appropriate Agency requirements. Inspections evaluate manufacturing processes; record-keeping systems; warehousing practices; packaging or labeling processes; quality control laboratories; and, integrated livestock feeding practices. During FY 2000, ORA conducted 15,146 inspections, including 880 foreign and 14,266 domestic inspections.

- Domestic inspections funded by FDA appropriations may be conducted by either FDA staff or by States under contract to FDA. When States conduct inspections under contract, FDA is required to audit these inspections. There were a total of about 13,900 State contract inspections. Of these, approximately 8,900 were inspections of mammography facilities; about 1,000 were of feed mills; another 350 were tissue residue; and, the rest, about 3,700, were food inspections.

Partnership and Support for States

- **FDA Funding of State/Local Task Forces.** FDA funded 19 State Food Safety Task Forces with Small Conference Grants totaling $96,500 and 13 grants totaling $530,000 for Innovative Food Safety Projects to State and local regulatory agencies that were intended to complement, develop and/or improve food safety programs.

- **State Contracts.** FDA awarded 39 state food contracts for over 5,100 food inspections for a total of $2,617,000;19 state medicated feed contracts for 453 GMP/BSE inspections and 96 BSE-only inspections for a total of $330,000; 15 state tissue residue contracts for 548 inspections for a total of $260,000; and negotiated and awarded 47 Mammography Quality Standards Act (MQSA) contracts.

- **Partnerships**. At the close of FY 2000, there were over 177 Partnership Agreements between FDA and various State/local regulatory agencies, associations, industry, and academia. This represents an increase of approximately 12.7 percent over FY 1999.

Enforcement Activities

Protection of Participants in Gene Therapy Trials

- FDA and NIH announced two new programs to further strengthen the safeguards for individuals enrolled in clinical studies for gene therapy. These two new programs -- the Gene Therapy Clinical Trial Monitoring Plan and the Gene Transfer Safety Symposia -- are part of ongoing efforts to ensure the safety of patients enrolled in gene therapy clinical trials.

- **University of Pennsylvania.** From November 1999 to January 2000, FDA conducted an inspection of the Institute for Human Gene Therapy located at the University of Pennsylvania. Subsequently, FDA placed all trials sponsored by Dr. James Wilson, Director of the Institute, on clinical hold. Following issuance of a Warning Letter, the University determined that it would no longer conduct experiments on humans.

- **St. Elizabeth's Medical Center.** In February 2000, FDA put the gene therapy research being conducted at St. Elizabeth's Medical Center of Boston on clinical hold. Following an inspection in March 2000, a Warning Letter was issued concerning violations of regulations governing the proper conduct of clinical studies and the protection of human subjects.

Consent Decrees

- **Abbott Laboratories.** In November 1999, Abbott Laboratories signed a Consent Decree of Permanent Injunction related to manufacturing problems concerning many of its in-vitro diagnostic tests. As an equitable remedy of disgorgement, the firm also agreed to pay $100,000,000 to the U.S. Treasury. The dollar amount sets a precedent as the largest amount of money ever paid by an FDA-regulated company for a civil violation of the Federal, Food, Drug and Cosmetic Act.

- **Wyeth-Ayerst Laboratories**. In October 2000, Wyeth-Ayerst Laboratories Division of American Home Products Corporation and Wyeth-Ayerst Pharmaceuticals, Inc., signed a Consent Decree of Permanent Injunction based on a failure to comply with FDA's GMP regulations. As an equitable remedy of disgorgement, Wyeth also agreed to pay $30,000,000 to the U.S. Treasury.

Recalls

- **Clinipad Antiseptic Sterile Products.** An FDA inspection of Clinipad Corp., Charlotte, NC, in January and February 2000, resulted in the recall of over 925,000,000 sterile products and 900,000,000 non-sterile products because of CGMP deviations. Recall of these products involved three program areas – Drugs, Devices, and Biologics.

- **Rich's MSM Eye & Ear Drops.** In response to a consumer complaint, FDA laboratory analysis of a sample of Rich's MSM Eye & Ear Drops revealed contamination with yeast and a bacteria that can cause severe, and potentially sight-threatening, eye injuries. This resulted in a Class I recall in August 2000.

- **Dialysis Catheter Anticoagulant – TriCitrasol.** In April 2000, a Class I recall resulted when an FDA investigation that was initiated in response to an adverse medical report disclosed that triCitrasol, an unapproved dialysis catheter anticoagulant, may cause death when infused into patients. A patient death was, in fact, associated with use of the product.

- **Dietary Supplements Containing the Prescription Diabetic Drug Glycuride.** During February and March 2000, several recalls of herbal products were initiated due to the presence of undeclared prescription diabetic drugs, glycuride and phenformin. Both drugs are used to lower blood sugar. Recalls of such products were initiated by Sino American Health Products, Inc.; Chinese Angel Health Products, Inc.; and, Diabetic Capital (US) LLC.

Internet Drug Sales

- FDA continues to take regulatory and enforcement actions against violative Internet drug firms. There are several reviews for regulatory action underway, and numerous active criminal investigations. ORA continues to issue cyber letters to violative foreign pharmacy sites and is extending the use of cyber letters to domestic sites. Sites selling

recreational drugs, as well as those identified in a recent rash of cases involving the sale of bulk active drug ingredients to persons who distributed it illegally in capsules are receiving increased attention. The Internet Prescription Drug Sales Act of 2000 was transmitted to Congress in support of this activity.

- **Christian Brothers Contracting Corporation Case.** In April 2000, Judge John Gleeson of the Eastern District of New York, signed an order granting the Government preliminary injunctive relief against Christian Bros. Contracting Corp., and its President, Jason Vale, who had promoted laetrile (amygdalin), an illegal cancer treatment, via multiple web sites.

Imports

- **Global Harmonization**. In the area of medical devices, ORA has been involved in many activities that fall under the concerns of global harmonization. ORA has representation on the Global Harmonization Task Force which has membership from Canada, the EU, Japan, and Australia as well as industry members. The group has been developing guidance on quality auditing, quality auditor qualifications, and quality audit reports.

- **BSE Issues.** FDA provided technical expertise and assistance to USDA in identifying entry criteria for import examination. FDA provided early information to its field offices in the identification of products susceptible to BSE contamination, and instructions regarding forwarding of this information to local USDA/APHIS offices.

- On December 7, 2000, USDA/APHIS enacted an immediate prohibition on the importation of all meat and bone meal (MBM), bone/meat/blood meals, tankage, offal or any product containing such, which originates directly from Europe or was rendered/processed in European plants processing animal materials, regardless of the species of origin, including poultry and fish meal. This action was deemed necessary because of the possibility of cross contamination with the BSE agent. FDA issued an import bulletin (71-B02) on December 20, 2000, to disseminate this information to field import offices and to provide guidance to districts when they encounter any of these products. An import alert is currently being developed and should issue in 2001 to further enhance enforcement strategy with regards to these products. ORA's Division of Import Operations and Policy is working very closely with CVM on this issue as well as with counterparts in USDA/APHIS.

- **API/Bulk Drugs.** FDA has provided joint FDA/Customs enforcement instruction to approximately 200 field personnel. FDA has engaged a private contractor (Battelle) to examine FDA's import strategy/procedures and to develop new Information Technology products to assist in import surveillance.

Training

- **Investigator Certification.** Certification is designed to provide investigators with training to facilitate standardization of scientific investigations (and inspections) across the Agency. The Device Certification Program has expanded into the Seafood Products and Blood Bank and Plasma Center areas. There are ten seafood investigators certified at the Level II; twelve certified at Level II in the Blood Banks and Plasma Center Program. Currently 110 investigators have been certified in the Medical Device Program.

- **Partnership and Support for States.** ORA trained 1,879 State, local health department officials to further compliance with FDA policies and procedures for investigators. This training is critical to the mission of the Agency to train State employees to conduct investigations and meets ORA's commitment to work proactively with state agencies to protect the public health.

- **FACTS.** The Field Accomplishments and Compliance Tracking System (FACTS) was developed to centralize the data gathered by ORA into one nation-wide system. Four courses were conducted during the past year with 124 participants in attendance.

Emergency Operations

- FDA tracked and investigated 98 pathogen-related incidents during FY 2000. Examples of food borne pathogens tracked which spread across several states include a "salmonella meunchen outbreak" in mangoes that broke out in 13 states; a norwalk-like virus in potato salad that occurred in 11 states; and, a salmonella anatum outbreak which occurred in frozen carrots and peas that occurred in 8 states and Canada.

- Non-pathogen related incidents were also investigated by FDA. Approximately 97 non-pathogen related incidents were recorded. Examples of non-pathogen-related incidents are grouped in several areas: adverse reactions; injuries; chemical contaminants; tampering; infections; recalls; foreign objects; natural disasters; counterfeit labeling; drug residues; and, death. For instance, an example of an adverse reaction incident involves a reaction to a vaccine that resulted in the death of an infant; or, counterfeit labeling in infant formula in the state of California. Other types of non-pathogen related incidents happen in natural disasters such as a tornadoes in Texas and Minnesota; Hurricane Irene; a fire in Los Alamos, New Mexico; and flooding in New Jersey.

PROGRAM ACTIVITY DATA CHARTS

FIELD FOODS

PROGRAM OUTPUTS - DOMESTIC	FY 2000 Actuals	FY 2001 Estimate	FY 2002 Estimate
Domestic Inspections - FSI by FDA			
Non-HACCP Domestic	3,742	6,200	6,300
Seafood HACCP Domestic	2,362	4,700	4,700
Domestic Inspections - FSI by State Contract			
Non-HACCP	3,160	3,660	4,700
Seafood HACCP	546	542	600
Domestic Inspections - FSI by State Partnerships			
Non HACCP	1,956	1,000	1,000
Seafood HACCP	418	400	400
Field Exams			
Field Exams - FSI by FDA	81	80	100
Field Exams - Non-FSI by FDA	1,363	1,720	2,000
Laboratory Samples Analyzed .			
FSI	4,777	5,980	6,340
Non-FSI	4,735	7,750	7,750
PROGRAM OUTPUTS - IMPORT/FOREIGN			
Foreign Inspections - FSI by FDA			
HACCP	8	10	10
Non-HACCP	160	250	250
Seafood Importer (HACCP)	529	700	700
Import Inspections - FSI by State Partnerships			
Seafood Importer HACCP	15	10	10
Field Exams			
Field Exams - FSI by FDA	8,713	3,650	3,650
Field Exams - Non-FSI by FDA	4,448	7,200	7,200
Import Laboratory Samples Analyzed			
FSI	10,565	12,000	12,000
Non-FSI	4,549	9,200	9,200
Import Line Entry Decisions	4,134,307	4,590,000	5,139,770

FIELD COSMETICS

PROGRAM OUTPUT - DOMESTIC	FY 2000 Actuals	FY 2001 Estimate	FY 2002 Estimate
Domestic Inspections - by FDA	81	80	80
Domestic Laboratory Samples Analyzed - by FDA	48	45	45
PROGRAM OUTPUT - IMPORT/FOREIGN			
Import Field Exams/Tests by FDA	241	240	240
Import Laboratory Samples Analyzed - by FDA	120	115	115
Import Line Entry Decisions	428,686	505,849	566,551

FIELD HUMAN DRUGS

PROGRAM OUTPUT - DOMESTIC	FY 2000 Actuals	FY 2001 Estimate	FY 2002 Estimate
Non-Clinical/Clinical Study Investigations (Bio-Research Monitoring Inspections)	620	600	680
Domestic Inspections (Other)	912	1,450	1,450
Domestic Inspections by State Partnership	166	160	160
Domestic Preapproval Inspections(NDA/ANDA)	308	360	360
Domestic Inspections - Compressed Medical Gases	617	460	460
Domestic Samples Analyzed	1,593	1,360	1,460
Domestic Field Exams/Tests by FDA	21	20	20
PROGRAM OUTPUT - IMPORT/FOREIGN			
Foreign Inspections (Other) by FDA	42	240	240
Preapproval Inspections (NDA/ANDA)	210	280	280
Import Field Exams/Tests by FDA	1,031	3,700	3,700
Import Laboratory Samples Analyzed by FDA	137	200	200
Non-Clinical/Clinical Study Investigations (Bio-Research Monitoring Inspections)	77	100	100
Import Line Entry Decisions	102,414	111,631	125,027

FIELD BIOLOGICS

PROGRAM OUTPUT - DOMESTIC	FY 2000 Actuals	FY 2001 Estimate	FY 2002 Estimate
Non-Clinical/Clinical Study Investigations (Bio-Research Monitoring Inspections)	155	110	160
Domestic Inspections by FDA	1,754	2,060	2,070
PROGRAM OUTPUT - IMPORT/FOREIGN			
Foreign Inspections by FDA	48	70	70
Import Field Exams/Tests by FDA	13	10	10
Non-Clinical/Clinical Study Investigations (Bio-Research Monitoring Inspections)	12	10	10
Import Line Entry Decisions	18,802	24,067	26,955

FIELD ANIMAL DRUGS AND FEEDS

PROGRAM OUTPUT - DOMESTIC	FY 2000 Actuals	FY 2001 Estimate	FY 2002 Estimate
Domestic Inspections - Feed Mill/BSE (Medicated Feed Establishments) by FDA	445	760	1,760
Domestic Inspections - Feed Mill by State Contract	972	450	4,450
Domestic Inspections - Feed Mill by State Partnership	89	80	80
Domestic Inspections - Tissue Residue by FDA	209	120	150
Domestic Inspections - Tissue Residue by State Contract	341	340	340
Domestic Inspections - Tissue Residue by State Partnership	30	30	30
Domestic Inspections - Bimo/Pre-Approval by FDA	108	110	110
Domestic Inspections - All Other (Including Feed Contaminant) by FDA	219	450	450
Domestic Inspections - All Other (Including Feed Contaminant) by State Partnership	11	10	10
Domestic Field Exams/Tests by FDA	4	0	0
Domestic Laboratory Samples Analyzed by FDA	2,320	4,200	4,800
PROGRAM OUTPUT - IMPORT/FOREIGN			
Foreign Inspections - All Other (Including Feed Contaminant) by FDA	2	50	50
Foreign Inspections Bimo/Pre-Approval by FDA	30	40	40
Import Field Exams/Tests by FDA	199	100	100
Import Lab Samples Analyzed - FDA	277	170	770
Import Line Entry Decisions	146,310	155,089	173,699

FIELD MEDICAL DEVICES AND RADIOLOGICAL HEALTH

PROGRAM OUTPUT - DOMESTIC	FY 2000 Actuals	FY 2001 Estimate	FY 2002 Estimate
Non-Clinical/Clinical Study Investigations (Bio-Research Monitoring Inspections)	236	250	325
Domestic Inspections Pre-Approval	156	200	200
Domestic Inspections by State Partnership	32	150	150
Domestic Inspections (MQSA) by FDA	564	630	630
Domestic Inspections (MQSA) by State Contract	8,879	8,960	8,960
Domestic Inspection (All Other)	1,106	1,310	1,460
Domestic Field Exams/Tests by FDA	1,046	1,340	1,340
Domestic Laboratory Samples Analyzed by FDA	154	340	340
PROGRAM OUTPUT - IMPORT/FOREIGN			
Foreign Inspections by FDA	282	250	250
Foreign Inspections (MQSA)	16	16	16
Foreign Inspections Pre-Approval	51	30	30
Import Field Exams/Tests by FDA	503	1,100	1,100
Import Laboratory Samples Analyzed by FDA	1,305	1,380	1,380
Non-Clinical/Clinical Study Investigations (Bio-Research Monitoring Inspections)	13	10	10
Import Line Entry Decisions	1,532,167	1,761,992	1,973,431

FIELD OPERATION DEFINITIONS

Inspection (Foreign and Domestic)
Any visit to an establishment during which all or part of one or more phases of the establishment's operation are evaluated against appropriate Agency requirements. Phases of an operation include such activities as: a manufacturing process; a record-keeping system; warehousing practices; packaging/labeling processes; quality control laboratories; and integrated livestock feeding practices.

