Foods

	FY 2001 Actual Obligations	FY 2002 Current Estimate	FY 2003 +/-FY 2002 Current Estimate	FY 2003 Baseline Estimate
Total Program Level	**$287,504,000**	**$404,599,000**	**+ $7,498,000**	**$412,097,000**
Center	*$125,888,000*	*$145,293,000*	*+ $2,819,000*	*$148,112,000*
FTE	*879*	*909*	*+ 13*	*922*
Field	*$161,616,000*	*$259,306,000*	*+ $4,679,000*	*$263,985,000*
FTE	*1,566*	*1,942*	*+ 234*	*2,176*
Current Law BA	**$287,504,000**	**$404,599,000**	**+ $7,498,000**	**$412,097,000**
Counter Terrorism	*378*	*92,947*	*0*	*92,947*
Pay Increase[1/]			*+ $7,895,000*	*$7,895,000*
Mgmt. Efficiencies			*($397,000)*	*($397,000)*
Current Law BA Accrual Costs[2/]	**$14,078,000**	**$16,856,000**	**+ $1,063,000**	**$17,919,000**
Total Current Law BA with Accrual Costs	**$301,582,000**	**$421,455,000**	**+ $8,561,000**	**$430,016,000**
FTE	**2,445**	**2,851**	**+ 247**	**3,098**

1/Pay increases shown on separate line, and not reflected in individual initiative areas.
2/Reflects 2001 and 2002 comparable estimates.

Historical Funding and FTE Levels

Fiscal Year	Program Level	Budget Authority	User Fee	Program Level FTE
1999 Actuals	$235,168,000	$235,168,000	0	2,339
2000 Actuals	$279,704,000	$279,704,000	0	2,386
2001 Actuals	$287,504,000	$287,504,000	0	2,445
2002 Current Estimate[3/]	$404,599,000	$404,599,000	0	2,851
2003 Estimate	$412,097,000	$412,097,000	0	3,098

3/ Includes FDA's FY 2002 Appropriation and the Counter Terrorism Supplemental.

MISSION

- Ensure that the food supply, quality of foods, food ingredients, and dietary supplements are safe, nutritious, wholesome, and honestly labeled and that cosmetics are safe and properly labeled;

- Set standards and develop regulations for the food industry;

- Take timely and appropriate action on new food ingredients before they go on the market to ensure their safety and effectiveness;

- Research ways to provide the necessary basis for regulatory decisions;

- Identify food-related health hazards;

- Take corrective action to reduce human exposure to these hazards and the possibility of food-related illnesses and injuries; and,

- Educate and train consumers and industry on food safety.

PROGRAM RESOURCE CHANGES

The FY 2003 request builds upon funding FDA received from the FY 2002 appropriation plus the FY 2002 emergency supplemental for Counter Terrorism. As a result, while FDA has received increased funding to support counter terrorism, some of the programs are showing either no funding increase, or a slight decrease. The FY 2003 request annualizes those dollars received as one-time money in the supplemental -- a significant increase to the Agency of $152,276,000 in total. The funding changes shown below are the differences once these annualized dollars are removed.

For the Foods program, in FY 2003, FDA will continue to utilize $92,550,000 provided in the supplemental to maintain the level of effort and the frequency and quality of imported food inspections. The Agency will also continue to modernize the import data system to better detect tainted food, and deter and detain food thought to be contaminated.

Counter Terrorism – Food Safety: + 251 FTE ($92,550,000)

Under the Federal Food, Drug, and Cosmetic (FFD&C) Act (Sec. 704), FDA is granted general authority to inspect food establishments; under FFD&C Act (Sec. 903), the Agency shall be responsible for research relating to foods and cosmetics in carrying out this Act; and, under FFD&C Act (Sec. 801 and 803), the Agency shall assess potentially violative imports, enhance the safety of imported products through surveillance at the border, and provide that source country quality systems/standards/audits conform to the requirements of the FFD&C Act.

- Enhance the frequency and quality of imported food inspections, and modernize the import data system to enable better detection of tainted food, and deter and detain food thought to be

contaminated. These increased inspection and surveillance activities will work to ensure that our food supply is better protected;

- Hire 630 new employees over a two-year period to improve the Agency's capacity to respond to terrorist threats and attacks; increase field exams and sample collection and analysis, and for increased domestic inspections and laboratory analyst capacity. This will support compliance, policy and enforcement actions anticipated from the more than doubling of Field import staff and corresponding inspections, sampling, testing, and wharf exams;

- Procure High Performance Liquid Chromatography (HPLC) equipment needed for rapid analysis of suspect foods to assay for biological or chemical agents that could be intentionally introduced into a food. These rapid detection instruments, Bio-sensors, can be used in a variety of settings to detect food, environmental and waterborne pathogens. These instruments are special ordered from a sole source supplier and will be tested under an agreement with New Mexico State University;

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

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

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

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

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

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

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

- Upgrade field laboratory capabilities to rapidly detect bioterrorism contamination;

- Continue enhancements of strategic data systems for surveillance and inspection activities of the food supply that will help FDA inspectors focus their inspections and analyses of products suspected to have microbiological contamination;

- Develop preventative standards, education campaigns and research to improve food safety and security through rapid tests of detection and reduction; develop and implement sound risk communication strategies; and, continue national network of academic centers of excellence to strengthen scientific standards for compliance and threat assessment and reduction;

- Provide multiple government agencies engaged in food safety regulatory activities with the ability to rapidly detect, compare and communicate unusual findings in laboratory analyses through OASIS and eLEXNET. The eLEXNET system is an Internet based exchange of pathogenic findings in foods between laboratories, which will link State and local organizations with the Federal partners to respond more quickly to outbreak situations;

- Provide technical assistance to develop irradiation to kill anthrax spores in the mail participating with industry, which already uses irradiation to sanitize poultry, ground beef, spices, and medical equipment;

- Deploy Radiation Emergency Response teams working with other Federal and state agencies to monitor radiation threats to the food supply and provide technical and food processing assistance;

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

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

- Provide the operations and maintenance support necessary for the import and domestic product monitoring equipment and information systems purchased with the FY 2002 supplemental funds, and provide rapid methods to test products in the field.

Reduce the health risks associated with food and cosmetic products by preventing human exposure to hazards, monitoring product quality and correcting problems that are identified. (Strategic Goal #2)

Increase food import surveillance by hiring 300 new investigators and analysts who will increase the number of physical exams by 100 percent and conduct sample analyses of products with suspect histories. (Performance Goal #11011)

Pay Increase: + $7,895,000

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 people-intensive. Payroll accounts for over 60 percent of the total FDA budget.

This has a significant impact on all activities in FDA. FDA is requesting $28,552,000 to cover pay-related increases. The Foods program piece of this increase is $7,895,000.

Management Efficiencies: -$397,000 and 4 FTE

FDA's budget assumes savings of $2,578,000 associated with efficiency improvements and consolidations related to the President's Management Plan. The Foods program piece of this total reduction is $397,000 and four FTE.

JUSTIFICATION OF BASE

Activities Related to Increases for FY 2003

Counter Terrorism - Food Safety

- Further development of diagnostic tests to produce tools that are needed for field and import examinations to determine if a product has been tampered with or is otherwise tainted;

- Continue support of increased inspectors, analysts, and laboratory staff (provided by FY 2002 Supplemental) at the busiest Ports-of-Entry, including sample collections for laboratory analysis, and field physical examinations needed to evaluate products for contamination;

- Purchase equipment and train import inspectors to enhance and streamline import sample collections processes at ports of entry and to provide more rapid identification of suspect agents;

- Enhance strategic data systems for surveillance and inspection activities of the food supply that will help FDA inspectors focus their inspections and analyses of products suspected to have microbiological contamination;

- Enhance FDA's Adverse Event Reporting Systems. The Agency's Adverse Event Reporting Systems are designed to compile and assess large numbers of physician, health professional data and conclusions and provide likely associations and causative agents for follow-up through investigation and clinical testing;

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

- Perform FACTS data cleanup to improve accuracy of our inventory of food firms: The effort entails evaluation and standardization of poor quality data and resolving duplicates; then applying the same logic in real-time to incoming records from U.S. Customs Service and the FDA field force;

- Collaborate with other government agencies (e.g. DOD, CDC, NIH, NRC, and DOE) on counter terrorism activities and participate in counter terrorism response interagency working groups; and,

- Monitor security standards at laboratory facilities, plans for improved security measures and procedures, and effective coordination with all FDA components.

Payroll

- FDA's Foods Program has primary responsibility for assuring that the food supply of the U.S. is safe, sanitary, wholesome, and honestly labeled, and that cosmetic products are safe and properly labeled. Since foods continue to be susceptible to an ever-growing variety of potentially hazardous substances including microbial pathogens, chemical residues, natural toxins, and illegal food additives, FDA has an enormous responsibility that has a direct impact on the health of every man, woman and child in the nation. Payroll is devoted to meet these responsibilities; and,

- The field component of Foods inspects regulated industry, and collects and analyzes samples. Other activities are review and management of enforcement actions, and consumer complaints, trace back efforts to determine the cause of foodborne illness outbreaks, and review of import entries for admissibility decisions. These functions are inherently governmental and highly personnel intensive.

Domestic Inspections

- Conduct domestic inspections (food safety activities) at the following levels: 11,000 inspections conducted by FDA; 8,300 inspections conducted via State contracts;

- Inspect, annually, at least 95 percent of domestic firms which have been identified as high-risk food establishments, currently estimated at 7,000. Inspections will utilize associated laboratory support for sample analysis. High-risk firms include processors of infant formula, ready to eat foods, produce, seafood products, low-acid canned foods, and juice; and,

- Work with states to implement a three-year strategy to enhance FDA audit and evaluation of State inspection programs, and increase the rate of State contract audit inspections to ensure consistent application of regulations nationwide by FDA and States.

Inspect 95 percent of high-risk domestic food establishments once every year. (Performance Goal #11020)

Imports and Foreign Inspections

- Increase food import exams by 97 percent, from a little over 12,000 to almost 24,000 annually;

- Conduct foreign inspections, focusing on top priority high-risk foods so that the Agency can further assure that products offered for import are safe, effective, and properly labeled; and,

- Conduct foreign outreach and education/training to enhance food safety systems in foreign countries and thus, improve the quality of food products imported into the United States.

Import Monitoring

- Review more than 5,700,000 import line entries (including both food and cosmetic products) for admissibility into domestic commerce;

- Continue to support operations and maintenance support of (OASIS) to ensure continuity of import operations in the event of a disabling threat to existing facilities; and,

- Work with the U.S. Customs Service to better leverage resources to enhance the safety of imported products through surveillance at the border.

Bovine Spongiform Encephalopathy (BSE)

- Continue to identify food and cosmetic products containing brain, spinal cord, and other specific risk materials (SRMs), including the origin of the animal and country, and infectious agents in foods;

- Continue to conduct any necessary standard setting/compliance activities relating to BSE that may include, if appropriate, the development of proposed and final rules concerning the ban of bovine prohibited materials from cosmetics, dietary supplements, food additives, infant formula and all other food products. In addition, continue with activities relating to re-evaluation of certain gelatin products;

- Conduct research on decontamination/deactivation procedures;

- Conduct research on BSE Agency recovery/identification methods from foods/cosmetics;

- Conduct research on the risk factors and mechanism for Chronic Waste Disease (CWD) which affects elk, deer and other domestic game/pen-reared animals; and,

- Participate in international BSE meetings to ensure safety of the U.S. food supply, and provide up-to-date information on the emerging public health issues to the public.

International Activities

- Participate in the 17 Codex committees and related ad hoc task forces, as well as related working groups and scientific advisory committees (e.g., Joint Expert Committee on Food Additives (JECFA)) to ensure that source country standards, quality systems, and audits conform to the requirements of the Federal Food, Drug, and Cosmetic Act.

Premarket Activities

- Reduce the possibility of food related deaths or injuries and improve the health and well-being of consumers by ensuring that decisions related to approvals of petitions and notifications are scientifically justified and benefit the public health;

- Develop standards for premarket review of new products and emerging technologies such as genetically modified foods, dietary supplements, infant formulas and medical foods, to ensure that foods are properly labeled when there is a significant change in the modified food as compared to traditional food. Examples of significant changes include a nutritional change, compositional change, change in the condition of use, or when an allergenic component has been introduced in a food where it is not present in the traditional food;

- Improve the premarket review process for food and color additives using advanced computer and telecommunications technologies;

- Provide pre-filing assistance to petitioners through the publication of detailed guidance for food contact substances and food color additives; and,

- Target sampling and analysis of fresh produce through the development of Good Agricultural Practices (GAPs) and GMPs.

Provide consumers quicker access to new food ingredients bioengineered foods, and dietary supplements, while assuring their safety. (Strategic Goal #1)

Review 95 percent of premarket notifications for food contact substances in the receipt cohort of FY 2002 within the statutory time limit (120 days). (Performance Goal #11034)

Other

- Evaluate the risks of pesticides and chemical contaminants, and the level of food nutrients in the American diet, based on the revised FDA Total Diet Program. Data will provide information on levels of pesticides, industrial chemicals, toxic elements, and vitamins and minerals in foods that is more representative of today's consumer eating habits; and,

Maintain current level of monitoring for pesticides and environmental contaminants in foods through the collection and analysis of a targeted cohort of 8,000 samples. (Performance Goal #11027).

- Advance FDA's egg safety, as well as other compliance and enforcement programs.

Other Activities Related to High Priority Areas

Dietary Supplements

- Respond to 95 – 100 percent of premarket notifications for new dietary ingredients within the statutory time frame (75 days);

- Review the 30-day postmarket notifications for structure/function claims in a timely manner;

- Collaborate across the Agency to publish a proposal for labeling dietary supplements for women who are or may become pregnant;

- Publish a dietary supplement Good Manufacturing Practice (GMP) proposed rule and conduct an outreach program; and,

- Collaborate on dietary supplement research with the National Center for Natural Products Research in Oxford, Mississippi, as well as with the National Academy of Sciences' Institute of Medicine to review dietary supplement safety.