Examples of food inspections routinely conducted by FDA include: determining of adherence with good manufacturing practice (GMP) or good laboratory practice (GLP) regulations or similar process standards; evaluating of overall sanitary conditions; determining operational failures that led to the recall of a product; and determining the probable cause of a product's adverse reaction report or consumer complaint.

Domestic Field Exam/Test
The on-site examination of a domestic product (or a foreign product in domestic channels of trade) that is sufficient in itself to determine whether the product is in compliance with the Acts enforced by FDA. Examples of food exams include visual, organoleptic (sensory examination most often associated with the evaluation of decomposition of seafood), quick color (used for rapid test methods which do not require instrumentation and rely on the quick development of color as the test result) and rapid abrasion tests (used for the determination of toxic metals due to the fact that abrasion exposes colored surfaces likely to contain metals).

Import Field Exam (formerly Wharf Exam)
The examination of a product, in import status, sufficient in scope to determine whether the product is in compliance with the Acts enforced by the FDA for the attributes under consideration. An import field exam may be conducted on products discharged from vessels on to the wharves (piers), pier sheds, and other locations; on products in trucks, trains, etc., at border entry points; or on products set aside for FDA examination. Examples of food exams include visual, organoleptic, quick color, and rapid abrasion tests.

Import Sample Analysis
The physical analysis of a product in import status to determine whether or not the product is in compliance with the Acts enforced by the FDA. The physical analysis of a product of domestic origin, or a foreign origin if the product was collected in domestic channels of trade, to determine whether or not the product is in compliance with the Acts enforced by the FDA. Each food sample may be analyzed for one or more of the following determinations: filth, decomposition, microbiological contamination, pesticides, industrial chemicals, toxic elements, dioxins, mycotoxins, natural seafood poisons, radionuclides, and food and color additives.

Map ORA Offices

Map ORA Current Labs

Map ORA Future Labs

Other Activities

	FY 2000 Actual	FY 2001 Appropriation	FY 2001 Current Estimate [1/, 4/]	FY 2002 Estimate [3/]	FY 2002 +/- FY 2001 Current Estimate
Total Program Level [2/]	**$78,120,000**	**$79,020,000**	**$78,873,873**	**$94,796,000**	**+$15,923,000**
FTE	**783**	**774**	**774**	**787**	**+ 13**
Total Budget Authority [2/]	**$66,601,000**	**$66,878,000**	**$66,731,000**	**$80,666,000**	**+$13,935,000**
Pay Increases					*+3,235,000*
BSE			*274,000*	*574,000*	*+ 300,000*
Imports/Inspections			*20,557,000*	*20,857,000*	*+300,000*
Patient Safety/AERS			*2,889,000*	*3,289,000*	*+ 400,000*
Human Subject Protect.			*1,563,000*	*1,863,000*	*+300,000*
Food Safety			*20,700,000*	*20,800,000*	*+100,000*
Management Priorities			*0*	*8,300,000*	*+ 8,300,000*
Total User Fees	**$11,519,000**	**$12,142,000**	**$12,142,000**	**$14,130,000**	**+ $1,988,000**
PDUFA	*11,353,000*	*11,961,000*	*11,961,000*	*13,944,000*	*+1,983,000*
MQSA	*166,000*	*181,000*	*181,000*	*186,000*	*+ 5,000*

[1/] Reflects the enacted levels adjusted for the 0.22 rescission, accounting for $148,000 in the Other Activities Program.
[2/] Reflects increase in base funding from FY 2001 of $1,000,000, for Human Subject Protection & Bioterrorism.
[3/] Pay increases are shown on separate line and not reflected in individual program areas.
[4/] The FY 2001 Current Estimate for Other Activities in the following activities (BSE, Imports/Inspections, Patient Safety/AERS, Human Subject Protection, and Food Safety) was determined by a formula that reflects Other Activities as a percentage of the total FY 2000 FDA budget.

Historical Funding and FTE Levels

Fiscal Year	Program Level	Budget Authority	User Fees	Program Level FTE
1998 Actuals	$89,824,000	$78,669,000	$11,155,000	957
1999 Actuals	$84,639,000	$74,615,000	$10,024,000	905
2000 Actuals	$78,120,000	$66,601,000	$11,519,000	783
2001 Current Estimate	$78,873,000	$66,731,000	$12,142,000	774
2002 Estimate	$94,7961,000	$80,666,000	$14,130,00	787

MISSION

- Provide central program direction and administrative services for Agency programs to ensure that FDA's consumer protection efforts are effectively managed and that available resources are put to the most efficient use.
- Provide Agency-wide policy development in medical affairs, scientific coordination, regulatory requirements, legislation, planning and evaluation, consumer communications and public information.
- Provide management expertise and coordination in financial management, personnel, equal opportunity and Agency-wide diversity program functions, contracts and grants administration, procurement, property and space control, and communications systems. Specific programs include Freedom of Information Act activities, administration of internal controls required under the Federal Managers' Financial Integrity Act, the Small Business Program to assist businesses in carrying out regulatory requirements, and participating in FDA's regulatory decision-making process.

REQUESTED INCREASES

Pay Increase + $3,235,000

FDA's request for funds to cover pay cost increases is vital to the Agency 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 other government agencies. Payroll accounts for over 60 percent of the total FDA budget. This has a significant impact on all activities in FDA, particularly the field. The costs of the pay increases are necessary to ensure the integrity of the Agency's work through the oversight and coordinating functions of the Other Activities program.

In order to maintain the level of activities carried out in FY 2001, FDA is requesting $40,000,000 million to cover the cost of the FY 2002 pay raise, annualization of the FY 2001 pay raise, anticipated within grade increases, and one extra day of pay. The Other Activities program portion of this increase is $3,235,000. The cost of living absorption reduces the FTE available to support the Agency's core activities.

Bovine Spongiform Encephalopathy (BSE) + $300,000 and 2 FTE

To protect consumers, it is essential that a multi-layered safeguard system be implemented and monitored to ensure that BSE regulations are followed. Many products regulated by FDA contain banned substances that could lead to BSE disease. Hence, it is important to establish and fully support a comprehensive monitoring system to identify products that may pose a health risk and ensure that they do not enter the U.S. The Office of Chief Counsel (OCC) will use the additional $300,000 and 2 FTE to do the following:

- Provide advice and counsel on legal matters, render opinions, and support rulemaking proceedings, legislative matters, policy deliberations, and domestic and international negotiations; and,

- Provide litigation support for enforcement, defensive and third-party matters.

Patient Safety/AERS + $400,000 and 3 FTE

FDA must continue to target resources that will develop and enhance surveillance of FDA regulated products to identify harm resulting from use of products; understand harm through expert analysis; and prevent harm to other patients by taking action. The requested funds will provide an increase of $400,000 and 3 FTE to the Office of Chief Counsel to:

- Provide advice and counsel on legal matters, render opinions, and support rulemaking proceedings, legislative matters, policy deliberations, and domestic and international negotiations; and,

- Provide litigation support for enforcement, defensive and third-party matters.

Human Subject Protection + $300,000 and 2 FTE

The funds requested in the FY 2002 budget will provide legal support in the Office of the Chief Counsel to provide services to facilitate the Agency's consumer protection activities via litigation work and counseling advice. In particular, the Office of Chief Counsel will use the additional $300,000 and 2 FTE to:

- Provide advice and counsel on legal matters, render opinions, and support rulemaking proceedings, legislative matters, policy deliberations, and domestic and international negotiations; and,

- Provide litigation support for enforcement, defensive and third-party matters.

Food Safety + $100,000 and 1 FTE

FDA is currently focusing its food safety efforts to expand the scope of the highly successful multi agency Food Safety Initiative beyond just microbiological contamination of foods to include chemical and physical hazards as well. The increased funding of $100,000 and 1 FTE will provide the Office of Chief Counsel additional resources to:

- Provide advice and counsel on legal matters, render opinions, and support rulemaking proceedings, legislative matters, policy deliberations, and domestic and international negotiations; and

- Provide litigation support for enforcement, defensive and third-party matters.

Imports and Inspections + $300,000 and 2 FTE

FDA uses its inspectional authority, as directed by statute, to ensure the safety of products produced and distributed by more than 100,000 domestic establishments. FDA is also responsible for ensuring the safety of almost 7 million import line entries that cross the U.S. border annually. The offices under Other Activities provide Agency-wide support to FDA's program centers on the postmarketing side. With the requested resources for OCC of $300,000 and 2 FTE will:

- Provide advice and counsel on legal matters, render opinions, and support rulemaking proceedings, legislative matters, policy deliberations, and domestic and international negotiations; and

- Provide litigation support for enforcement, defensive and third-party matters.

Management Priorities + $8,300,000 and 3 FTE

This past year, the DHHS Inspector General performed a management review of FDA's existing financial system during the annual Chief Financial Officers (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 FDA's system, some of which can only be corrected by an investment in a new financial system. In addition, the expertise needed to maintain this large and complicated system is limited to a few individuals with knowledge of COBOL programming. The FDA Financial System supports all of the Agency's financial activities providing excellent information and internal controls and is considered to be a mission critical system needed to support FDA's public health mission. The FY 2002 request is for $8,300,000 and 3 FTE to:

- Begin initial acquisition and implementation of the new financial system. Funding to complete the project will be requested in subsequent fiscal years.

- Purchase off-the-shelf fully integrated financial system which is less costly than developing in-house applications. Software upgrades are affordable and are regularly available. In addition, FDA is working to minimize other costs by taking advantage of work already performed by other DHHS agencies that are similar to FDA in size, scope, and transaction volume. FDA is coordinating with the Centers for Disease Control (CDC) in their procurement and implementation for a new financial system.

Current Law User Fees +$1,988,000

Prescription Drug User Fee Act (PDUFA) + $1,983,000

The Food and Drug Administration 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. The FY 2001 President's Budget requested $149,273,000 and 920 FTE for PDUFA in FY 2001. In FY 2002, based on the information currently available and the statutory PDUFA formulas, an increase of 20 FTE and $12,443,000 over the FY 2001 current estimate, for a total level of $161,716,000 and 1,102 FTE is expected. Included in the FY 2002 total budget request for PDUFA, is $1,983,000 for the Other Activities program.

Mammography Quality Standards Act + $5,000

The Mammography Quality Standards Act of 1992 was reauthorized in 1998 for an additional five years (P.L. 105-298). The Mammography Quality Standards Act (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. FDA requests an increase of $5,000 for Other Activities in MQSA authorized inspection user fees to cover inflation, for a total of $186,000 and 2 FTE in FY 2002. The fees collected will pay for the costs of inspections.

JUSTIFICATION OF BASE

Payroll

FDA's Other Activities program provides central program direction and administrative services for Agency programs to ensure that FDA's consumer protection efforts are effectively managed and that available resources are put to the most efficient use. This is accomplished through: Agency-wide policy development in medical affairs, scientific coordination, regulatory requirements, legislation, planning and evaluation, consumer communications and public information; management expertise and coordination in financial management, personnel, equal opportunity and Agency-wide diversity program functions, contracts and grants administration, procurement, property and space control, and communications systems.

The Office of the Commissioner (OC): Provides leadership and expertise to manage the Agency including advice and assistance on legal and science issues, equal employment opportunity and civil rights activities which impact on policy development and execution of program goals.

- Advise the Commissioner and other key Agency officials on scientific issues that have an impact on Agency policy, direction and long-range goals, and ensures coordination and communication throughout the Agency. Provides leadership in science management areas such as peer review of Agency science programs, recruitment and retention for key scientific positions, scientific resource management, and joint FDA/industry training on new technology. Advises on specific scientific issues such as dioxin in meat and milk, mercury in food, antibiotic resistance, safety of dietary supplements, safety of bioengineered foods, coordination of activities in clinical trials, human subject protection, and bioterrorism preparedness.

- Provide a full range of legal services and advice, including responses to and/or review of the Department's Office of the General Counsel controlled actions, press/talking papers, legislative requests, congressional requests, materials for congressional hearings, Federal Register documents, disposition of FOIA requests, and legal support to FDA enforcement activities, including injunctions, seizures, subpoenas, and defensive litigations.

The Office of Policy, Planning and Legislation (OPPL): Provides advice and assistance in Agency policy development and oversees Agency rulemaking. It is the focal point for overall legislative liaison activities and advises and assists Congress on Agency actions, policies and issues. The office develops program and planning strategies and conducts operations research, and economic and special studies as a basis for forecasting trends, needs and major problems. The office works to identify emerging issues and establishes forums for dialogue among FDA leaders to shape new strategies, while ensuring that internal and external stakeholders clearly understand FDA's challenges, achievements and future directions.

The Office of International and Constituent Relations (OICR): Coordinates responsibilities for women's health issues, special health issues, consumer affairs functions and international program issues that include the coordination of the international conference on harmonization and World Health Organization functions. OICR has expanded outreach into patient advocate communities, primarily in AIDS and cancer areas and has also served as a catalyst for scientific research to further Agency needs in product review and women's health.

The Office of the Senior Associate Commissioner (OSAC): Advises the Commissioner, Deputy Commissioners, Senior Associate Commissioners, and other key Agency officials on

Agency-level activities and issues that affect Agency-wide programs, projects, and strategies. Coordinates activities involving emergency or crisis situations, and resolves complex problems and issues related to Agency programs that are sensitive and controversial which impact upon Agency relations with other federal agencies and foreign governments. Oversees and directs the Agency's ombudsman, public affairs, orphan products, executive secretariat, and advisory committee functions to ensure coherence in decision making and the efficient operation of these functions internally and across Agency jurisdictions.

Office of Management and Systems: Facilitates the effective and efficient management of people, money, tangible items, and systems for FDA.

- Provides human resource and management services to approximately 9,000 headquarters and field employees across the country.

- Manages FDA's $1.3 billion budget, including Agency-wide budget formulation and execution, accounting, payment processing, financial reporting, foreign and domestic travel, employee relocation, payroll liaison and financial systems for two direct appropriations and four separate and unique user fee activities.

- Provides nationwide logistical support for real and personal property, purchasing, grants, physical security, engineering services, environmental, safety, health and long range planning for FDA's future facilities.

- Oversee building and maintaining an information technology infrastructure, and ensuring interoperability of FDA systems and support of a wide-area network.

Selected FY 2000 Accomplishments

The Office of the Commissioner:

Office of Science Coordination and Communication (OSCC)
Anti-Bioterrorism Preparedness. OSCC has been designated the FDA's focal point for anti-terrorism preparedness activities. Responsibilities include providing overall coordination of anti-terrorism preparedness and response activities within the FDA and coordination of both internal and external communication on these issues. The Agency has created an Anti-Bioterrorism Preparedness Steering Committee. Ongoing activities include:

- Coordinated with industry and outside organizations to review and resolve issues related to preparedness and response activities, such as the regulatory issues related to development and deployment of the National Pharmaceutical Stockpile, and the deployment of in vitro diagnostic devices for the detection of biologic agents in the National Laboratory Response Network;

- Developed an FDA anti-bioterrorism preparedness strategic plan; and,

- Enhanced communication between the FDA Centers through the Steering Committee.

Antimicrobial Resistance. The FDA Task Force on Antimicrobial Resistance developed an Action Plan and Recommendations that provides a list of priorities for the FDA as it moves forward in addressing the problem of antimicrobial resistance, a critical public health issue. To put these recommendations into action, the Office of the Commissioner has established an Implementation Committee whose mission is to provide overall coordination of the Centers' implementation of the action items in the plan. The Action Plan and Recommendations have been posted on the FDA Website.