Respond to 95 percent of notifications for dietary supplements containing "new dietary ingredients" within 75 days. (Performance Goal #11025)

SELECTED FY 2001 ACCOMPLISHMENTS

Counter Terrorism

- Supported emergency response efforts associated with food outbreaks connected with suspected or actual counter terrorist activities; and,

- Prepared field staff to safely seize, remove, and dispose of contaminated products by developing procedures and providing appropriate facilities and equipment.

Post Market Assurance Adverse Event Reporting

- Completed development of the first prototype model of the CFSAN Adverse Events Reporting System (CAERS). CAERS will integrate the multiple adverse events reporting systems currently in existence in CFSAN, including the current system for dietary supplements.

Transmissible Spongiform Encephalopathy (TSE)/Bovine Spongiform Encephalopathy (BSE)

- Reinforced the existing import ban, in collaboration with USDA/APHIS, with more specific product information on CFSAN-regulated products, including food products, dietary supplements and cosmetics that contain bovine materials from BSE-identified countries, so that banned products do not enter the United States.

Imports and Foreign Inspections

- Published a proposed rule that will require marking, prior to exportation, all foods refused for safety reasons. The proposed rule will address concerns about adequate controls by the U.S. Customs Service (USCS) as it assures that marked products are exported and not re-entered into the U.S. marketplace. It will also address communication with Customs about refused shipments while FDA and USCS develop procedures about marking of refused foods; and,

- Designed industry partnerships to assure food safety and provided training supported certification of procedures for the reconditioning of imported spices; and sponsored training of industry in product security and safety.

Domestic Inspections

- Awarded Innovative Food Safety Grants to13 State and Local regulatory agencies in the amount of $505,000; $140,000 to 28 States in Small Conference Grants to support Food

Safety Task Force Meetings; and 38 State food contracts for over 6,443 food inspections costing a total of $3,450,000.

Emergency Operations

- Managed, tracked, and investigated 146 food emergencies (outbreaks, tampering reports, and adverse reactions); and,

- Initiated and conducted 24 food product tracebacks, including pathogen-related incidents. Examples of foodborne pathogens tracked which affected a multi-state area include a *salmonella-Thompson* outbreak in tomatoes; a *shigella sonnei* in salsa; hepatitis A found in green onions and tomatoes; *s.* typhimurium found in pericardial membranes in Japan and the United States; *salmonella poona* found in cantaloupes; and, *vibrio vulnificus* found in oysters.

International Outreach

- Conducted two Regional Food Safety Workshops ("Roadshows") on key U.S. food safety initiatives (Asia and South Africa); and,

- Developed provisions and negotiating language with leading Mexican officials for a cooperative agreement that will improve the safety of the food supplies in both countries. The arrangement, which relies on mutual assurances to protect confidentiality of non-public information, will help reduce the incidence of food-borne illnesses (including contamination) in both countries.

Seafood Safety

- Developed an overall public health strategy for methylmercury in commercial seafood, including a determination if the current consumer guidance should be revised;

- Completed an evaluation of FDA's Seafood HACCP program for calendar years 1998 and 1999, available at: www.cfsan.fda.gov/~comm/seaeval.html. The report showed substantial progress by the seafood processing industry in implementing the full range of preventive controls that became mandatory in December 1997, as measured against a baseline study performed in 1992;

- Issued a "Mid-Course" correction to the Seafood HACCP program to focus on high risk processors, including firms that need to control the spread of pathogens; firms that need to control the spread of histamines, which can cause allergic reactions; and firms that do not have HACCP plans. The General Accounting Office (GAO) released a report evaluating FDA's seafood HACCP program which concluded that while FDA has made progress in ensuring the safety of seafood through HACCP, the program needs to be strengthened in order to reach its full objective. Accordingly, FDA is instituting a Mid-Course Correction to further strengthen its Seafood HACCP program. The document is at: www.cfsan.fda.gov/~comm/shaccp1.html; and,

- Published the *Vibrio parahaemolyticus* risk assessment and worked with the Interstate Shellfish Sanitation Conference (ISSC) on control plan implementation.

Fruits and Vegetables

- Published the final rule "Hazard Analysis and Critical Control Point (HAACP); Procedures for the Safe and Sanitary Processing and Importing of Juice" (66 FR 6137; January 19, 2001). FDA adopted final regulations to ensure the safe and sanitary processing of fruit and vegetable juices that mandate the application of HACCP principles;

- Completed an evaluation of the FDA Survey of Domestic Fresh Produce analyzing 1,000 imported produce samples for the presence of microbial pathogens. A copy of this evaluation is available at: www.cfsan.fda.gov/~dms/prodsur6html; and,

- Conducted two Regional Good Agriculture Practices Training Programs, in Central America and Brazil, as "Train-the-Trainer" courses in collaboration with the Joint Institute of Food Safety and Applied Nutrition (JIFSAN).

Egg Safety

- Published the final rule "Food Labeling, Safe Handling Statements, Labeling of Shell Eggs; Refrigeration of Shell Eggs Held for Retail Distribution" (65 FR 76091; December 5, 2000). FDA revised its food labeling regulations to require a safe handling statement on cartons of shell eggs that have not been treated to destroy Salmonella microorganisms. FDA also is requiring that, when held at retail establishments, shell eggs be stored and displayed under refrigeration at a temperature of 7.2 deg. C (45 deg. F) or less. FDA took these actions due to the number of outbreaks of foodborne illnesses and deaths caused by *Salmonella Enteritidis (SE)* associated with the consumption of shell eggs; and,

- Conducted an education campaign for the egg labeling and refrigeration rule where print materials for consumers were produced.

Listeria

- Published, jointly with USDA, a draft risk assessment on *Listeria monocytogenes* contamination in food (66 FR 5515; January 19, 2001), and convened a public meeting to solicit comments on the draft risk assessment and draft action plan on *Listeria*; and,

- Finalized a *Listeria* control and interventions research plan. This document will be made available as a reference to facilitate further discussion or analysis relevant to FDA's *Listeria* research efforts. It will also be a planning tool for identifying and incorporating new research needs in FDA's overall research plan.

Education

- Distributed a senior citizen food safety video and 25 publications as a package to 800 offices of the Administration on Aging; 10,000 senior day care centers; FDA field public affairs specialists; and all county and state Extension service offices;

- Created and distributed *Science and Our Food Supply*, an innovative, interactive supplementary curriculum for use in middle level and high school science classes in the

United States, in collaboration with the National Science Teachers Association. Schools were encouraged to include this in their 2000-2001 school year curriculum;

- Established a microbiology laboratory especially designed for rapid throughput of imported food samples collected for microbiological analysis at FDA's Northeast Regional Laboratory in New York. Using specialized methods and equipment, this lab was able to cut analysis time from over 20 hours to less than eight hours per sample. FDA intends to expand this concept to other field microbiology laboratories;

- Installed new mass spectrometry equipment in its field pesticide laboratories, and trained its analysts in the use of a method developed by a FDA scientist. Using this new technique, FDA laboratories can detect over 100 pesticides, undetectable by older methods; and,

- Oversaw the development of eLEXNET, the nation's first seamless data exchange system for food safety testing information, and facilitated data exchange between local, state, and federal agencies. After a successful pilot with E. coli 0157:H7, the program is being expanded to include data concerning other microorganisms including Salmonella, Listeria and Campylobacter.