Human Subject Protection. In response to problems encountered in clinical research, FDA strengthened its programs for human subject protection during FY 2000. An Office of Clinical Science position was created, elevating FDA's policy-making on human subject protection into the Office of the Commissioner and enhancing the coordination of human subject protection activities. Together with this new office, a Human Subject Protection Steering Committee was developed, bringing together senior policy-makers from across the FDA's Centers and Offices. The Office of Clinical Science has spearheaded the close coordination of FDA's human subject activities and activities with those of the new DHHS Office of Human Research Protection (OHRP), activities of FDA's sister agencies, and extra-governmental stakeholders.

Office of Chief Counsel (OCC)
OCC provided leadership and direction in the effective use of enforcement actions, such as cases involving Wyeth, American Red Cross, and Abbott, to achieve FDA compliance objectives. Provided legal review and clearance of regulations to achieve significant public health objectives, including physician labeling, juice HACCP, biotech premarket notification, structure/function claims, blood safety, xenotransplantation, and gene therapy disclosure. Coordinated with the Department of Justice the legal strategy and approach to effectively defend significant litigation challenging FDA program objectives, including Cholestin (dietary supplements), American Bioscience and Watson (generic drug approvals), and ABI (food biotech policy).

The Office of International and Constituent Relations:

Office of Women's Health (OWH)
Science Program. OWH's scientific research program addresses gaps in current knowledge, encourages new directions, and sets new standards of excellence in women's health. The program consists of four distinct components:

- Special Funding Activities - This program provides funding for regulatory projects which require the Agency's immediate attention. This includes workshops, conferences, small scientific research projects, focus group testing and publications. As an example, focus groups determine if young women were using tampons safely. The focus groups showed that young women read tampon labels, use tampons properly, but tend to overestimate the risk of Toxic Shock Syndrome.

- Women's Health Program - National Center for Toxicological Research - This pilot program was developed as a five-year research program aimed at applying the developing techniques of genomics and protenomics to address gender differences in the safety of medical products. FY 2000 projects focused on addressing gender differences in the safety of medical products and dietary supplement/drug interactions.

- Centers of Excellence in Women's Health - The National Centers of Excellence in Women's Health (CoEs) serve as demonstration models for the Nation to provide innovative, comprehensive, multidisciplinary, and integrated health care systems for women. OWH funded six contracts for research projects at these Centers to determine dietary supplement use in women and to investigate dietary supplement/drug interactions. These extramural projects at academic medical institutions are ongoing.

Mammography. The FDA/OWH sent a letter to all 10,000 certified mammography facilities inviting them to showcase the availability of our "Mammography Today" brochure and distribute a one-page abbreviated version of the brochure to inform patients about their new rights.

Health Promotion. OWH and Public Affairs Specialists provided a range of women's health educational materials to consumers at approximately 75 national conferences. In support of these efforts one million copies of our various publications were distribution to the public. A range of topics were presented including heart disease, breast and cervical cancer, osteoporosis, diabetes, arthritis, clinical trails, and depression.

The Office of Policy, Planning & Legislation:

Office of Planning
Mandated under the Government Performance and Results Act (GPRA), the FY 2002 Annual Performance Plan and Summary was redesigned so that it focuses on key strategies in language that is easily understandable to lay people. This format also allows Agency managers to use the results of complying with the GPRA. Each strategy highlighted FDA's Key Performance Goals; explained FDA's contribution; outlined its proposed actions; identified barriers to achieving the goal and the consequences of not achieving the goal, as well as an assessment of the present status of the strategy.

Coordinated Leadership activities that developed budget strategies for FY 2002. These strategies involved four, cross-agency teams that identified opportunities to work with other organizations, benefits of successfully implementing the strategy and allocation of resources to each strategy.

Office of Evaluation
Produced and provided the FY 1999 PDUFA Performance Report to Congress. The PDUFA of 1992 requires that an annual report on the Agency's performance under PDUFA be sent to Congress. The FY 1999 report showed detailed statistics on the Agency's performance against the progressively more stringent review performance goals and against a new set of goals designed to make the Agency more responsive to sponsors and to speed up the early stages of drug development.

Office of Policy
Pediatric Exclusivity. In 1997, as part of the FDAMA, Congress enacted a provision which provides six months of exclusive marketing to drug manufacturers in return for conducting needed pediatric studies. The "pediatric exclusivity provision" has been highly effective in generating pediatric studies on many drugs and in providing useful new information in product labeling. By

the end of FY 2000, FDA had issued over 150 requests to manufacturers to conduct over 300 pediatric studies. Almost 60 pediatric studies had already been conducted. As a result of the pediatric exclusivity provision, critical drugs used to treat a variety of conditions, e.g., gastroeophageal reflux disease, diabetes mellitus, pain, asthma, and hypertension, have or soon will have pediatric use information in their labeling.

The Office of Senior Associate Commissioner:

Office of Public Affairs

- Received, coordinated, and monitored processing of 25,011 FOIA requests.
- Managed FDA's denials and appeals process and issued 245 denials of FOIA requests.
- Posted approximately 1300 warning letters on the Electronic FOIA Reading Room Internet web page.
- Distributed 1,440,000 Agency consumer publications through GSA's Consumer Information Center, Pueblo CO.
- Published six issues of FDA Consumer, which won second place in the periodicals category in the Blue Pencil nationwide competition of the National Association of Government Communicators.

Office of Executive Secretariat

Plain Language at FDA. In FY 2000, FDA won two "No Gobbledygook" Plain Language Awards, bringing the total to four – more than any other Federal agency. FDA has always used plain, clear language in consumer publications. FDA continues to work to encourage the use of plain language tools and techniques in all regulations and guidance documents, reports to Congress, and budget documents.

The Office of Management and Systems:

Office of Financial Management

- Received an "unqualified opinion" from independent auditors on the FDA FY 1999 financial statements under the CFO; received, for the second year in a row, the Department's CFO Award in recognitition of the audit results.
- Awarded a contract to Arthur Andersen to assist in development of a business plan for the replacement of the current financial system to r improve and expand customer services.
- Participated in the formulation of a Financial System Workgroup, at the Department level. The efforts of the workgroup will reduce out year costs for the business case development by overseeing the contractor in analyzing the system requirements across the OPDIVS and documenting several viable business solutions.

Office of Information Resources Management

Computer Security (Critical Infrastructure Protection (CIP)). FDA's increasing reliance on computer-generated information meant greater focus on efforts to ensure this information and its supporting technological infrastructure remains secure. To that end, FDA accomplished the following in FY 2000:

- Completed physical and system security audits to evaluate access controls to ensure FDA's information is not compromised by internal or external threats; audit revealed that controls are adequate; periodic review of controls are being implemented; and,

- Provided leadership and focus to complete the Agency's Y2K remediation program for facilities, biomedical equipment, telecommunications, and outreach activities; and established the Agency's Y2K Day One program for final verification and validation of Y2K compliance. Also, coordinated a successful FDA-wide Y2K transition.

FDA Internet/Intranet Services and Support. The FDA public website provides critical health information to the public and offers information of interest to health professionals, patients, consumers, industry, State, and local officials and many others. The Internet web infrastructure has supported FDA by providing rich functionality, responding to changing needs, and by providing high performance and reliability. In FY 2000, FDA significantly expanded the FDA Internet website infrastructure and services provided to FDA developers and the public.

- Received numerous awards for the FDA website from Popular Science magazine, the Dow Jones Business Directory, and Tufts University's Nutrition Navigator. The Website links to 8,000 health, consumer, medical, and educational websites, and the site received an average of 1,321,236 hits per day. This website provides information such as status of FDA proposed and final regulations, letters to the public, import alerts, stakeholder meetings, and guidance for good manufacturing and agricultural practices.

Office of Facilities, Acquisitions and Central Services

- Hosted a Women-Owned and Small Business (WOSB) Seminar and Expo for WOSB vendors to display materials and discuss their capabilities for future FDA requirements. The Expo was designed to increase opportunities for women-owned small businesses.

- Provided engineering and contractual management and support for: the following major FDA facilities projects:

- **Headquarters Consolidation in Prince George's County, Maryland**--The General Services Administration (GSA) is constructing a 410,000 gross square foot building to consolidate the Center for Food Safety and Applied Nutrition (CFSAN) in College Park, Prince George's County, Maryland. This consolidation project has been authorized through the FDA Revitalization Act of 1990. The College Park building is scheduled to be complete in October 2001. CFSAN will move into the new building between October 2001 to February 2002. Based on the value of work in place, the construction is 75 percent complete and remains on schedule for completion by October 1, 2001.

- **Headquarters Consolidation in Montgomery County Maryland**. The GSA has developed a master plan for a 2.2 million gross square foot development to consolidate the

Center for Drug Evaluation and Research (CDER), the Center for Devices and Radiological Health (CDRH), the Center for Biologics and Research (CBER), headquarters components of the Office of Regulatory Affairs and the Office of the Commissioner. This consolidation project has been authorized through the FDA Revitalization Act of 1990. Groundbreaking for the first phase of the project occurred in October 2000 and will result in construction of an 114,000 gross square foot laboratory building for CDER. Design is underway for the second phase of the project that includes all the office space needed to fully consolidate CDER.

- **Field Laboratory Consolidation in Irvine California.** The new Los Angeles field laboratory project in Irvine, California is designed as a 120,000 gross square foot facility that will be occupied by three Los Angeles District components. Not only will this facility provide a safer location and improved working environment, but by concentrating the scientific talent and resources to one location it will permit better management of the analytical workload and will provide significant improvement in operational efficiency. FDA purchased a 10-acre land parcel located in Irvine, California. Design of the facility is complete. A groundbreaking ceremony was held on March 6, 2001.

Office of Human Resources and Management Services

- Coordinated the first Agency-wide workforce planning program, designed to engage FDA leadership in a systematic process for anticipating future workforce requirements and planning ways to fill the gaps between existing resources and future requirements.

- Initiated new Internet processes of accepting comments electronically and allowing the public to electronically register for public meetings, which helped the public keep up with and respond to FDA's regulatory programs. Many enhancements to FDA's Dockets Website improved access to FDA data and expanded the amount of material available on the Internet. Starting in January 2000, FDA began posting Advisory Committee Briefing packages on the Web, as required by a stipulation in a court case. During FY 2000, customers downloaded more than three million files directly from the Dockets web site.

- Facilitated the Hispanic Recruitment Retention and Advancement (HRRA) Work Group which included the production of an action plan and report for the Commissioner. As a result, the Commissioner established a Senior Advisory Board on Hispanic issues charged with making decisions on the implementation of action plan recommendations.

Rent Activities

	FY 2000 Actual	FY 2001 Appropriation	FY 2001 Current Estimate 1/	FY 2002 Estimate	FY 2002 +/- FY 2001 Current Estimate
Total Program Level Rent Activities:	**$125,792,000**	**$130,809,000**	**$130,534,000**	**$136,914,000**	**+ $6,380,000**
Budget Authority	*120,149,000*	*124,949,000*	*124,674,000*	*130,674,000*	*+ 6,000,000*
User Fee--PDUFA	*5,643,000*	*5,860,000*	*5,860,000*	*6,240,000*	*+ 380,000*
Total Program Level GSA Rent:	**$93,340,000**	**$104,954,000**	**$104,736,000**	**$105,116,000**	**+ $380,000**
Budget Authority	*87,697,000*	*99,094,000*	*98,876,000*	*98,876,000*	*0*
User Fee--PDUFA	*5,643,000*	*5,860,000*	*5,860,000*	*6,240,000*	*+ $380,000*
Other Rent & Rent-Related Activities:	**$32,452,000**	**$25,855,000**	**$25,798,000**	**$31,798,000**	**+$6,000,000**
Budget Authority	*32,452,000*	*25,855,000*	*25,798,000*	*25,798,000*	*0*
CDER Lab move	*0*	*0*	*0*	*6,000,000*	*+ 6,000,000*

[1/] Reflects enacted levels adjusted for the 0.22 percent rescission, accounting for $218,000 in the GSA Rent program and $57,000 in the Other Rent and Rent-Related program.

Historical Funding and FTE Levels
GSA Rent

Fiscal Year	Program Level	Budget Authority	User Fee	Program Level FTE
1998 Actuals	$46,294,000	$46,294,000	$0	0
1999 Actuals	$88,294,000	$82,866,000	$5,428,000	0
2000 Actuals	$93,340,000	$87,697,000	$5,643,000	0
2001 Current Estimate	$104,736,000	$98,876,000	$5,860,000	0
2002 Estimate	$105,116,000	$98,876,000	$6,240,000	0

Historical Funding and FTE Levels
Other Rent and Rent-Related Activities

Fiscal Year	Program Level	Budget Authority	User Fee	Program Level FTE
1998 Actuals	$25,647,000	$25,647,000	$0	0
1999 Actuals	$25,854,000	$25,854,000	$0	0
2000 Actuals	$32,452,000	$32,452,000	$0	0
2001 Current Estimate	$25,798,000	$25,798,000	$0	0
2002 Estimate	$31,798,000	$31,798,000	$0	0

MISSION

Rent is part of the Salaries and Expenses Appropriation and includes Rental Payments to GSA and Other Rent and Rent Related activities. GSA Rental Payments includes charges for all of FDA's GSA space, both government-owned and GSA-leased. The Other Rent and Rent-Related account includes rent and rent-related charges that are not part of the GSA account, such as costs associated with moving staff and equipment during the consolidation of FDA laboratory facilities.

REQUESTED INCREASES

Rental Payments to GSA +$380,000
Prescription Drug User Fees +$380,000

- For FY 2002, FDA is requesting an additional $380,000. This will bring the total to $6,240,000 in user fees to defray expected increases in costs for GSA space used in support of the user fee portion of the process for the review of human drug applications.

Other Rent and Rent Related Activities +$6,000,000

Construction of the Center for Drug Evaluation and Research (CDER) laboratory portion of the FDA Consolidated Headquarters facility at White Oak is scheduled to be completed in FY 2002. 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. FDA proposes to occupy its White Oak facility over a period of several years, and, thus, will require additional future year funding to support the phased-in relocation strategy.

- FDA is requesting an increase of $6,000,000 for facility-related costs not covered by GSA, bringing the total to $31,798,000. FDA requests funds for one-time costs to equip and occupy the CDER laboratory portion of the facility located at White Oak. The FY 2002 funds will support telecommunications equipment and necessary connections, and moving costs. The funds will relocate the CDER laboratory functions to a new state-of-the-art facility scheduled to open in 2002, and begin the consolidation of most FDA Headquarters activities in one location, resulting in more effective and efficient operations.

JUSTIFICATION OF BASE

Rental Payments to GSA

- FDA occupies over 4.1 million net square feet of GSA space, including parking, which is under the Agency's Salaries and Expenses appropriation. By FY 2002, FDA will occupy over 4.3 million net square feet of GSA space, including parking. As a result of negotiations between FDA and GSA to reduce rent at certain locations, increased resources are not required in FY 2001 to fund the increase in space planned.

- The GSA rent charges are billed directly to the Agency and indirectly to FDA through other agencies, and include the charges for all of FDA's GSA space, both government owned and GSA leased. About 47 percent of the GSA rent charges are for

government-owned or GSA-leased space in the Washington, D.C. area. The largest individual rent charges are for the Parklawn Building complex, Module II in Beltsville, CFSAN's new College Park location, and the Regional offices and laboratory in Jamaica, NY. The balance of the charges are for the Agency's field Regional Offices, District Office/Laboratory complexes, and over 130 leased offices which serve as resident posts for strategically placed field investigators.

Other Rent and Rent-Related Activities

- **The Commercial Rent and Related Services** account consists of recurring activities that FDA pays directly to non-Federal sources under the delegation of direct lease and service authority. (Note: This also includes recurring services for FDA-owned facilities.) Services include rental of space, and all recurring services for building operations; i.e., utilities; and services such as janitorial, guard, grounds maintenance; and operation and maintenance of heating, ventilation, and air-conditioning (HVAC) systems.

- The GSA Rent-Related Services include recurring reimbursable services provided by GSA that are over and above the standard eleven hours that GSA covers in its rent charges. Services include security systems, guard services, and HVAC beyond the standard level funded by GSA.

- **The GSA Building Delegation Services** account provides recurring services and one-time repairs to operate and maintain buildings delegated to FDA by GSA for management of day-to-day operations. Services include utilities and all recurring services for building operation, such as janitorial, guard, grounds maintenance, and operation and maintenance of HVAC systems.

- FDA will incur costs associated with CFSAN's move to a newly constructed facility in College Park, Maryland.

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Buildings and Facilities

	FY 2000 Actual	FY 2001 Appropriation	FY 2001 Current Estimate 1/	FY 2002 Estimate	FY 2002 +/- FY 2001 Current Estimate
Total Budget Authority	**$10,553,000**	**$31,350,000**	**$31,281,000**	**$34,281,000**	**+ $3,000,000**
LA Laboratory	*$0*	*$20,000,000*	*$20,000,000*	*$23,000,000*	*+ $3,000,000*

1/ Reflects enacted levels adjusted for the 0.22 percent rescission, accounting for $69,000 in the Building and Facilities program.

Historical Funding and FTE Levels

Fiscal Year	Program Level	Budget Authority	User Fee	Program Level FTE
1998 Actuals	$28,094,000	$28,094,000	$0	0
1999 Actuals	$16,178,000	$16,178,000	$0	0
2000 Actuals	$10,553,000	$10,553,000	$0	0
2001 Current Estimate	$31,281,000	$31,281,000	$0	0
2002 Estimate	$34,281,000	$34,281,000	$0	0

MISSION

FDA Buildings and Facilities (B&F) appropriation provides funding for needed repairs and improvements to existing owned or leased facilities nationwide. In addition, as specifically provided , the B&F appropriation funds construction of new FDA special-purpose laboratory facilities.

REQUESTED INCREASES

Complete Construction of the New Los Angeles Field Laboratory + $3,000,000

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 Los Angeles laboratory is an outmoded facility in a high crime area. The Los Angeles District is responsible for entry decisions on nearly 1.6 million import line entries, almost 25 percent of the Agency total. In FY 2000 alone, the Los Angeles laboratory analyzed 24.2 percent of the imported foods 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.

- In FY 2002, FDA requests an additional $3,000,000 for a total of $23,000,000, to continue construction of the Los Angeles replacement laboratory and office space project.

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. Total construction costs are currently estimated at $43,000,000. Updates to construction costs may be revised as necessary to reflect cost increases in equipment, construction delays, and other possible factors.

JUSTIFICATION OF BASE

Construction of FDA Los Angeles, California, Replacement Laboratory (Irvine)
In FY 2001, the Agency received $20,000,000 for the first phase of construction, for the core and shell of the project. The $20,000,000 recurs in FY 2002 to fund the majority of the $23,000,000 required to complete the project.

- The replacement laboratory is projected as a 75,000 gross square feet (gsf)/45,000 net square feet (nsf) state-of-the-art laboratory facility housing 75 scientific staff. The office portion of the new facility is projected at 44,200 gsf/28,000 nsf to house a staff of 120.

- On May 22, 2000, the solicitation for proposals for the construction were made available. Proposals were received on August 24, 2000, and procurement was completed. FDA awarded a contract to Hensel Phelps Construction Company on February 27, 2001. A ground-breaking ceremony was held on March 6, 2001.

Repairs and Improvements
Base resources of $8,281,000 covers the costs of repairs and improvements to FDA facilities, owned and leased. Included are Washington area headquarters components which are now located in some 40 buildings in eighteen separate locations; plus five regional offices, 19 field District complexes including 19 administrative and 13 specialized laboratory facilities nationwide; more than 120 field resident posts, eight field criminal investigation offices, two distinct program laboratory complexes outside the Washington Metro area; and the NCTR complex in Jefferson, Arkansas. With all of these Field facilities combined, FDA maintains offices and staff in 49 of the 50 States, and in the District of Columbia and Puerto Rico.

While industry components that FDA regulates spend between nine percent and 12 percent of the value of their physical plants on maintenance, alteration, and repair, FDA has been spending about two percent of the value of its physical plant (laboratories and laboratory support facilities only) for the same purpose.

The following table lists the planned repairs and improvements projects for the FY 2002 request of $8,281,000:

1. ORA, Nationwide -- Miscellaneous Repair and Improvement Projects	$1,000,000
2. ORA, San Juan, PR -- Office Construction	975,000
3. ORA, Seattle, WA -- Casework	300,000
4. ORA, Atlanta, GA – Elevator expansion	100,000
5. CFSAN, College Park, MD -- Anticipated changes	750,000
6. CFSAN, College Park, MD -- Mass Spec laboratory/office	550,000
7. CDER, White Oak, MD – Anticipated program changes	100,000

8. CBER, Bethesda, MD – TB vaccine project 750,000
9. CVM, Laurel, MD -- Epoxy floors in animal holding area of MOD II 281,000
10. NCTR, Jefferson, AR -- Renovations to various buildings 2,975,000
11. NCTR, Jefferson, AR -- Replace (partial) water lines 300,000
12. NCTR, Jefferson, AR -- Fire alarm for buildings 62 and 15 300,000
TOTAL $8,281,000

Continued Construction of Arkansas Regional Laboratory (ARL)

- A building dedication ceremony for Phases I & II, the laboratory portion, was held on February 17, 2000; ORA began occupying the laboratory facility in June 2000.

Building 50 Renovation and Common Area status:

- Phase III provides the renovation of the existing Building 50 in its entirety and completes the common ORA/NCTR administrative and support area.

- The FY 1999 appropriation included $3,000,000 to begin construction of a portion of Phase III. On January 26, 1999, the contractor was given notice to proceed on the first portion of Phase III.

- The FY 2000 appropriation included another $3,000,000 to continue the construction of a portion of Phase III.

- The FY 2001 appropriation included $3,000,000 to continue work on Phase III. The $3,000,000 will be utilized to fund site work between the lab building and Building 50, and restore the NCTR/ORA common area.

- The $3,000,000 in FY 2002 will be used to continue purchase of Building 50 major mechanical electrical equipment and start the fit out of the building interior.

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BUDGET AUTHORITY BY OBJECT (EXHIBIT H)–PROGRAM LEVEL

BUDGET AUTHORITY BY OBJECT (EXHIBIT H)–USER FEES

SALARIES AND EXPENSES BY OBJECT (EXHIBIT)

EXTRAMURAL RESEARCH FUNDING FY 2000

STATE	RECIPIENT	PROJECT TITLE	AMOUNT
AL	Auburn Univ.	Detection of Prohibited Proteins in Ruminant Feed	$160,000
CA	California Dpt. of Food & Ag.	Effect of Previously S. Enteritidis Contaminated Environment	$136,800
CA	California Pacific Medical Center	Gabapentin Therapy in Amyotrophic Lateral Sclerosis	$118,741
CA	Harbor-UCLA Research & Ed. Inst.	4-Aminopyridine Safety & Efficacy in Spinal Cord Injuries	$185,052
CA	Univ. of California	Consumer Handling & Washing of Fresh Fruits & Vegetables	$45,129
CA	Univ. of California	DCA Treatment of Congenital Lactic Academia	$142,847
CA	Univ. of Southern California	MART Response in Vaccinated Melanoma Patients	$215,696
CO	Colorado State Univ.	Antimicrobial Use and Resistance in Enteric Bacteria	$199,382
DC	National Food Processors Assoc.	Surrogates for Evaluating Efficacy of Thermal Processes	$122,175
DE	Delaware Department of Health	Innovative Inspection Methodologies	$50,000
FL	Florida Department of Health	Development of Methods for Virus Extraction from Food	$198,962
FL	Florida Dept. of Bus. & Prof. Reg.	Science-Based Educational Program	$48,510
FL	Univ. of Florida	Dichloroacetate Treatment of Congenital Lactic Acidosis	$182,488
GA	Univ. of Georgia Research Found.	Does Antibiotic Usage Create Drug-Resistant Campylobactor	$195,078
GA	Univ. of Georgia Research Found.	Dose Response Model for Food Borne Listeria	$338,919
GA	Univ. of Georgia Research Found.	Foodborne Protozoa: Inoculation & Inactivation Methods	$105,173
GA	Univ. of Georgia Research Found.	Non Thermal Method of Enhance Safety of Fresh Produce	$27,657
GA	Univ. of Georgia Research Found.	Non Thermal Method of Enhance Safety of Fresh Produce	$132,594
IA	Cerro Gordo County Dept. of Health	North Central Iowa Innovative Food Safety Program	$47,243
IA	Univ. of Iowa	OK-432 Sclerotherapy - A Multicenter Trial	$264,558
IL	Illinois Institute Technology	National Center for Food Safety & Technology	$3,207,093
IL	Univ. of Chicago	GNRH Agonist Therapy of Hypogonadotropism	$126,038
IN	Purdue Research Foundation	Effect of Inoculation on Efficacy of Chlorine Dioxide Gas	$104,669
KS	Kansas Department of Agriculture	Bilingual Education Materials to Protect Public Health	$11,015
MA	Aphios Corporation	Virus Inactivation Device for Medical Devices	$100,000
MA	Boston Univ.	Arginine Butyrate & Ganciclovir in Epstein Barr Virus	$163,000
MA	Children's Hospital	Effect Inhaled Nitric Oxide Pediatric Sickle Pain Crisis	$141,247
MA	Curis, Inc.	Chondrocyte-Alginate Gel Suspension for Pediatric VUR	$102,400
MA	Lincoln Technologies	Data Mining for Safety Signals in Clinical Data	$99,783
MA	New England Medical Center	Salmonelia Virulence & Antibiotic Resistance in Cattle/Feed	$190,219
MA	The Children's Hospital, Boston	Use of Oral Clotrimazole in Sickle Cell Disease	$253,623
MA	Trustees of Boston Univ.	Phase II Trail of Butyrate for Refractory Sickle Cell Ulcers	$308,772
MA	Tufts Univ.	Arthritis After Lyme Vaccine	$30,000
MA	Tufts Univ.	Dose Response Model for Human Crytosporidiosis	$407,763
MD	Johns Hopkins Univ.	Eff. of Abendazole Therapy in Epilepsy due to Cysticercosis	$131,041
MD	Johns Hopkins Univ.	Enbrel in Wegener's Granulomatosis Phase II	$253,912
MD	Johns Hopkins Univ.	Intraventricular Hemorrhage Thrombolysis Trial	$248,697
MD	Kennedy Krieger Research Center	DHA Therapy of Peroxisomal Disorders	$306,722
MD	Sigma-Tau Pharmaceuticals, Inc.	Cysteamine Hydrochloride Eye Drops	$152,746
MD	Univ. of Maryland	Dose Response to Vibrio Species	$330,828

STATE	RECIPIENT	PROJECT TITLE	AMOUNT
MD	Univ. of Maryland	Joint Inst. for Food Safety & Applied Nutrition	$3,348,840
MI	TSRL, Inc.	New Device for Drug Dissolution and Absorption Evaluation	$98,849
MI	Univ. of Michigan	Prevention of TPN-Cholestasis with Cholecystokinin	$215,340
MI	Univ. of Michigan	Therapy of Wilson's Disease with Tetrathiomolybdate	$276,912
MI	William Beaumount Hospital	Survey of Antimicrobial Resistant Enterococci in Animals	$120,849
MN	Mayo Clinic	Vapreotide to Prevent Complications of Pancreatic Resection	$141,086
MN	Olmsted County Public Health	Risk Factor Eval. & Develop. of Active Managerial Control	$40,488
MO	Jefferson County Health Center	Study of Baseline Microbiological Contaminate Levels	$50,000
MO	MetaPhore Pharmaceuticals, Inc.	Inactivation of Catecholamines in Septic Shock	$100,000
MO	Washington Univ.	Efficacy & Toxicity of Infusional Arsenic Trioxide in APML	$155,489
NC	Duke Univ.	Intrathecal Busulfan Therapy of Neoplastic Meningitis	$77,000
NC	North Carolina State Univ.	Antimicrobial Resistance of Salmonella Isolated from Swine	$118,535
NC	Univ. of North Carolina	Accutane, Cancer Chemoprevention and Dystrophic EB	$144,846
NC	Univ. of North Carolina	Alendronate Treatment for Osteoporosis in Cystic Fibrosis	$142,526
NC	Univ. of North Carolina	Dev. of Viral Extraction Processing & Detection Methods	$170,388
NJ	Univ. of Medicine & Dentistry	Study of Aminopterin for Patients with Acute Lym. Leukemia	$214,399
NJ	Univ. of Medicine & Dentistry	Aminopterin in Patients with Refractory Acute Leukemia	$135,025
NM	New Mexico State Univ.	WERC Design	$100,000
NY	Columbia Univ.	Therapy of Osteoporosis in Men with Parathyroid Hormone	$264,642
NY	Esensors, Inc.	Patient Dose Tracking System for Fluoroscopic Procedures	$74,437
NY	Mount Sinai Medical Center	Liquid Fluoxetine vs. Placebo in Child Autism	$201,752
NY	Mt. Sinai School of Medicine	IL-2 in Common Variable Immunodeficiency	$169,500
NY	Our Lady of Mercy Medical Center	Arsenic Trioxide in Leukemia	$331,925
NY	Research Foundation at SUNY	Cyclophosphamide to Mycophenolate Mofetil	$301,999
NY	Sloan-Kettering Inst. for Cancer	Phase II Trial of Bryostatin-1 & Paclitaxel	$325,699
NY	Sloan-Kettering Inst. for Cancer	Rebeccamycin Anal.: A Phase II Study in Neuroblastoma	$176,994
NY	State Univ. of New York	Collagenase in the Treatment of Dupuytren's Disease	$70,366
NY	SUNY	Vasoctive Intestinal Peptide in the Acute Respiratory Distress	$118,050
NY	Univ. of Rochester	Riluzole Dosing in Huntington's Disease	$345,915
NY	Univ. of Rochester Med. Cntr.	Mexiletine Treatment of Myotonic Dystrophy	$295,565
OH	Case Western Reserve Univ.	Electrical Activation of Diaphragm for Ventilatory Assist	$110,522
OH	Case Western Reserve Univ.	Implantable FNS System for Standing Transfers	$281,606
OH	Children's Hospital Medical Center	Anti-resorptive Bone Ther. for Osteopenia In Gaucher Disease	$248,951
OH	Children's Hospital Medical Center	Multisite Trial of Pergolide in Children with Tourette's	$236,757
OH	Children's Hospital Medical Center	Tauroursodeoxycholic Acid Prophylaxis for TPN	$144,816
OH	Univ. of Cincinnati	Cultured Skin Substitutes for Closure of Burn Wounds	$296,959
PA	Discovery Labs	KL-4 Surfactant-Meconium Aspiration Syndrome	$194,390
SC	Interstate Shellfish Sanitation Conf.	Shellfish Safety Assistance Project	$320,005
SC	Medical Univ. of South Carolina	Phase II Study of Alendronate in Juvenile Osteoporosis	$150,380
TN	Tennessee State Univ.	Home Refrigeration Knowledge and Practices of Consumers	$163,632
TN	Univ. of Tennessee	Evaluation and use of BAM	$162,643