Premarket Review of Food and Color Additives and Food Ingredients

- Approved nine of 10 food additive petitions subject to expedited review that are intended to decrease the incidence of foodborne illnesses through their antimicrobial actions against human pathogens that may be present in food. Pending and completed petitions eligible for expedited review are listed at: http://www.cfsan.fda.gov/~dms/opa-expd.html; and,

- Completed the safety evaluation of 20 of 22 (91percent) of food and color additive petitions that did not qualify for expedited review for the petition receipt cohort of FY 2000 within 360 days of filing; and, 22 of 37 (59.9 percent) food and color additive petitions thereby exceeding the goal of reducing by 50 percent the number of pending food and color additive petitions that were more than one year overdue.

Nutrition, Health Claims and Labeling

- Issued a letter to manufacturers regarding conventional foods that contain novel ingredients, such as botanicals, that often bear claims to provide certain health benefits. A copy of this letter is available at: http://www.cfsan.fda.gov/foi/warning.html; and,

- Issued warning letters to define boundaries among product categories and prevent misleading claims and ensure ingredients in product are safe. Issued warning letters to ten manufacturers of "protein bars" and to four manufacturers of conventional foods that contain botanical ingredients. These letters are at: www.cfsan.fda.gov/foi/warning.html.

Dietary Supplements

- Issued a final determination on a proposed health claim for vitamin B and reduced risk of vascular disease in dietary supplement labeling. A copy of this letter is available on our web site at http://www.cfsan.fda.gov/~dms/ds-ltr12.html;

- Issued a final determination on a proposed health claim for antioxidant vitamins and reduced risk of certain kinds of cancer in dietary supplement labeling. FDA determined that there is no significant scientific agreement for the relationship between consumption of antioxidant vitamins and reduced risk of certain kinds of cancer, and that the scientific evidence for a relationship outweighs the scientific evidence against the relationship. Therefore, FDA determined that such a proposed claim could not be made non-misleading with a disclaimer or other qualifying language. A copy of this letter is available at: www.cfsan.fda.gov/~dms/ds-ltr23.html;

- Issued a final determination on a proposed health claim for vitamin E and reduced risk of heart disease in dietary supplement labeling. FDA determined that there is no significant scientific agreement for the relationship between consumption of supplemental vitamin E and reduced risk of heart disease, and that the scientific evidence for a relationship outweighs the scientific evidence against the relationship. Therefore, FDA determined that such a proposed claim could not be made non-misleading with a disclaimer or other qualifying language. A copy of this letter is available at: www.cfsan.fda.gov/~dms/ds-ltr16.html; and,

- Announced in the *Federal Register* the rendering of a single source cooperative agreement with the University of Mississippi's National Center for Natural Products Research (NCNPR) to implement a collaborative research program for botanical dietary supplements. This cooperative agreement serves as the vehicle for a long-term working relationship with the University of Mississippi.

Chemical Contaminants, Pesticides and Other Hazards

- StarLink™ Corn Related Activities: Published guidance to the industry entitled "FDA Recommendations for Sampling and Testing Yellow Corn and Dry-Milled Yellow Corn Shipments Intended for Human Food Use for Cry9C Protein Residues". Cry9C is a pesticidal protein that was introduced into the StarLink™ variety of yellow corn using recombinant deoxyribonucleic acid (DNA) techniques to make the corn more resistant to certain types of insects. StarLink™ corn is lawful only for use in animal feed, not human food. However, some Cry9C-containing corn was commingled with yellow corn intended for human use;

- Collected 236 samples of foods made from corn products or cornmeal and tested them for the presence of StarLink™ corn. Six products were found to contain StarLink™ corn. All products remaining on the market with positive findings were recalled; and,

- Participated in interagency meetings and meetings with industry representatives to ensure timely and thorough review of issues resulting from the inadvertent contamination of food products with StarLink™ corn.

International Activities

- **Codex Committees and Working Groups:** Participated in 17 Codex committees, ad hoc task forces, and related drafting and working groups and scientific advisory committee meetings. The Codex Alimentarius system presents a unique opportunity for all countries to

join the international community in formulating and harmonizing food standards and ensuring their global implementation; and,

- **North American Free Trade Agreement (NAFTA) TWGs**: Participated in the NAFTA Technical Working Group (TWG) on Labeling, Packaging and Standards in Washington, DC. Topics discussed at this meeting included; dietary supplements, functional foods, health claims, structure/function claims, nutrition labeling, trans fatty acid labeling, shell egg labeling, biotech labeling, food allergens, and standards of identity.

Biotechnology

- Published the biotechnology mandatory premarket notification proposal (66 FR 4706; January 18, 2001). FDA proposed that manufacturers be required to submit to the Agency, data and information regarding plant-derived bioengineered foods that would be consumed by humans or animals. FDA needs information about bioengineered foods to ensure that all market entry decisions by the industry are made consistently and in full compliance with the law.

Food Allergens

- Established a strategy for developing clearer labeling of food allergens on food labels, emphasizing the eight major food allergens. To further increase awareness, these allergens were incorporated into broader food safety programs, including the 2001 Food code, the draft Juice Hazards and Controls Guide, the Seafood Hazards and Controls Guide (3rd edition), and the Pasteurized Milk Ordinance; and,

- Established a web site for all allergen-related documents. The site address is www.cfsan.fda.gov/~dms/wh-alrgy.html.

FDA University/Education

- As a part of FDA University conducted in-house development and implementation of seminars, professional meetings and courses that increased the science-based knowledge of the FDA's review staff which can help reduce review times and backlogs. Also initiated key "core training" activities.