STATE	RECIPIENT	PROJECT TITLE	AMOUNT
TN	Vanderbilt Univ. Medical Center	Growth Hormone in Renal Failure	$187,732
TX	Lynntech, Inc.	Elimination of Pathogens from Fresh Produce	$100,000
TX	Retina Foundation	DHA Supplementation & X-linked Retinitis Pigmentosa	$179,060
TX	Univ. of Texas Anderson Cancer	Development of ATRAGEN (Liposomal Tretinoin)	$279,317
TX	Univ. of Texas Anderson Cancer	HHT, IFN-A & Ara-C in Early Chronic Myelogenous Leuk.	$240,577
TX	Univ. of Texas Anderson Cancer	Phase II Study of L-NDDP for Malignant Pleural Meso.	$259,694
TX	Univ. of Texas Anderson Cancer	Subcutaneous Homoharringtonine in Chronic Myelogenous Leuk.	$189,275
TX	Univ. of Texas	Relapsed Acute Promyelocytic Leukemia Patients	$233,878
TX	Univ. of Texas Medical Branch	Tin Mesoporphyrin and Heme Therapy in Acute Porphyria	$300,000
VA	Lighthouse Instruments LLC	Validation of a Rapid and Nondestructive Gas Analyzer	$97,931
WA	Children's Hospital & Reg. Med.	Ketorolac in Surgical Infants: Pharmaokinetics/analgesia	$126,590
WA	Children's Hospital & Reg. Med.	TOBI in Young Children with Cystic Fibrosis	$274,000
WA	NeoRx Corporation	Ho-166-COTMP for Treatment of Multiple Myeloma	$205,009
WA	Wash. State Univ.	Livestock Feeds as a Means of Dissemination of Antimicrobial	$188,976
WA	Washington State Univ.	On Farm Risk Factors for Zoonotic Enteropathogens	$165,050
WI	Univ. of Wisconsin	Natural Variation in Escherichia Coli	$90,566
		Total	$23,342,304

FY 2001 SIGNIFICANT ITEMS AND REPORTS FROM HOUSE, SENATE, AND CONFERENCE REPORTS
APPROPRIATIONS SUBCOMMITTEES
FY 2001 BUDGET

House Report No. 106-619

Item

Competitive Exclusion Products -- "The Committee finds that competitive exclusion products offer an innovative and valuable approach to reducing salmonella and other harmful bacteria in poultry and livestock. The Committee is concerned, however, that only one competitive exclusion product has been approved to date despite public statements by FDA, USDA, and the President's Food Safety Council supporting this emerging technology. In view of significant public health benefits of competitive exclusion products, the FDA should review new animal drug applications for these products on an expedited basis."

Action to be taken

FDA announced on March 5, 2001, the availability of a guidance for industry entitled "Expedited Review for New Animal Drug Applications for Human Pathogen Reduction Claims." The guidance provides advice to industry about the process that the Center for Veterinary Medicine (CVM) plans to use to grant Expedited Review Status (ERS) for applications for new animal drugs intended to reduce human pathogens in food-producing animals.

FDA believes it is in the interest of public health to grant ERS to applications for new animal drugs that may decrease the incidence of human illness through their action against human pathogens in animals and that meet the criteria in this guidance.

Specifically, the guidance provides procedures for requesting and criteria for granting ERS to new animal drug applications submitted to the Agency for approval of new animal drugs for which the label would bear human pathogen reduction claims. Under CVM's expedited review program, such products that potentially offer important advances in human pathogen reduction in food-animals should receive expedited review commencing at the Investigational New Animal Drug stage. ERS does not affect the approval standard; applications are expected to meet the same standards for data quality and evaluation that apply for other new animal drug approvals.

Item

Contact Dermatitis – The Committee is aware that contact dermatitis is the most common occupational illness in the United States costing the U.S. economy over $1 billion annually. The American Academy of Dermatology and the American Contact Dermatitis Society estimate that nearly 3,000 chemicals and other materials can induce allergic contact dermatitis and over 50,000 chemicals are capable of producing skin irritation. The Committee grows increasingly concerned that U.S. physicians lag behind their counterparts in other countries in their ability to effectively diagnose, test and train future physicians to care for this epidemic. Only 24 allergens have been

approved by FDA for use in patch test kits, the only available test for this skin disease. International physicians have over 400 allergens available for testing. The Committee directs FDA to return regulatory authority for patch test kits and their allergens to Center for Devices and Radiological health, and further directs the Center to reinstate those allergens that were available to United States physicians prior to 1986, and expedite approval of all other allergens currently used in Europe and Canada, but which have not been approved for use in the United States.

Action to be taken

FDA is encouraged by the interest the Committee has expressed on the issue of contact dermatitis and appreciates the Committee's support of FDA in its efforts to provide safe and effective agents to help ensure the safety of the consumer. With regard to expediting approval of all allergens currently used in Europe and Canada, but which have yet to gain approval in the United States, the Agency will rapidly review contact dermatitis allergen patch test kit applications when they are submitted, and approve safe and effective products. However, these products cannot be approved without an application being submitted by a sponsor. The ability to diagnose occupational illness caused by allergic contact dermatitis through the use of allergen patch test kits is a goal that FDA unequivocally supports. Presently, there are only two licensed manufacturers of patch test kits. Of the two, only one manufacturer currently produces the patch test kits. There are no pending allergen patch test kit applications pending in the Agency at this time.

We believe there are several factors contributing to this situation. Overall, the number of physicians specializing in dermatology is declining nationwide. Add to this fact that fewer medical schools teach the discipline and technique required to expertly use allergen patch test kits.

Reinstating those allergens that were available in the U.S. prior to 1986 presents a public health risk. Allergen test kit products available in the U.S. prior to 1986 were imported from Europe and were unapproved. Those products were not standardized, and lacked sufficient data to support their safety and efficacy.

The Agency has examined the feasibility of transferring regulatory authority for patch test kits and their allergens from the Center for Biologics Evaluation and Research (CBER) to the Center for Devices and Radiological Health (CDRH), and has major concerns. CDRH did not previously have the regulatory authority for allergen patch test kits. In fact, these products have always been regulated by CBER, and the application review expertise for those products lies in CBER. The Public Health Service Act defines biological product to include allergenic products. The law governing the regulation of the test kits is independent of the program area regulating the product. If authority were transferred to CDRH, CDRH would use the same regulatory authority and scientific review process that are currently used in CBER, but the review staff and expertise would have to be developed in CDRH. Thus, any reviews in the near term that would be needed for new applications would take considerably longer. Further, the CBER staff that review allergen patch test kit applications also review other biological products. Duplication of resources in CBER and CDRH would be required to ensure adequate review of these products.

Item

Dietary Supplements - Health Claims -- "The Committee directs the Food and Drug Administration to report on the implementation of the decision in the U.S. Court of Appeals for the D.C. Circuit in Pearson v. Shalala regarding dietary supplement health claims. This report is to include the specific steps the Agency plans to follow to carry out the decision regarding dietary supplements, as well as the Agency's basis for treating dietary supplements differently from conventional foods."

Action to be taken

The Agency has prepared a report to respond to the Committee's direction. The report is undergoing final clearance within the Administration, and we expect it to be transmitted to the Committee within the next month.

Item

The Committee instructs the Food and Drug Administration to report to the Committee within 6 months of enactment of the bill, a summary of the total dollar amount spent in fiscal year 2000 in assessing the safety of dietary supplements, and in meeting the legal statutory burden under the Dietary Supplement Health and Education Act of 1994 for demonstrating safety problems with dietary supplements.

Action to be taken

The Agency has prepared a report to respond to the Committee's direction. The report is undergoing final clearance within the Administration and we expect it to be transmitted to the Committee within the next month.

Item

Dietary supplement - Ten Year Plan -- "The Committee instructs the FDA to report to the Committee, within 6 months of the enactment of the bill, on the dollar cost to implement the Dietary Supplement Strategy 10 Year Plan."

Action to be taken

The Agency has prepared a report to respond to the Committee's direction. The report is undergoing final clearance within the Administration and we expect it to be transmitted to the Committee within the next month.

Item

Generic Drugs -- "In recent years Congress has provided increased appropriations for the Office of Generic Drugs to hire more reviewers to reduce the backlog of generic applications and to accelerate generic drug approval. Despite such increases, current approval times for generic

drugs are three times the statutory requirements. In an effort to continue to reduce approval times, the Committee directs that an increase of $1,500,000 (from within funds provided) shall be used for the upgrade of information technology systems that allow for the electronic submission of generic drug applications."

Action to be taken

As a result of a congressionally approved reprogramming of tobacco funds, FDA received $1,500,000 in FY 2000 to upgrade information technology systems in the Office of Generic Drugs (OGD) to improve the electronic submission of generic drug applications. The money was used to upgrade reviewers' computers, to obtain software programs with which reviews might be done more efficiently, and to purchase specialized equipment to allow review of applications submitted electronically. In addition, a portion of the funding is being applied to contracts related to information technology endeavors. One such endeavor is the upgrade to the inactive ingredient database. This database is critical to the generic industry for use in the development of generic drug products and the Office's review of these products.

Item

Genetically Modified Foods -- "The Committee expects the Food and Drug Administration to develop a unified effort to respond to consumer safety and environmental concerns while providing sufficient information that would allow consumers to make informed choices about the production and consumption of bioengineered foods. Any regulatory decision should be based on sound, verifiable science. The Committee also expects FDA to coordinate its activities with those of the Department of Agriculture to provide a unified approach across agency jurisdictions."

Action to be taken

As part of a government-wide initiative to strengthen science-based regulation and improve public access to information about bioengineered foods, FDA has proposed a regulation to require developers of bioengineered foods to notify the Agency 120 days prior to marketing a new bioengineered food. As part of that proposal, FDA would make readily available to the public additional information about bioengineered foods about which the Agency had been notified. In response to consumer requests for more information on the labeling of bioengineered foods, the Agency also announced guidance to assist manufacturers who may wish to voluntarily label foods to indicate whether they have or have not been developed using bioengineering. FDA will continue to work with the Department of Agriculture as appropriate to provide a unified approach across agency jurisdictions to respond to consumer safety and environmental concerns.

Item

Medical Devices -- " The Committee notes that advances in research and development in the medical device industry are likely to increase the number of new technologies submitted for review by the Center for Devices and Radiological Health (CDRH) and the Center for Biologics, Evaluation and Research (CBER). Therefore, the Committee requests the FDA to dedicate a level of funds in the fiscal year 2002 budget request to meet statutory review times for medical

devices. Further, the Committee urges the Center to continue its work to expand the list of eligible devices so as to improve the success of the third-party review program for medical devices, and to actively utilize its authority to contract with outside technical expertise when such expertise is needed to assist in the prompt and efficient review of breakthrough technologies."

Action to be taken

Device technologies are developing rapidly and are becoming more complex. Additional resources of $13 million would be used to give our reviewers the capability to do high quality, interactive, and timely reviews required by FDAMA, and allow us to keep the public well informed about medical product safety associated with new technology and products reviewed by FDA. The funds would be used as follows:

$3 million for research and guidance development on emerging technologies;
$5 million for IT support and reviewer training; and
$5 million for risk communication.

As the number of clinical trials and the complexity of the research conducted to support research and marketing applications escalated in the last decade, FDA's resources for its Human Subjects Protection program have remained static. Based on the recent Inspector General report, FDA currently inspects approximately 3.5 percent of the clinical investigators that are conducting studies in a given year. The FY 2002 budget includes an increase request of $1.5 million for Human Subjects Protection. The $1.5 million for Human Subjects Protection will allow FDA to make sufficient headway towards providing a comprehensive patient protection program for device-related clinical trials.

FDA is working with the medical device industry to increase the use of third parties to review premarket applications for low to moderate-risk devices. FDA has accredited twelve third parties, seven of which have reviewed three or more 510(k)s. The program now has 674 eligible devices. This represents a 300 percent increase in the number of eligible devices, and includes all Class I and Class II devices regulated by the Agency that meet the statutory criteria for review by Accredited Persons. In FY 2000, FDA received 47 510(k)s with a third-party review compared to 32 510(k)s received in FY 1999. This increase represents only 3-to-4 percent of 510(k)s that were eligible for review. FDA anticipates that the expansion will generate wider use of the third party review program in FY 2001.

FDA used its authority where feasible to contract with outside technical expertise when needed. For example, in FY 2000, FDA hired 70 Special Government Employees to participate on the medical devices advisory committees. FDA has also contracted with the Oak Ridge Institute for Science and Education fellowship program to recruit experts to participate in reviews. FDA continues to contract with other experts when the need arises.

Item

Mutual Recognition Activities/International Harmonization - The Committee is concerned about the worldwide proliferation of regulatory regimes for medical devices and pharmaceutical products. In order to ensure that patients around the world receive the latest technology

promptly, it is critical that the regulatory systems of the various nations of the world coordinate activities in such as a way to ensure the safety and efficacy of products, while limiting the burden of regulatory barriers to innovation and manufacture. The Committee is particularly concerned about the potential for barriers to the global marketing of products that are approved for use in the United States. Therefore, the Committee directs the Food and Drug Administration to report on the nature and scope of its activities to promote mutual recognition and international harmonization aimed at approval systems as well as product surveillance. This report is to be submitted to the Committee by January 1, 2001.

Action to be taken

The Agency forwarded the report on Mutual Recognition Agreements to the Committee on February 16, 2001.

Item

National Center for Food Safety and Technology – Within the amounts provided for food safety, the Committee recommends $3,000,000 for the National Center for Food Safety and Technology in Summit-Argo, Illinois, to continue collaborative research in food safety among government, academia, and private industry.

Action to be taken

The Agency will provide $2,993,400 (reflects enacted levels adjusted for the 0.22 percent rescission) to support The National Center for Food Safety and Technology's (NCFST) collaborative research in food safety among government, academia, and private industry. NCFST is the nation's only research consortium of industry, government, and academia to address the food safety implications of emerging technologies in food processing, packaging, biotechnology. The NCFST is a cost effective resource for developing and exploring new technologies. By spreading the cost and risk of doing research, companies can control their costs while putting themselves on the cutting edge of new technology developments.

Item

Radiopharmaceuticals – The Committee believes that there is a need to have the Food and Drug Administration (FDA) clarify its existing enforcement authority and position on the compounding of radiopharmaceuticals. Radiopharmaceuticals are excluded from the exemptions provided by section 127 the Food and Drug Administration Modernization Act of 1997 (FDAMA) (see 21 USC 353a(e)(21). With respect to radiopharmaceuticals, FDAMA was not intended to change the law that was in effect at the time of its enactment (H. Rep. No. 105 399, 105th Cong., 1st Sess. 95 1997). Furthermore, the law at the time FDAMA was enacted did not exempt radiopharmaceuticals from the adulteration, misbranding, and new drug requirements of the Federal Food, Drug and Cosmetic Act. Therefore, FDA should clarify its enforcement policy on the compounding of radiopharmaceuticals to stop the compounding of radiopharmaceuticals that are essentially copies of approved and commercially available drug products. The Committee urges the Agency to promptly issue guidance setting forth its enforcement policy with regard to the compounding of radiopharmaceuticals, but nothing herein shall preclude the Agency from

taking enforcement action under current law prior to issuance of such guidance."