Foods
Program Activity Data

Program Workload and Output	FY 2001 Actual	FY 2002 Estimate	FY 2003 Estimate[4/]
FOOD & COLOR ADDITIVE PETITIONS			
Applications Submitted	50	50	50
Percent Reviewed	66	60	60
PROGRAM OUTPUTS - DOMESTIC INSPECTIONS[1/]	**FY 2001 Actual**	**FY 2002 Estimate**	**FY 2003 Estimate**
Domestic Food Safety Program Inspections	4,666	5,000	6,000
Imported and Domestic Cheese Program Inspections	392	300	400
Domestic Low Acid Canned Food/Acidified Foods Inspections	809	1,435	2,000
Domestic Fish & Fishery Products (HAACP) Inspections	3,283	4,715	5,000
Import (Imported Seafood Program including HAACP) Inspections	650	700	800
Interstate Travel Sanitation (ITS) Inspections	1,446	1,894	2,500
State Food Safety (Non HAACP) Inspections	4,365	8,300	9,000
State Contract Domestic Seafood HAACP Inspections	673	700	1,000
State Partnership Inspections	1,870	1,900	2,000
Total FDA and State Contract Inspections	**18,154**	**24,944**	**28,700**
Domestic Field Exams/Tests[2/]	2,016	3,000	5,000
Domestic Laboratory Samples Analyzed[3/]	10,889	14,090	14,090
PROGRAM OUTPUTS - IMPORT/FOREIGN INSPECTIONS[1/]			
All Foreign Inspections	209	250	250
Import Field Exams/Tests[2/]	12,169	24,000	48,000
Import Laboratory Samples Analyzed[3/]	14,863	21,200	21,200
Import Line Entry Decisions	4,589,081	5,139,770	5,396,759

FIELD COSMETICS

PROGRAM OUTPUTS - DOMESTIC INSPECTIONS[1/]	FY 2001 Actual	FY 2002 Estimate	FY 2003 Estimate
All Inspections	128	100	100
Domestic Field Exams/Tests[2/]	25	75	75
PROGRAM OUTPUTS - IMPORT/FOREIGN INSPECTIONS[1/]			
Import Field Exams/Tests[2/]	282	700	700
Import Laboratory Samples Analyzed[3/]	129	125	125
Import Line Entry Decisions	505,849	566,551	594,879

1/An inspection is any visit to a firm during which all or part of one or more phases of that establishment's operation is evaluated against appropriate agency requirements.
2/A Field Exam is the on-site examination of a product that is sufficient in itself to determine whether the product is in compliance with Agency requirements. Examples of exams include visual, organoleptic, quick color, and rapid abrasion.
3/Laboratory Samples Analyzed are product samples physically analyzed by the laboratory to determine whether or not the product is in compliance with agency requirements.
4/When fully implemented, the FY 2003 requested increase for all Field programs will provide additional domestic inspections performed by FDA depending on progress in hiring, training, and equipping new staff.

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Human Drugs

	FY 2001 Actual Obligations	FY 2002 Current Estimate	FY 2003 +/-FY 2002 Current Estimate	FY 2003 Baseline Estimate
Total Program Level	**$322,480,000**	**$366,897,000**	**+ $91,082,000**	**$457,979,000**
Center	*$248,463,000*	*$281,869,000*	*+ $74,071,000*	*$355,940,000*
FTE	*1,784*	*1,906*	*+ 128*	*2,034*
Field	*$74,017,000*	*$85,028,000*	*+ $17,071,000*	*$102,039,000*
FTE	*748*	*835*	*+60*	*895*
Current Law BA	**$218,515,000**	**$260,709,000**	**+ $16,608,000**	**$277,317,000**
Counter Terrorism	*$775,000*	*$15,063,000*	*+ $3,034,000*	*$18,097,000*
Pay Increase 1/			*+ $7,188,000*	*$7,188,000*
Medical Errors	*$25,940,000*	*$30,040,000*	*+ $2,200,000*	*$32,240,000*
Generic Drugs	*$35,155,000*	*$41,220,000*	*+ $4,582,000*	*$45,802,000*
Mgmt. Efficiencies			*($396,000)*	*($396,000)*
Current Law BA Accrual Costs2/	**$11,466,000** 2/	**$11,841,000**	**+ $1,215,000**	**$13,056,000**
Current Law BA with Accrual Costs2/	**$229,981,000**	**$272,550,000**	**+ $17,823,000**	**$290,373,000**
FTE	**1,824**	**2,019**	**+ 89**	**2,108**
Current Law User Fees	**$103,965,000**	**$106,188,000**	**($106,188,000)**	**$0**
PDUFA II	**711**	**722**	**(722)**	**0**
FTE				
Current Law User Fee Accrual Costs2/	**$4,324,000**	**$4,741,000**	**$0**	**$0**
Current Law User Fees with Accrual Costs2/	**$108,289,000**	**$110,929,000**	**$0**	**$0**
FTE	**711**	**722**	**0**	**0**
Proposed User Fees				
PDUFA III	**$0**	**$0**	**+ $180,662,000**	**$180,662,000**
FTE	**0**	**0**	**+ 821**	**821**
Proposed Law User Fee Accrual Costs2/	**$0**	**$0**	**+ $5,168,000**	**$5,168,000**
Proposed Law User Fees with Accrual Costs	**$0**	**$0**	**+ $185,830,000**	**$185,830,000**
FTE	**0**	**0**	**+ 821**	**821**

1/Pay increases shown on separate line, and not reflected in individual initiative areas.
2/Reflects 2001 and 2002 comparable estimates.

Historical Funding and FTE Levels

Fiscal Year	Program Level	Budget Authority	User Fee	Program Level FTE
1999 Actuals	$278,299,000	$200,423,000	$77,876,000	2,456
2000 Actuals	$311,234,000	$215,538,000	$95,696,000	2,509
2001 Actuals	$322,480,000	$218,515,000	$103,965,000	2,532
2002 Current Estimate 3/	$366,897,000	$260,709,000	$106,188,000	2,741
2003 Estimate	$457,979,000	$277,317,000	$180,662,000	2,929

3/ Includes FDA's FY 2002 Appropriation and the Counter Terrorism Supplemental.

MISSION

- Ensure the safety and effectiveness of all drug products used for the prevention, diagnosis, and treatment of disease;
- Ensure the prompt approval of safe and effective new drugs so that patients can enjoy the benefits provided by therapies to treat and prevent illness and disease;
- Review premarket applications for new and generic drugs in a timely and quality manner, as well as new and generic drug supplemental applications;
- Monitor adverse drug events to detect safety problems that only become evident after the approval and actual use of a drug;
- Evaluate reports of adverse events, medication errors and product defects associated with drug products;
- Enhance DHHS' ability to react to terrorist attacks and assure public health;
- Use postmarket surveillance reporting, and the collection and analysis of drug product samples to evaluate compliance with quality standards and labeling requirements;
- Conduct inspections to determine if fraudulent drugs are marketed in commercial channels, and evaluate foreign and domestic compliance with GMPs; and,
- Oversee the orphan product program that reviews and approves requests for orphan product designations, which includes granting sponsors seven years of marketing exclusivity. Award grant funding to defray costs of qualified clinical testing incurred in connection with the development of drugs for rare diseases and conditions.

PROGRAM RESOURCE CHANGES

The FY 2003 request builds upon funding FDA received from the FY 2002 appropriation plus the FY 2002 emergency supplemental. As a result, while FDA has received increased funding to support counter terrorism, some of the programs are showing either no funding increase, or a slight decrease. The FY 2003 request annualizes those dollars received as one-time money in the supplemental -- a significant increase to the Agency of $152,276,000 in total. The funding changes shown below are the differences once these annualized dollars are removed.

For the Human Drugs program, in FY 2003, FDA will continue to utilize $14,250,000 provided in the supplemental, plus an additional $3,034,000 to maintain efforts begun in FY 2002. FDA received the increase to enhance the Agency's ability to react to terrorist attacks by assuring the availability of medicines to the American public.