Action to be taken

FDA convened a workgroup in September 2000 to clarify its existing enforcement authority and policy on the compounding of radiopharmaceuticals. The workgroup consists of representatives from various components of the Center for Drug Evaluation and Research, including the Division of Medical Imaging and Radiopharmaceutical Drug Products, the Regulatory Policy Staff, and the Office of Compliance. The Agency has also contracted with an expert in the field of nuclear pharmacy to assist in this effort. The workgroup has made substantial progress in developing a draft guidance document that addresses the types of radiopharmaceutical compounding that: 1) fall within the scope of the ordinary practice of nuclear pharmacy, routinely regulated by State and local officials; or 2) exceed the scope of the ordinary practice of nuclear pharmacy, subject to regulation by FDA. The Agency intends to release a draft guidance document regarding the Agency's enforcement policy on radiopharmaceutical compounding and will seek public comment on that document.

On February 6, 2001, the U.S. Court of Appeals for the Ninth Circuit declared section 503A of the FFD&C Act to be invalid (Western States Medical Center v. Shalala, D.C. No. CV-98-01650 (RLH)(9th Cir. 2001)). The Agency is currently assessing the impact of that ruling on the radiopharmaceutical guidance document.

Item

Secondary Market for Prescription Drugs – The Committee supports the recent FDA action to delay the effective date for implementing certain requirements of the Prescription Drug Marketing Act until October 1, 2001, and reopen the administrative record in order to receive additional comments. The Committee believes the Agency should thoroughly review the potential impact of the proposed provisions on the secondary wholesale pharmaceutical industry. The Committee directs the FDA to provide a report to the Committee by January 15, 2001, summarizing the comments and issues raised and Agency plans to address the concerns.

Action to be taken

The Agency published a notice that delayed the effective date for certain parts of the final rule for implementing certain requirements of the Prescription Drug Marketing Act until October 1, 2001. A Part 15 public hearing to develop a factual basis for decision. After the hearing, the Agency decided to further delay the effective date until April 1, 2002. The Agency believes that this additional time will relieve existing pressures on industry to begin implementing the regulation, provide time for Congress to determine whether legislative changes are appropriate, and provide the Agency time to conduct rulemaking with respect to authorized distributors and blood centers.

The report is in final clearance within the Administration and should be forwarded within the next month.

Item

Shellfish Safety -- "FDA's Office of Seafood has a memorandum of understanding with the Interstate Shellfish Sanitation Commission (ISSC) to develop shellfish regulations. The Committee understands that the Agency funds this agreement at a level of $200,000, and directs that this level of effort is to continue in fiscal year 2001."

Action to be taken

The Food and Drug Administration is a member of the ISSC and, as such, consults extensively with the ISSC on research and similar activities that benefit the ISSC and its member states, including regulations when necessary. The FDA laboratory at Dauphin Island, Alabama is almost entirely dedicated to research projects designed to improve safety measures for molluscan shellfish. Such safety measures would be applied through control strategies adopted by the ISSC for use by the state programs. The three categories of projects underway at Dauphin Island involve learning more about vibrio bacteria, viruses, and marine toxins that can all affect molluscan shellfish.

- For vibrios, Dauphin Island is working to identify the most hazardous strains of vibrios so that control strategies can focus on those that are the most hazardous, and is also studying the effectiveness of post-processing technologies in eliminating vibrios from oysters. That laboratory is also attempting to improve our understanding of how vibrios survive and grow in various environmental conditions. The lab has also instituted a training program for personnel from state laboratories in order to improve their ability to detect *Vibrio parahaemolyticus*, an organism that caused hundreds of illnesses a few years ago.

- For viruses, Dauphin Island is working to find superior "indicators," i.e., bacteria in the water that indicate the likely presence of viruses in shellfish. The lab is also working to detect and identify viruses directly in shellfish, thus potentially eliminating the need to infer their presence from "indicators" in the growing waters.

- Dauphin Island is performing similar types of experiments to better understand marine toxins that can cause severe illness if present in shellfish.

This level of effort will continue in FY 2001.

Item

Vibrio Vulnificus -- "The Committee expects that FDA will continue its work with the Interstate Shellfish Sanitation Commission (ISSC) to promote educational and research activities related to *Vibrio Vulnificus*. The Committee directs the use of $250,000 for this effort, within the amounts appropriated for the Food Safety initiative."

Action to be taken

FDA is working with the Interstate Shellfish Sanitation Commission and the Committee to assure that these activities are funded at an appropriate level. We have already sent $200,000 to the ISSC and plan to send another $50,000 for a total of $250,000 for vibrio work plus other shellfish activities as noted above.

Item

Waste-Management Education and Research Consortium – Within the sums provided for food safety, the Committee directs the Food and Drug Administration to provide not less than $100,000 for the Waste-Management Education and Research Consortium (WERC) to Continue its work in minimizing microbial hazards.

Action to be taken

FDA will maintain the level of funding of $99,780 (reflects enacted levels adjusted for the FY 2001 0.22 percent rescission) within the appropriated amount for the Food Safety Initiative for the Waste-Management Education and Research Consortium (WERC) to continue its work in minimizing microbial hazards.

Senate Report No. 106-288

Item

Within the total funding available for food safety, at least $1,800,000 is for FDA activities in support of *Codex Alimentarius*.

Action to be taken

FDA will provide $1,796,040 (reflects enacted levels adjusted for the 0.22 percent rescission) from within the appropriated amount for the Food Safety Initiative in support of *Codex Alimentarius* activities. FDA is participating in the Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology to develop international principles and guidelines for safety assessment of bioengineered foods.

Item

In addition, the funding provided for food safety will ensure the expansion of food contract inspections in the State of Alaska. Specifically, it will allow the FDA to contract with the State of Alaska. ..... The contract proposal to begin July 1, 2000, for approximately $121,000, will fund 200 inspections which includes about 140 seafood/HACCP inspections and 60 other food inspections. The establishments to be inspected will be mutually agreed upon by FDA and the State of Alaska.

Action to be taken

Within the funding of $121,000 provided for food safety, FDA will provide resources to ensure the expansion of food contract inspections, in particular in Alaska. Every year it is the Agency's goal to increase high-risk state contract inspections. In FY 2001, we are increasing inspections from 200 to 350 in the State of Alaska.

Item

Included in the total increase provided for premarket review is $1,000,000 to analyze risks associated with emerging biotech foods and develop criteria for evaluating the safety of biotech foods used for animal feeds

Action to be taken

FDA will provide $997,800 (reflects enacted levels adjusted for the 0.22 percent rescission) within the funding provided for premarket review, to support biotechnology risk-based research and evaluate the safety of biotechnology foods used for animal feeds. FDA published a proposed rule on January 18, 2001, that, if finalized, would require developers to notify FDA 120 days prior to marketing a food developed using the tools of modern biotechnology. Also, FDA has drafted guidance to industry for evaluating whether proteins introduced into foods using bioengineering may cause allergic reactions in sensitive individuals. FDA has committed funding to the National Research Council concerning a proposal on assessing or predicting unintended health effects of

bioengineered foods. In addition, FDA will provide resources to develop benchmarks to evaluate the safety of biotechnology foods used for animal feeds.

Item

Included in the premarket review increase for Biologics is $2,200,000 to improve the quality and safety of the Nations's blood supply by improving, developing diagnostic tests and identifying validation criteria.

Action to be taken

FDA expects to use premarket review increases of $2,200,000 to improve the quality and safety of the Nations's blood supply by improving, developing diagnostic tests and identifying validation criteria.

Item

Included in the Device premarket review increase is $2,800,000 to ensure the safety and efficacy of reprocessed devices. FDA will focus on increasing product review activities and development of standards for high-risk reuse applications. FDA will accomplish these activities through hospital outreach, such as mailings, conferences, and web notices.

Action to be taken

The Agency expects to use $2,800,000 to ensure the safety and efficacy of reprocessed devices. FDA will focus on increasing product review activities and development of standards for high-risk reuse applications. FDA will accomplish these activities through hospital outreach, such as mailings, conferences, and web notices.

Item

The Committee continues to provide $500,000 for clinical pharmacology grants awarded on a competitive basis, an increase of $40,000 from the fiscal year 2000 funding level.

Action to be taken

In FY 2001, FDA awarded $500,000 in clinical pharmacology grants to Indiana University. Indiana University was the grantee recipient as well in FY 2000 in the amount of $459,992. Previous grantees in this program include: University of Illinois at Peoria, Meharry Medical College, State University of New York at Binghamton, and the Mayo Clinic.

Item

Dietary Supplements – An increase of $1,000,000 is included in the total funding recommended for fiscal year 2001 for the Foods Program for collaborative research on dietary supplements with the National Center for Natural Products Research, Oxford, MS.

Action to be taken

To date, FDA is currently collaborating with the National Center for Natural Products Research in Oxford, Mississippi, to review botanicals in dietary supplements. To support these research efforts, FDA will provide funds at a level of $997,800 (reflects enacted levels adjusted for the 0.22 percent rescission). The ability to identify and analyze specific components in ingredients, including botanical ingredients and in finished products is an essential component of research and regulatory programs directed at ensuring the safety and effectiveness of dietary supplements. The goals of the contract are to: (1) Convene scientific workshops to identify and discuss general principles and criteria for authenticating botanical reference materials; (2) Obtain, document, and characterize authenticated reference materials for botanical ingredient sources of ephedrine alkaloids; and (3) Review the available scientific literature relative to the safety of Mayapple (Podophyllum peltatum L.). By the end of the contract year, a final report will be prepared summarizing all accomplishments in all activities.

Item

Gene Therapy Patient Tracking System – The Committee believes FDA should establish a gene therapy tracking system designed to measure both short-term and long-term outcomes of treatment protocols. The FDA was urged in 1994 to set up such a system. Between December 1994 and 1996, FDA developed a pilot gene therapy patient tracking system, known as Gene Therapy Information Network (GTIN). This model was used to develop the National Xenotransplantation Database (NXD). However, no gene therapy patient tracking system has been put into operation to date by FDA. Given the long time that FDA has had to develop such a tracking system, and the recent reported deaths of gene therapy patients, the Committee believes that FDA should move aggressively to establish such a tracking system. Therefore, the Committee within 3 months from the date of enactment of this Act on a full plan, including the budget needed to establish this tracking system and its integration into FDA' adverse event reporting system within the upcoming 12 months.

Action to be taken

A report on the Gene Therapy Information Network has been provided to the Department for forwarding to the Committee.

Item

Biotechnology-- "The Committee understands that the FDA frequently receives requests from foreign governments for FDA regulators to visit foreign countries to educate regulators on the evaluation of the safety of biotechnology. Providing information on the soundness of the U.S. regulatory process will promote the understanding of the benefits of biotechnology to human health and the environment and improve the climate for acceptance of U.S. Agricultural products

abroad. The Committee directs the FDA to allocate adequate funding so that Agency representatives may perform this service."

Action to be taken

FDA will allocate adequate funding so that Agency representatives may visit foreign countries to educate regulators on the evaluation of the safety of biotechnology.

Item

Heart Healthy Labeling of Salmon – The Food and Drug Administration is considering adoption of a health claim that "consumption of Omega 3 fatty acids may reduce the risk of coronary artery disease" and accepted public comment through November 22, 1999. The Committee has been advised that the scientific evidence was overwhelming on the positive effects that Omega 3 fatty acids found in salmon have on preventing heart disease and, in some cases, even reversing it. The Committee directs the Agency to expedite consideration of this issue and report back to the Senate Committee on Appropriations on its decision no later than December 1, 2000.

Action to be taken

The Agency submitted the report to the Committee on February 5, 2001.

Item

Direct Food Additive Reviews – The Congress provided FDA with additional funds for fiscal year 2000 to accelerate the rate of review of direct food and color additive petitions, including those with food safety benefits. The Committee expects FDA to establish performance benchmarks to measure its progress in utilizing these resources to meet its application review goals. The Committee also expects FDA to seek public input on program enhancements, including those intended to optimize prefiling interactions between the Agency and potential applicants of new direct additives and other food ingredients. These actions should occur as soon as possible. FDA should report to the Committee by December 3, 2000, on its use of fiscal year 2000 funds to reduce the backlog of food additive petitions.

Action to be taken

The Agency has prepared a report to respond to the Committee's direction. It was forwarded to the Department for transmittal to the Committee on March 9, 2001.

Item

Expedited Review of Competitive Exclusion Products – "The Committee understands that competitive exclusion products offer an innovative and valuable approach to reducing Salmonella and other harmful bacterial in poultry and livestock. The Committee is concerned, however that only one competitive exclusion product has been approved to date despite public statements by FDA, USDA, and the President's Food Safety Council supporting this emerging

technology. In view of the significant public health benefits of competitive exclusion products, the FDA should review new animal drug applications for these products on an expedited review basis."

Action to be taken

FDA announced on March 5, 2001 the availability of a guidance for industry entitled "Expedited Review for New Animal Drug Applications for Human Pathogen Reduction Claims." The guidance provides advice to industry about the process that the Center for Veterinary Medicine (CVM) plans to use to grant Expedited Review Status (ERS) for applications for new animal drugs intended to reduce human pathogens in food-producing animals.

FDA believes it is in the interest of public health to grant ERS to applications for new animal drugs that may decrease the incidence of human illness through their action against human pathogens in animals and that meet the criteria in this guidance.

Specifically, the guidance provides procedures for requesting and criteria for granting ERS to new animal drug applications submitted to the Agency for approval of new animal drugs for which the label would bear human pathogen reduction claims. Under CVM's expedited review program, such products that potentially offer important advances in human pathogen reduction in food-animals should receive expedited review commencing at the Investigational New Animal Drug stage. ERS does not affect the approval standard; applications are expected to meet the same standards for data quality and evaluation that apply for other new animal drug approvals.

Item

Salmonella enteritidis – "In developing a rule concerning on-farm standards for prevention of *Salmonella enteritidis* in shell eggs pursuant to any plan to eliminate *Salmonella enteritidis* illnesses due to eggs, the FDA shall--a) consider one environmental test per laying cycle for each layer house for verification of the producers *Salmonella enteritidis* reduction plan; b) consider when it is appropriate to require diversion of shell eggs to treatment, such as pasteurization, and base any requirement for testing that would necessitate diversion, which may include the receipt of a positive egg test result, on sound science; c) conduct or support research to develop cost-effective and improved tests for determination of *Salmonella enteritidis*; and, d) solicit comments on appropriate options for implementing a *Salmonella enteritidis* reduction plan in shell eggs, including comments on conducting and funding testing, through state and federal programs."

Action to be taken

FDA is considering provisions in its deliberations. Specifically, the President's Council on Food Safety has identified egg safety as one component of the public health issue of food safety that warrants immediate federal interagency action. In response, the "Egg Safety From Production to Consumption: An Action Plan to Eliminate *Salmonella enteritidis* Illnesses Due to Eggs" was developed. The Action Plan identifies the systems and practices to be implemented to reduce and ultimately, eliminate eggs as a source of human *Salmonella enteritidis* (SE) illnesses. An interim goal of the Egg Safety Action Plan is a 50 percent reduction in egg-associated SE illnesses by 2005.

To consolidate egg safety oversight responsibilities and provide clarity, the President's Council on Food Safety identified one responsible agency for each stage of the farm-to-table continuum based on the strengths of each agency. FDA will develop standards for the producer and State agencies will provide inspection and enforcement of the standards on the farm. FSIS will develop standards for both shell egg packers and egg products processors and will provide inspection and enforcement for both. CDC will conduct surveillance and monitoring activities focusing on human health and FDA will conduct surveillance and monitoring of the food supply.

The Center for Food Safety and Applied Nutrition has included the following Egg Safety goals in its FY 2001 Program Priorities Workplan:

- Published, on December 5, 2000, a final rule on egg labeling and refrigeration.
- Work with States to implement the egg label and refrigeration rule.
- Conduct education campaigns for the egg label and refrigeration rule.
- Publish proposed egg safety rule for farm and retail.
- Solicit comments through public meetings on egg safety proposal.
- Initiate SE research plan.