Counter Terrorism – Safe and Effective Medical Products: + $3,034,000 and 42 FTE ($14,250,000 annualized from the CT Supplemental)

Under Section 505 of the Federal Food, Drug, and Cosmetic Act, the Human Drugs Program is responsible for reviewing data submitted in research and marketing applications for new drug products and determining the safety and effectiveness of these products.

- Expedite review of active Investigational New Drug (IND) applications for use either to mitigate or prevent pathological effects of bioterrorism-related pathogens in humans and products under development to treat adverse events associated with the smallpox vaccine;

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

- Develop staff expertise regarding the threat agents and numerous treatment options under development in order to build the capability of expediting the review and approval of safe and effective products;

- Continue support for expedited review and research of drugs, therapeutics, vaccines, and antitoxins that would be administered to humans in the event of a bioterrorism attack;

- Continue review and approval of every drug, therapeutic, vaccine, and anti-toxin that is to be administered to humans and every diagnostic tool that is to be used clinically must be reviewed and approved by FDA;

- Increase coverage by investigators at our border locations and at seaport and airport locations. Increase import field exams, sample collections and physical examinations of regulated products; and

- Monitor clinical research and conduct in-plant pre-approval inspections to ensure that manufactured products are safe and effective.

Publish guidance for Industry on developing antimicrobial drugs for inhalation anthrax (post-exposure). (Performance Goal)

Facilitate the initiation of research in a non-human primate model of pneumonic plague. (Performance Goal)

Expedite the review of protocols for investigational new drugs (INDs) to treat organophosphorous nerve agents in the event of chemical attack. Encourage sponsors of these new drug applications (NDAs) to update current labeling for Antidote Treatment Nerve Agent, Autoinjectors (ATNAA). (Performance Goal)

Identify and begin to address labeling gaps in the therapeutic armamentarium for the prevention, mitigation, and treatment of illnesses case by chemical and biological attacks, including the needs for special populations, such as pregnant women, pediatric, and geriatric populations. (Performance Goal)

Facilitate human clinical trials in pneumonic plague for antimicrobial drugs that are not yet labeled for this treatment indication. (Performance Goal)

Develop guidance for Industry on developing antiviral drugs for treatment of smallpox. (Performance Goal)

Pay Increase: + $7,188,000

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 people-intensive. Payroll accounts for over 60 percent of the total FDA budget. This has a significant impact on all activities in FDA. FDA is requesting $28,552,000 million to cover pay-related increases. The Drugs program piece of this increase is $7,188,000.

Medical Errors: + $2,200,000 and 11 FTE

Under 21 United States Code 355 (the new drug provisions of the Federal Food, Drug, and Cosmetic Act), FDA is granted authority to take action on the sale of pharmaceuticals if the Agency discovers imminent hazard to public health. FDA must collect safety information to determine where the hazards exist.

- Continue improving the Adverse Event Reporting System (AERS) to include electronic data entry initiatives. This will encourage more reporting by making it easier for drug manufacturers to submit reports. The Agency will continue drafting regulations to support electronic submissions;

- Further enhance Agency postmarket surveillance through implementation of International Conference on Harmonization (ICH) commitments in the U.S. In addition, the Agency will participate in ICH initiatives, including global analysis and evaluation of adverse event reports and assessment of a product's risk versus benefits profile;

- Implement the third phase of the Medical Device Surveillance Network (MeDSuN) to include drug products. MeDSuN is a pilot program designed to train hospital personnel to accurately identify and report injuries and deaths associated with medical products;

- Conduct additional risk management and risk communication research, including pilot initiatives to minimize preventable adverse drug reactions and medication errors;

- Continue participation in DHHS' Patient Safety Task Force. The DHHS task force coordinates the collection and analysis of data from existing federal systems; develops efforts to help avert risks to patient safety; and communicates with other entities regarding reporting systems and safe practices;

- Continue developing an electronic drug registration and listing system that enable FDA to obtain more accurate information on drugs currently marketed; and,

- Enhance communications with the medical community on import drug issues.

Prevent unnecessary injury and death to the American public caused by adverse drug reactions, injuries, medication errors and product problems. (Strategic Goal #2)

Streamline the adverse event reporting system. (Performance Goal #12007)

Generic Drugs: + $4,582,000 and 40 FTE

Under Section 505 of the Federal Food, Drug, and Cosmetic Act, the Human Drugs Program is responsible for reviewing data submitted in research and marketing applications for new drug products and determining the safety and effectiveness of these products.

- Hire additional reviewers and staff that support OGD to accelerate the review and approval of Abbreviated New Drug Applications (ANDAs). Guided by an overall plan, resources will also be used for technology upgrades needed to meet the expected increase in generic drug applications;

- Improve the review of ANDAs without sacrificing product quality. This will allow the Agency to set a more challenging goal or reviewing 75 percent of ANDAs within 6 months after submission. FDA will meet statutory requirements for all but the most complicated generic drug applications;
- Hire additional inspectors to increase inspections of domestic and foreign firms by 15 percent. This is critical to reducing total approval times for generic drug applications. The resources will also be used to provide for team inspections (reviewer and inspector) to increase efficiency;

- Increase coverage of imported generic drugs by 10 percent so that FDA can better monitor the quality of finished drug products and bulk drug substances entering the U.S. from overseas; and,

- Analyze generic drugs that are stockpiled by the Department of Defense (DOD) in the event of a terrorist attack. Generic drugs that are close to their expiration date (shelf life) are tested, and if they are still at 100 percent potency, they are approved for continued storage, saving DOD millions of dollars each year.

Review and act upon 75 percent of fileable original generic drug applications within six months. (Performance Goal #12003)

Management Efficiencies: -$396,000 and -4 FTE

FDA's budget assumes savings of $2,578,000 associated with efficiency improvements and consolidations related to the President's Management Plan. The Human Drugs program piece of this total reduction is $396,000 and 4 FTE.

Proposed Law User Fees

Prescription Drug User Fee Act III (PDUFA) III: + $185,830,000 and 821 FTE

The FDA Modernization Act of 1997 reauthorized the collection of user fees to enhance the review process of new human drugs and biological products and established fees for applications, establishments, and approved products. PDUFA expires at the end of 2002. FDA is working on a proposal to reauthorize PDUFA and make enhancements to it. FDA strongly believes in the success of PDUFA and that it serves as a model for reinventing government with Congress, the Agency, the industry, and consumer groups all working together providing necessary resources, setting performance goals, and establishing accountability. Human Drugs would receive $185,830,000 of the FY 2003 budget request of $272,038,000 in new user fees to reauthorize (PDUFA).