Conference Report, 106-948

Item

The conference agreement provides increases from the fiscal year 2000 levels of $1,000,000 for orphan product grants, as recommended by the Senate; and $1,200,000 for the Office of Generic Drugs to reduce generic drug application review and approval times.

Action to be taken

The Office of Generic Drugs (OGD) continues to refine the review process to increase efficiency. The number of new staff hired in the last fiscal year are now fully trained and are demonstrating high levels of productivity. For FY 2001, OGD was provided with additional staff above the prior year's allocation. The Agency continues to examine every aspect of the review process to try to identify problem areas to be addressed. We also plan to revise the current system for amendment designation (major versus minor) to improve total review times. At the end of January 2001, there were 408 ANDAs awaiting review with only 32 waiting more than six months. The goal for FY 2001 is to complete a first review cycle for 50 percent of the applications within the statutory 180-day time frame. OGD's goals for FY 2000 was 45 percent..

As recommended by the Senate, the Orphan Grants program has $12,514,000 available for grants in FY 2001 and increase of $1,000,000 over FY 2000 less $28,000 for the recision.

Item

The conferees direct that FDA provide $1,500,000 from sums provided for food safety for a contract with New Mexico State University's Physical Science Laboratory to establish an agricultural products testing laboratory in Dona Ana County, New Mexico. The laboratory will conduct rapid screening analyses of fresh fruits and vegetables (imported and domestic) for microbiological contamination of products in the Texas, New Mexico, Arizona area. The laboratory will augment FDA's capabilities and facilitate rapid testing of these perishable products.

Action to be taken

FDA will provide $1,497,000 (reflects enacted levels adjusted for the 0.22 percent rescission) to contract with New Mexico State University's Physical Science Laboratory (NMSU/PSL). FDA and NMSU/PSL participated in a meeting on March 1, 2001. The NMSU Project Manager and FDA agreed that the project should focus on method evaluation of rapid testing methods. These would include micro and biochemical lab tests as well as evaluation of field test kits for our investigators. While the lab is not ready to handle regulatory samples it could be used to gather data in evaluation of rapid testing methods. The lab's work will help in the goal of reducing the time that it takes for perishable products to go from harvest to market. In order to allow for time to evaluate the work of the laboratory, no resources are requested for this project in FY 2002.

Item

Electronic Facial Toning -- "It has been brought to the conferees' attention that makers of electronic facial toning appliances have been informed by the FDA that their product may be medical devices under the law. The conferees encourage that FDA to consider the companies claims that products are purely cosmetic and not "intended to affect the structure of any function of the body". Nothing in this conference report language should be taken to diminish or attempt to diminish the responsibility under the law for the FDA to continue to protect American consumers. FDA will report to the Appropriations Committee of the House and Senate on their findings."

Action to be taken

In evaluating the intended use of a product, FDA evaluates all relevant information. The intended physiological effect of the electrical facial toning mask, Rejuvenique, is to introduce electrical current to the face. The manufacturer is claiming that this physiological effect will produce a particular cosmetic result. The Agency concludes that the Rejuvenique product is an electrical muscle stimulator that is intended to affect the structure or function of the body as defined in section 201 of the Act, and should be regulated as a device. FDA has always regulated electrical muscle stimulators that impart electrical current to the body, and has consistently maintained that electrical facial muscle stimulators are devices.

Products can fall within the definition of a device, and also be used for cosmetic purposes. The Agency has a long history of regulating as devices many products used to improve and enhance the appearance of healthy individuals. These include, but are not limited to, breast implants, collagen injections, scalpels, and other surgical instruments that are used to perform face lifts,

liposuction, and other cosmetic surgery. Indeed, collagen is a device that is used, like Rejuvenique, to eliminate wrinkles.

The particular promotional language of any manufacturer of such devices does not alter the fact that it delivers electrical current directly to the body and creates special risks to consumers. Unlike cosmetic creams or exercise equipment that make similar claims to Rejuvenique for improving appearance, products like Rejuvenique (electric muscle stimulators) create special risks to consumers. This product needs to be reviewed before it is marketed to the public.

Item

Labeling of Irradiated Foods -- "The conferees expect FDA to make final the regulations regarding labeling of irradiated foods by March 1, 2002, and report to the House and Senate Committees on Appropriations on the status by November 15, 2000. This agreement changes the dates proposed for final regulations by the House of September 30, 2001 and by the Senate of October 30, 2001."

Action to be taken

FDA provided the report on Food Irradiation Labeling Concerns to Congress on January 5, 2001. FDA will make final by March 2002 regulations that prescribe alternative truthful and nonmisleading labeling disclosures that may be used on foods treated by ionizing radiation in lieu of the existing FDA-required disclosure.

Table of Estimates and Appropriations
Salaries and Expenses

Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
1988	454,109,000[1]	450,504,000	454,109,000	450,504,000
1989	481,844,000[2]	481,844,000	481,844,000	481,844,000[3]
1990	556,571,000[4]	550,171,000	581,871,000	567,079,000[5]
1991	654,808,000[6]	654,808,000	661,652,000	656,519,000[7]
1992	737,604,000[8]	725,962,000	704,734,000	725,962,000
1993	757,038,000[9]	744,135,000	744,135,000	792,035,000[10]
1994	867,339,000[11]	867,339,000	692,339,000	870,123,000[12]
1995	926,007,000[13]	914,394,000	754,587,000	897,104,000[14]
1996	965,462,000[15]	917,694,000	917,694,000	917,694,000[16]
1997	964,178,000[17]	920,903,000	920,902,000	920,903,000[18]
1998	987,735,000[19]	866,467,000	978,227,000	962,671,000[20]
1999	1,153,259,000[21]	1,010,230,000[22]	1,240,250,000[22]	1,117,525,000[23]
2000	1,301,992,000[24]	1,214,231,000	1,196,819,000	1,199,677,000[25]
2001	1,354,989,000[26]	1,256,806,000	1,233,424,000	1,234,425,000[27]
2002	1,372,479,000[28]			

[1] The FY 1988 request includes Amendments of +$8,880,000 for AIDS, -$2,357,000 for reduced FERS Agency contribution rate, and $33,800,000 proposed to be available from user fees.

[2] The FY 1989 request includes funding of $40,420,000 for AIDS-related work which was proposed to be funded in the AIDS Research and Education Account.

[3] The FY 1989 appropriation does not include $5,000,000 added in the Anti-Drug Abuse Act.

[4] The FY 1990 request includes $56,941,000 which was included in the proposed National HIV Program account, $13,900,000 requested as a supplemental appropriation, and $100,000,000 proposed to be available from user fees.

[5] The FY 1990 appropriation includes $7,092,000 which was subsequently sequestered.

[6] The FY 1991 request includes $157,175,000 proposed to be available from user fees.

[7] The FY 1991 appropriation includes $8,868 which was subsequently sequestered.

[8] The FY 1992 request includes $197,500,000 proposed to be available from user fees.

[9] The FY 1993 appropriation request includes $200,000,000 proposed to be available from user fees.

[10] The FY 1993 appropriation includes $1,900,000 to fund a clinical pharmacology pilot program; and a $3,000,000 supplemental for Mammography Quality Standards Act (MQSA) to be transferred from HCFA, NIH and CDC; and $36,000,000 for the Prescription Drug User Fee Act.

[11] The FY 1994 request includes $54,000,000 for the Prescription Drug User Fee Act (PDUFA); $64,600,000 for Investment Initiatives; $200,000,000 proposed to be available from User Fees.

[12] The FY 1994 appropriation includes $56,284,000 for PDUFA ($2,284 which was a supplemental appropriation), and $40,000,00 for Investment Initiatives.

[13] The FY 1995 1995 request includes $79,423,000 for PDUFA; $24,000,000 for Device User Fees; $6,500,000 for MQSA fee collections; and other user fees of $228,000,000. Also included is a transfer from Office of the Secretary, Office of General Counsel to FDA of $2,745,000 and 34 FTE.

[14] The FY 1995 appropriation includes an amended S&E BA of $817,681,000 and $79,423,000 for PDUFA. The amount does not include anticipated collections of MQSA inspections fees of $6,500,000. The level reflects the amended appropriation which rescinded $2,290,000.

[15] The FY 1996 request includes S&E BA of $828,999,000; $84,723,000 for PDUFA; $13,000,000 for MQSA fee collections; $23,740,00 for MDUFA; and $15,000,000 for Import fees.

[16] The FY 1996 appropriation includes S&E BA of $819,971,000; $84,723,000 for PDUFA; and $13,000,000 for MQSA fee collections.

[17] The FY 1997 request includes S&E BA of $823,771,000; $87,528,000 for PDUFA; $13,403,000 for MQSA fee collections; $24,476,00 for MDUFA; and 15,000,000 for Import fees.

[18] The FY 1997 appropriation includes S&E BA of $819,971,000; $87,528,000 for PDUFA; and $13,403,000 for MQSA fee collections.

[19] The FY 1998 request includes S&E BA of $750,922,000; $91,204,000 for PDUFA; $13,966,000 for MQSA; $131,643,000 for new user fees. Does not reflect proposed PDUFA Supplemental request of $25,618,000 requested with the FY 1999 President's Budget.

[20] The FY 1998 appropriation includes S&E BA of $857,501,000; $91,204,000 for PDUFA; and $13,966,000 for MQSA fee collections.

[21] The FY 1999 request includes S&E BA of $878,884,000; $132,273,000 for PDUFA; $14,385,000 for MQSA; 1,000,000 for Export Certification, and $127,717,000 for new user fees.

[22] The FY 1999 House Action, Senate Action and Appropriation included the GSA Rent within the S&E Appropriation (BA of $82,866,000; PDUFA of $5,428,000).

[23] The FY 1999 appropriation includes S&E BA of $888,001,000; GSA Rent of $82,866,000 $132,273,000 for PDUFA; and $14,385,000 for MQSA fee collections.

[24] The FY 2000 request includes S&E of $1,109,950,000 (including $100,180,000 of GSA Rent of which 5,643,000 is PDUFA); $145,434,000 for PDUFA; $14,817,000 for MQSA; $12,700,000 for Seafood Transfer User Fees, and $17,000,000 for new user fees.

[25] The FY 2000 appropriation includes S&E BA of $1,109,950,000 (including $94,537,000 of GSA Rent, $3,000,000 for Seafood Transfer); $145,434,000 for PDUFA; $14,817,000 for MQSA; $12,700,000 for Seafood Transfer User Fees, $17,000,000 for new user fees, and $13,400,000 for Bioterrorism.

[26] The FY 2001 request includes S&E of $1,156,905,000 (including $99,094,000 of GSA Rent); $149,273,000 for PDUFA; $15,128,000 for MQSA; $12,700,000 for Seafood Transfer User Fees, $1,500,000 for Export Certification; and $19,483,000 for new user fees (Food Additive $8,400,000; Premarket Medical Devices $5,833,000; Foods Export Certification $5,250,000).

[27] The FY 2001 appropriation includes S&E BA of $1,068,524,000; GSA Rent of $104,954,000 (of which 5,860,000 is PDUFA); $149,273,000 for PDUFA; $14,947,000 for MQSA; and $1,500,000 for Export Certification. Does not include $22,950 million for drug importation which is not available until requested by the President.

[28] The FY 2002 request includes S&E BA of $1,173,673,000; $161,716,000 for PDUFA; $15,590,000 for MQSA; $1,500,000 for Export Certification; and $20,000,000 for new user fees. Does not include $22,950 million for drug importation which is not available until requested by the President.

Table of Estimates And Appropriations
Rental Payments to GSA

Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
1988	34,495,000	25,612,000	34,495,000	25,612,000
1989	25,612,000	25,612,000	25,612,000	25,612,000
1990	25,612,000	25,612,000	25,612,000	25,612,000
1991	25,612,000	25,612,000	25,612,000	25,612,000[1]
1992	25,612,000	25,612,000	25,612,000	25,612,000
1993	25,612,000	25,612,000	25,612,000	25,612,000
1994	48,575,000	48,575,000	48,575,000	48,575,000[2]
1995	48,575,000	46,294,000[3]	46,294,000	46,294,000[4]
1996	46,294,000	46,294,000	46,294,000	46,294,000[5]
1997	46,294,000	46,294,000	46,294,000	46,294,000[6]
1998	46,294,000[7]	46,294,000	46,294,000	46,294,000[7]
1999	82,866,000[8]	82,866,000[9]	82,866,000[9]	88,866,000[9]
2000	100,180,000[10]	95,888,000	93,697,000	99,954,000
2001	99,094,000[11]	99,094,000	99,094,000	99,094,000
2002	98,876,000[12]			

[1] Does not reflect $333 which was subsequently sequestered.

[2] Includes $15,000,000 reserved for use by FDA for repairs and improvements to facilities.

[3] Reflects a GSA rent reduction of $2,281,000 to the rent cap.

[4] Includes an authorized reduction of GSA rent payments of $3,970,000 to cover FDA's Building Delegation expenses.

[5] Includes an authorized reduction of GSA rent payments of $3,957,000 to cover FDA's Building Delegation expenses.

[6] Includes an authorized reduction of GSA rent payments estimated to be $4,705,000 to cover FDA's Building Delegation expenses.

[7] Includes an authorized reduction of GSA rent payments estimated to be $4,832,000 to cover FDA's Building Delegation expenses.

[8] Includes an authorized reduction of GSA rent payments estimated to be $4,917,0000 to cover FDA's Building Delegation expenses and $5,428,000 of PDUFA collections.

[8] In FY 1999, Congress included GSA Rent in the S&E Appropriation. Includes an authorized reduction of GSA rent payments estimated to be $4,917,0000 to cover FDA's Building Delegation expenses and $5,428,000 of PDUFA collections.

[10] PDUFA collections of $5,643,000 are not included.

[11] PDUFA collections of $5,860,000 are not included.

[12] PDUFA collections of $6,240,000 are not included.

Table of Estimates And Appropriations
Buildings and Facilities

Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
1988	1,450,000[1]	1,450,000	1,450,000	1,450,000
1989	26,450,000[1]	23,710,000	25,736,000	23,950,000
1990	1,450,000[1]	6,950,000	12,250,000	8,350,000
1991	4,752,000[1]	8,350,000	10,850,000	8,350,000
1992	10,000,000[1]	10,400,000	8,350,000	8,350,000[2]
1993	8,350,000	8,350,000	8,350,000	8,350,000
1994	8,350,000[3]	8,350,000	8,350,000	8,350,000
1995	8,350,000[4]	18,150,000	8,350,000	18,150,000[5]
1996	8,350,000	15,150,000	8,350,000	12,150,000[6]
1997	8,350,000	21,350,000	21,350,000	21,350,000[7]
1998	22,900,000[8]	21,350,000	21,350,000	21,350,000[8]
1999	8,350,000	11,350,000	12,350,000	11,350,000[9]
2000	31,750,000[10]	31,750,000	8,350,000	11,350,000
2001	31,350,000[11]	11,350,000	31,350,000	31,350,000
2002	34,281,000[12]			

[1] Funding of facilities projects - 1984 through 1992 - was included in the Program Expenses request but appropriated in this account.

[2] Does not include $200,000,000 provided to GSA in the Treasury, Postal Service, General Government Appropriation Act of 1992 for consolidation of FDA headquarters facilities.

[3] Does not include $73,900,000 provided to GSA in the Treasury, Postal Service, General Government Appropriation Act of 1994 for consolidation of FDA headquarters facilities.

[4] Does not include $45,000,000 provided to GSA in the Treasury, Postal Service, General Government Appropriation Act of 1995 for consolidation of FDA headquarters facilities.

[5] Includes $9,800,000 to purchase land and begin engineering and design work for replacement of FDA's Los Angeles District office and laboratory.

[6] Includes $3,800,000 for continuing work on an Arkansas Regional Laboratory at Jefferson, AR.

[7] Includes $13,000,000 for continuing modernization of Arkansas Regional Laboratory at Jefferson, AR.

[8] Includes $14,550,000 for continuing modernization of Arkansas Regional Laboratory at Jefferson, AR.

[9] Includes $3,000,000 for continuing modernization of Arkansas Regional Laboratory at Jefferson, AR.

[10] Includes $20,400,000 for construction of Phase I of the new Los Angeles Laboratory and $3,000,000 for continuing modernization of Arkansas Regional Laboratory at Jefferson, AR.

[11] Includes $20,000,000 for construction of Phase I of the new Los Angeles Laboratory and $3,000,000 for continuing modernization of Arkansas Regional Laboratory at Jefferson, AR.

[12] Includes $23,000,000 for construction of Phase I of the new Los Angeles Laboratory and $3,000,000 for continuing modernization of Arkansas Regional Laboratory at Jefferson, AR.

Food and Drug Administration
Detail of FTE by Grade
Program Level

	FY 2000 Actual	FY 2001 Estimate	FY 2002 Estimate
Executive Level I.....	0	0	0
Executive Level II...	0	0	0
Executive Level III.....	0	0	0
Executive Level IV..... .	1	1	1
Executive Level V...	0	0	0
Total, Exec. Level Salaries	**1**	**1**	**1**
ES-6.....	0	2	4
ES-5.....	13	10	11
ES-4.....	20	22	20
ES-3.....	8	8	10
ES-2.....	7	10	16
ES-1.....	10	14	5
Total, ES Salaries	**58**	**66**	**66**
GS/GM - 15.....	611	634	663
GS/GM - 14.....	1,243	1,290	1,349
GS/GM - 13.....	2,414	2,504	2,622
GS-12.....	1,412	1,465	1,532
GS-11.....	449	466	487
GS-10.....	69	72	75
GS-9.....	467	485	507
GS-8.....	237	246	257
GS-7.....	530	550	575
GS-6.....	176	183	191
GS-5.....	153	159	166
GS-4.....	86	89	93
GS-3.....	33	34	36
GS-2.....	26	27	28
GS-1.....	7	7	7
Subtotal, GS Salaries	**7,913**	**8,211**	**8,588**
Admin Law Judge	1	1	1
Scientific, Legal	1	1	1
Scientific, Technical	2	2	2
Research Service	42	42	42
Com. Corps, 08/07/06	210	210	210
Com Corps, Other	265	265	265
Subtotal, CC Salaries	**476**	**476**	**476**
AD (includes Title 42)...	255	270	285
Wage Grade.....	68	68	68
Consultants...	13	13	13
Total FTE (End of Year)	**8,830**	**9,150**	**9,542**
Average ES level...	3.3	3.2	3.4
Average ES Salary...	127,800	129,600	135,300
Average GS/GM grade..... .	11.7	11.7	11.7
Average GS/GM salary..... .	64,800	68,400	72,200
TARGET TOTAL	8,830	9,150	9,472

Detail of Full-Time Equivalent Employment (FTE)
Program Level

Project	FY 2000 Actual	FY 2001 Estimate	FY 2002 Estimate
Center for Food Safety and Applied Nutrition	860	910	936
Center for Drug Evaluation and Research	1,780	1,850	1,894
Center for Biologics Evaluation and Research	781	858	875
Center for Veterinary Medicine	271	306	320
Center for Devices and Radiological Health	1,021	1,015	1,028
National Center for Toxological Research	217	230	232
Tobacco	21	0	0
Office of Regulatory Affairs	3,093	3,204	3,467
Other Activities			
Office of the Commissioner	100	105	115
Office of Senior Associate Commissioner	120	98	96
Office of Deputy Commissioner for International & Constituent Relations	70	66	66
Office of Policy, Legislation & Planning	8	97	97
Office of Management and Systems	398	411	416
TOTAL	**8,830**	**9,150**	**9,542**

Five Year History of GS/GM Average Grade

Year	Grade
FY 1998	11.6
FY 1999	11.7
FY 2000	11.7
FY 2001	11.7
FY 2002	11.7

Geographical Distribution of FDA Facilities

Location	Activities
Washington, D.C. area:	
Rockville, MD	FDA Headquarters and headquarters operations of the Human Drugs, Biologics, Animal Drugs, Device and Radiological Health products programs and laboratories.
Washington, D.C.	Foods program headquarters and laboratories
Bethesda, MD	Human Drugs and Biologics laboratories
Beltsville, MD	Foods and Animal Drugs Research facilities
Field Operations Facilities:	
Jefferson, AR	Arkansas Regional Laboratory
Oakland, CA	Pacific Regional Office
Alameda, CA	San Francisco District Office and laboratory
Los Angeles, CA	Pacific Regional Laboratory Southwest
Irvine, CA	Los Angeles District Office
Denver, CO	Denver District Office and laboratory (special emphasis in animal drugs residue testing)
Maitland, FL	Florida District Office
Atlanta, GA	Southeast Regional Office, Southeast Regional Laboratory, and Atlanta District Office
Chicago, IL	Chicago District Office
Lenexa, KS	Kansas City District Office and laboratory (special emphasis in pesticides and total diet analysis)
New Orleans, LA	New Orleans District Office
Stoneham, MA	New England District Office
Winchester, MA	Winchester Engineering and Analytical Center (testing of Medical Devices and Radiological Health Research products)- Testing facility for Radionuclides and Radiopharmaceutics.
Baltimore, MD	Baltimore District Office
Detroit, MI	Detroit District Office and laboratory
Minneapolis, MN	Minneapolis District Office
Parsippany, NJ	New Jersey District Office
Jamaica, NY	Northeast Regional Office, Regional laboratory and New York District Office
Cincinnati, OH	Cincinnati District Office and Forensic Chemistry Center (elemental analysis)
Philadelphia, PA	Central Regional Office, Philadelphia District Office and laboratory (special emphasis on Human Drugs)
San Juan, PR	San Juan District Office and laboratory (special emphasis on human drugs products testing)
Dallas, TX	Southwest Regional Office and Dallas District Office
Bothell, WA	Seattle District Office and Pacific Regional Laboratory Northwest (special emphasis on seafood products testing)
Other Specialized facilities:	
Dauphin Island, AL	Fishery research (CFSAN)
Jefferson, AR	National Center for Toxicological Research (NCTR)
St. Louis, MO	Specialized human drugs product testing laboratory (CDER)

User Fee History

MEETING THE LEGAL CONDITIONS FOR PDUFA USER FEES

PDUFA, as amended, contains three legal conditions or "triggers" that must be satisfied each year before FDA can collect and spend user fees. As an example, the following calculations summarize how those conditions were met for FY 2000. All of the conditions for FY 2001 will not be known until after the end of the fiscal year in October 2001.

The first condition is that FDA's Salaries and Expenses Appropriation (excluding user fees) must meet or exceed FDA's FY 1997 Salaries and Expenses Appropriation (excluding user fees and adjusted for inflation). In FY 2000, FDA's Salaries and Expenses Appropriation (excluding user fees and rent to GSA, both of which were not included in the FY 1997 Appropriated amount) totaled $940,458,000. FDA's FY 1997 total Salaries and Expenses appropriation, excluding user fees, and adjusted as required by the statute, was $850,719,913. Therefore, since the FY 2000 amount is greater, the first condition was met.

The second condition is that the amount of user fees collected each year must be specifically included in FDA's appropriations. For FY 2000, FDA's appropriation acts specified that $145,434,000 would come from PDUFA fees, in addition to sums provided in regular appropriations. The appropriation act specified that the fees collected could remain available until expended. Thus, the second condition was met.

The third condition is that user fees may be collected and used only in years when FDA also uses a specified minimum amount of appropriated funds for the drug review process. The specified minimum is the amount FDA spent on the drug review process from appropriations (exclusive of user fees) in FY 1997, and adjusted for inflation. In FY 1997, FDA's actual obligations for the process for the review of human drug applications, excluding obligations paid from user fees, was $147,959,689, as reported in the FY 1997 Financial Report to Congress. Multiplying this amount by the adjustment factor of 1.0375, FDA's 1997 adjusted costs for the process for the review of human drug applications paid from appropriations exclusive of fees, is $153,508,177. As shown in the FY 2000 PDUFA Financial Report, FDA obligated $167,646,122 from appropriated funds in FY 2000 for the drug review process, which exceeded the specified minimum amount. Thus, the third condition was met.

GLOSSARY OF ACRONYMS

510(k)	Premarket notification (Medical devices substantially equivalent to products already on the market)
AADA	Abbreviated Antibiotic Drug Application
ADE	Adverse Drug Event
ADAA	Animal Drug Availability Act of 1996
ADR	Adverse Drug Report
AERS	Adverse Events Reporting System
AHI	Animal Health Institute
AIDS	Acquired Immune Deficiency Syndrome
ANDA	Abbreviated New Drug Application
ANSI	American National Standards Institute
APHIS	Animal Plant and Health Inspection Service (USDA)
BLA	Biologics License Application
BIMO	Bioresearch Monitoring
BSE	Bovine Spongiform Encephalopathy (Mad Cow Disease)
CABS	Conformity Assessment Bodies
CARS	Compliance Achievement Reporting System
CBER	FDA Center for Biologics Evaluation and Research
CDC	Centers for Disease Control and Prevention
CDER	FDA Center for Drug Evaluation and Research
CDRH	FDA Center for Devices and Radiological Health
CFO	Chief Financial Officer
CFSAN	FDA Center for Food Safety and Applied Nutrition
CGMPs	Current Good Manufacturing Practices
CJD	Creutzfeldt-Jakob Disease
CMC	Chemistry, Manufacturing, and Controls
COMSTAS	Compliance Status Information System
COBOL	Common Business Oriented Language
CRADA	Cooperative Research and Development Agreement
CRS	Contamination Response System
CTS	Correspondence Tracking System
CVM	FDA Center for Veterinary Medicine
DHHS	Department of Health and Human Services
DNA	Deoxyribonucleic Acid
DOD	Department of Defense
DOL	Department of Labor
DQRS	Drug Quality Reporting System
DRLS	Drug Registration and Listing System
DSHEA	Dietary Supplement Health and Education Act
EDR	Electronic Document Room
EDMS	Electronic Data Management System
EIP	Emerging Infection Program
EIR	Establishment Inspection Report

ELA	Establishment License Application
EPA	Environmental Protection Agency
ERS	Economic Research Service
ETS	Environmental Tobacco Smoke
EU	European Union
FACTS	Field Accomplishment and Compliance Tracking System
FAO	United Nations Food and Agricultural Organization
FAS	USDA Foreign Agriculture Service
FDAMA	Food and Drug Administration Modernization Act of 1997
FFD&C Act	Federal Food, Drug and Cosmetic Act
FIS	Field Information System
FLQ	Fluoroquinolone
FORCG	Food Outbreak Coordination Response Group
FPL	Final Printed Label
FPLA	Fair Packaging and Labeling Act
FSI	National Food Safety Initiative
FSIS	Food Safety Inspection Service (USDA)
FTC	Federal Trade Commission
FTE	Full-time Equivalent
FY	Fiscal Year (October – September)
GAO	General Accounting Office
GAPs	Good Agricultural Practices
GATT	General Agreement on Tariffs and Trade
GPRA	Government Performance and Results Act of 1993
GMPs	Good Manufacturing Practices
GRAS	Generally Recognized as Safe Food Ingredients
GSFA	General Standards for Food Additives
HACCP	Hazard Analysis Critical Control Points (A quality assurance and inspection technique)
HDE	Humanitarian Device Exemption
HIV	Human Immunodeficiency Virus
HUD	Humanitarian Use Device
ICH	International Conference on Harmonization
IDE	Investigational Device Exemption
INAD	Investigational New Animal Drug
INADA	Investigational New Animal Drug Application
IND	Investigational New Drug
IOM	Institute of Medicine
ISO	International Standards Organization
ISRS	Individual Safety Reports
IT	Information Technology
IVD	In Vitro Diagnostic
JECFA	Joint Expert Committee on Food Additives
JIFSAN	Joint Institute for Food Safety and Applied Nutrition
JINAD	Generic Investigational New Animal Drug

LACF	Low Acid Canned Foods
LAN	Local Area Network
LBITF	Least Burdensome Industry Task Force
MATS	Management Assignment Tracking System
MDR	Medical Device Reporting System
MERS-TM	Medical Event Reporting System for Transfusion Medicine
MMBM	Mammalian Meat and Bone Meal
MOU	Memorandum of Understanding
MPRIS	Mammography Program Reporting and Information Systems
MQSA	Mammography Quality Standards Act
MRA	Mutual Recognition Agreement
NADA	New Animal Drug Application
NAFTA	North Atlantic Free Trade Agreement
NAFTA TWG	North American Free Trade Agreement Technical Working Group
NARMS	National Antimicrobial Resistance Monitoring System
NASS	National Agricultural Statistics Survey
NCI	National Cancer Institute
NCIE	Notice of Claimed Investigational Exemptions
NCTR	FDA National Center for Toxicological Research
NDA	New Drug Application
NDE/MIS	New Drug Evaluation Management Information System
NIAID	National Institute of Allergy and Infectious Diseases
NIDA	National Institute on Drug Abuse
NIEHS	National Institute for Environmental Health Sciences
NIH	National Institute of Health
NLEA	Nutrition Labeling and Education Act
NME	New Molecular Entity
NPR	National Partnership for Reinventing Government
NPRM	Notice of Proposed Rulemaking
NRC	National Research Council
NTP	National Toxicology Program
NVPO	National Vaccine Program Office
OASIS	Operational and Administrative System for Import Support
OBRR	Office of Blood Research and Review (CBER)
OPA	Office of Premarket Approvals (CFSAN)
ORA	FDA Office of Regulatory Affairs
ORISE	Oak Ridge Institute for Science and Education
OSHA	Occupational Safety and Health Administration
OTC	Over-the-Counter
OTR	Office of Testing and Research (CDER)
OTRR	Office of Therapeutics Research and Review (CBER)
OVRR	Office of Vaccines Research and Review (CBER)
PAS	FDA Public Affairs Specialist
PDPs	Product Development Protocols
PDUFA	Prescription Drug User Fee Act of 1992

PIFSI	Produce and Food Safety Initiative
PLA	Product License Application
PMA	Premarket Approval (Application to market medical device that requires premarket approval)
PODS	Project-Oriented Data System
PQRI	Product Quality Research Initiative
QSIT	Quality System Inspection Technique
RA	Rheumatoid Arthritis
RCHSA	Radiation Control for Health and Safety Act
REGO	Reinventing Government Initiative
RIMS	Regulatory Information Management Staff (CBER)
RMS-BLA	Regulatory Management System-Biologics License Application
RVIS	Residue Violation Information System
SAB	Science Advisory Board
SAMHSA	Substance Abuse and Mental Health Services Administration
SE	Salmonella Enteriditis
SN/AEMS	Special Nutritional Adverse Events Monitoring System
STARS	Submission Tracking and Review System
StmDT104	Salmonella Tphimurium DT 104
TB	Tuberculosis
TRIMS	Tissue Residue Information System
UK	United Kingdom
UMCP	University of Maryland-College Park
USDA	United States Department of Agriculture
VAERS	Vaccine Adverse Event Reporting System
VFD	Veterinary Feed Directive
VICH	Veterinary International Conference on Harmonization
WHO	United Nations World Health Organization
WTO	World Trade Organization