JUSTIFICATION OF BASE

Activities Related to Increases for FY 2003

Counter Terrorism - Safe and Effective Medical Products

- Enhance DHHS' ability to react to terrorist attacks by assuring the availability of medicines to the American public. Prepare for a bioterrorist attack involving smallpox, anthrax, plague, botulinum, or other infectious agents. These may be genetically engineered to resist current therapies and evade vaccine-induced immunity;

- Develop a ready response field capability to quickly detect and respond to a potential bioterrorism agent;

- Assure product availability through expansion of the drug shortage program to ensure there is an adequate supply of critical drugs;

- Start the regulatory review process as early as possible with sponsors and organizations that are developing therapeutics for biological or chemical agents;

- Proactively work with organizations to obtain approvals, including inspections of manufacturing processes to assure compliance with Good Manufacturing Practices, and post-marketing surveillance of adverse events;

- Utilize contractual services and collaborate with the Department of Defense (DOD) in the development of primate models that would be used to study the treatment of Yersenia and Smallpox;

- Hire reviewers to research the regulatory and scientific background of combination regimens and to create a framework for addressing future regulatory applications on the use of both a vaccine and drug. This would help FDA determine if combination regimens could permit the use of fewer doses, reduce the degree of side effects, increase tolerance of the product, and facilitate compliance of the product; and,

- Participate in exercises related to responding to a bioterrorist attack.

Payroll

- FDA's Human Drugs program ensures the safety and effectiveness of all drug products used for the prevention, diagnosis, and treatment of disease. FDA also ensures the prompt approval of safe and effective new drugs so that patients can enjoy the benefits provided by therapies to treat and prevent illness and disease. The Agency reviews premarket applications for new and generic drugs in a timely and quality manner, as well as new and generic drug supplemental applications; and,

- The field component of Human Drugs inspects regulated industry, and collects and analyzes samples. Other activities that often arise are review and management of enforcement actions, and consumer complaints, trace back efforts, and review of import entries for admissibility decisions. These functions are inherently governmental and highly personnel intensive.

Medical Errors

Ensure that products are safe throughout their entire life cycle by using surveillance systems to monitor the safety of the products, their use and their consumption;

- Receive adverse event and medical error reports via the AERS database. Monitor these reports to specifically detect outbreaks of illness that might have been caused by a chemical or biological attack. FDA receives and records over 260,000 individual postmarketing safety reports (ISRs) per year;

- Operate the MedWatch Program directed toward health care professionals to voluntary report observed or suspected defects and quality problems associated with marketed drug products. FDA reviews the reports to identify potential health hazards, initiates investigational follow-up and takes appropriate enforcement action. The Agency reviews hundreds of thousands of reports per year and numerous reports result in product recalls and voluntary corrective actions by industry;

- Maintain the Agency's program of postmarketing surveillance and risk assessment to identify adverse drug events (ADEs) that did not appear during the drug development process by collecting, evaluating and acting upon information on ADEs associated with marketed products;

- Identify health hazards associated with the manufacturing, labeling, and packaging of pharmaceuticals and remove unsafe and ineffective products from the marketplace; and,

- Participate in the Patient Safety Task Force, established within DHHS to integrate medical error data collection efforts, coordinate research and analysis efforts, and to develop strategies to implement patient safety programs.

Expedite processing and evaluation of adverse drug events through implementation of AERS that allows for electronic periodic data entry and acquisition of fully coded information from drug companies. (Performance Goal #12007)

Generic Drug Review

- Support an active generic drugs program to review and act upon Abbreviated New Drug Applications (ANDAs). Focus on expanding the availability of high quality generic drug products to the public and providing consumers with information on their safety and effectiveness; and,

- Increase efficiency and improve review times; evaluate ways to increase resources devoted to information technology; and continue development and implementation of generic drug education programs.

Other Activities Related to High Priority Areas

New Drug Application Review

- Regulate the testing of investigational new drugs (INDs) and evaluate new drug applications (NDAs) received from sponsors;

- Review and act upon standard and priority efficacy supplements -- supplemental applications proposing to add a new use of an approved drug to a product's labeling;
- Review and act upon manufacturer applications that notify FDA in advance of packaging, location, machinery, processes or supplier changes; and,

- Electronic Submissions: Leverage information technology to make FDA a results-oriented and customer-focused agency. Approximately 75 percent of original NDAs now include sections that conform to the electronic submission guidance. CDER averaged approximately 100 electronic submissions per month, including full NDAs, supplemental NDAs, and amendments.

Pediatric Drug Studies

- Grant six months of marketing exclusivity to manufacturers who conduct and file pediatric studies. The six months is an economic incentive offered to the manufacturers provided in return for FDA to gain additional information about a drug's usage in the pediatric population; and,

- Publish a list of drugs for which pediatric information may be beneficial; work with sponsors to develop and issue written requests for pediatric studies; review submitted studies; and make exclusivity determinations; and,

- Establish an Office of Pediatric Therapeutics, which will coordinate all FDA pediatric activities. Among other responsibilities, the Office will review all adverse event reports related to pediatric patients.

Implement, evaluate, track and report on the clinical trials FDA is requesting under FDAMA or requiring under the Pediatric Rule. (Performance Goal #12026)

Over-the-Counter Drugs

- Review over-the-counter (OTC) drugs to ensure their safety and effectiveness and assist consumers on how to best use OTC products. FDA took steps to remove phenylpropanolamine from all drug products and requested that all drug companies discontinue marketing products containing phenylpropanolamine.

Give consumers and health professionals more easily understandable prescription and OTC drug information. (Performance Goal #12027)

Import Monitoring and Inspections

- Focus on product quality standards and compliance by manufacturers with the good manufacturing practices (GMP) regulations to ensure that the highest possible quality products are marketed;

- Conduct field inspections and compliance actions, including post approval human drug inspections, surveillance GMP inspections for human drugs, as well as appropriate follow-up to complaints or adverse event reports;

- Conduct criminal investigations of reported product tampering, counterfeit products and other fraudulent criminal activities involving regulated drug products;

- Perform laboratory validation of analytical methods submitted to support premarket product applications; and,

- Collaborate with the European Union to assess equivalence of regulatory systems to ensure imported products comply with U.S. standards. FDA will continue equivalence assessments through FY 2002. This agreement will ultimately allow reciprocal reliance on inspections of

pharmaceutical manufacturing plants between equivalent regulatory authorities and improve border operations.

Antimicrobial Resistance

- Participate, in cooperation with other Public Health Service Agencies, in several major initiatives to address what is considered to be a major threat to the Public Health in the new millennium: the emergence of drug-resistant bacteria; and,

- Address the growing problem of the development of antibiotic resistance by encouraging the development of new antimicrobials and preserving the usefulness of those already available.

Clinical Pharmacology

- Provide financial assistance to investigators who conduct research as part of their clinical pharmacology training. Previous grantees in this program include: Indiana University, the University of Illinois at Peoria, Meharry Medical College, the State University of New York at Binghamton, and the Mayo Clinic.

Human Drug Related Research

- Leverage scientific capabilities to respond and contribute to major breakthroughs in pharmaceutical research and technology via continued professional development/ training, and continued stakeholder collaborations; and,

- Continue to collaborate with research scientists from academia and industry within the Product Quality Research Initiative (PQRI). The PQRI conducts research in the areas of pharmaceutical chemistry, biopharmaceutics, and science management to identify better test methods for assessing quality of products and to identify optimal manufacturing and management processes.

  CDER will conduct laboratory research on at least three projects identified as related to the mission of PQRI. (Performance Goal #12016)

Outreach with Stakeholders

- Maintain various lines of communication with stakeholders. Outreach programs include the pharmacist education outreach program to help pharmacists better explain the drug approval process to consumers, and a generic drug outreach program that will help consumers understand that generic drugs are as safe and effective as their brand name counterparts; and,

- Collaborate with industry and scientific and regulatory experts to discuss electronic submissions, user fees, risk management, product quality, drug safety and other issues on drug development and manufacturing.

Diabetes

- Review an Investigational New Drug (IND) submitted by NIH to examine the effect of various interventions on the risk of diabetes.

Asthma

- Participate in a DHHS group that addresses asthma initiatives; and,

- In conjunction with the Asthma and Allergy Foundation of America, develop a public health flier entitled, "What People Should Know About CFC-free MDIs".

Human Subject Protection

- Conduct inspections of clinical investigators and sponsors. Monitor Investigational Review Boards (IRBs), non-clinical laboratories, and bioequivalence facilities to ensure the protection of the rights and welfare of human subjects who participate in clinical studies;

- Verify the reliability and accuracy of data collected by regulated industry in clinical and non-clinical (animal) studies;

- Review Establishment Inspection Reports (EIRs) pertaining to clinical investigators, sponsors, non-clinical laboratories, and bioequivalence facilities for violations and take corrective actions such as disqualification of clinical investigators;

- Conduct inspections and data audits to monitor all aspects of the conduct and reporting of drug product research involving human subjects; and,

- Conduct inspections to assure the quality and integrity of data submitted to the Agency in support of new drug applications.

> *Protect human research subjects who participate in drug studies and assess the quality of data from these studies by conducting approximately 780 onsite inspections and data audits annually. (Performance Goal #12032)*

Prescription Drug User Fee Act (PDUFA)

The FDA Modernization Act of 1997 reauthorized the collection of user fees to enhance the review process of new human drugs and biological products and established fees for applications, establishments, and approved products. PDUFA expires at the end of 2002. FDA is working on a proposal to reauthorize PDUFA and make enhancements to it.
Review performance monitoring is being done in terms of cohorts, e.g., the FY 2000 cohort includes applications received from October 1, 1999 through September 30, 2000. The FY 2000 cohort review performance goals covered under PDUFA for New Drug Applications (NDA), Product License Application (PLA), and Biologics License Application (BLA) are:

- Reviewed and acted on 90 percent of standard original NDAs/PLAs/BLAs filed during FY 2000 within 12 months of receipt and reviewed and acted on 50 percent within 10 months of receipt in compliance with PDUFA goals; and,

- Reviewed and acted on 90 percent of priority original NDA and PLA/BLA submissions filed during FY 2000 within six months of receipt.

SELECTED FY 2001 ACCOMPLISHMENTS

Counter Terrorism

- Collaborated with NIH to develop antiviral agents for the treatment of smallpox. Also worked with various government agencies to define appropriate animal models for developing drugs to treat smallpox;

- Approved one "emergency" investigational new drug and expedited the approvals of two manufacturing supplements to respond to needs resulting from the September 11, 2001 terrorist attacks. The drug products involved were topical antibiotics used to treat burns;

- Developed a draft guidance regarding the safe and effective use of potassium iodide as an adjunct to other public health protective measures in the event that radioactive iodine is accidentally released into the environment;

- Obtained and reviewed all available data on patients with pneumonic plague in the U.S. from 1957 through 1999. Worked with the CDC and the U.S. Army to determine what additional data, such as animal data or other clinical data, are necessary to support the labeling of gentamicin for plague;

- Created a counter terrorism website (www.fda.gov/cder/drugprepare/default.htm) which provides links to the most current information on drug therapy and vaccines, plus advice on purchasing and taking medication. This site complements the Agency's comprehensive counter terrorism website, (www.fda.gov/oc/opacom/hottopics/bioterrorism.html);

- Collaborated and created websites on counter terrorism with the Johns Hopkins University Center for Civilian Biodefense: www.hopkins-biodefense.org; and,

- Continued to enhance the drug registration and listing databases to have current information on the location of manufacturing facilities of important life saving drugs.

Generic Drug Review

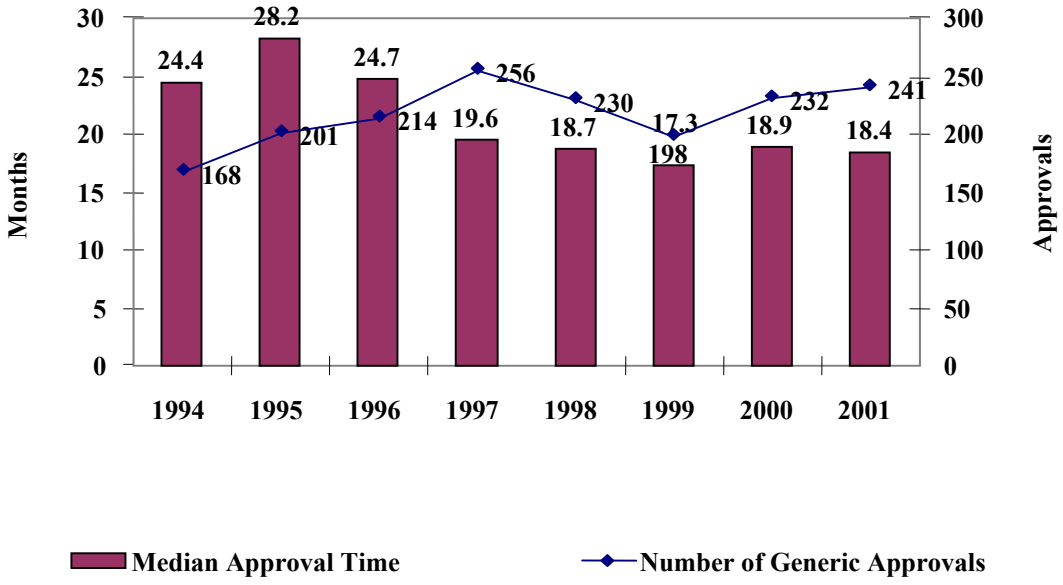
- Supported an active generic drugs program focused on expanding the availability of high quality products to the public;

- With an increase in FY 2001, fully annualized positions filled in the Office of Generic Drugs (OGD) in FY 2000 and hired additional staff, reviewing and acting upon 55.6 percent of original generic drug applications within 6 months after the submission date for an increase of more than 27 percent over FY 1999. The Agency also anticipates that this increase will help meet its FY 2001 goal (final FY 2001 data will not be available until April 2002);

- Decreased the median approval time from 18.9 months to 18.4 months in FY 2001 (see Figure 2). FDA continues to refine the review process to increase efficiency. There are certain factors outside the control of OGD that lengthen the approval process for generic drugs. These include the need to adhere to the review queue structure, timeliness of inspecting the manufacturing plants, and legal issues raised late in the review process. FDA

continues to examine every aspect of the review process to identify problem areas that need to be addressed; and,

Figure 2
Generic Drug Approvals



- Examples of important first time generic approvals are listed in Table 3 below.

Table 3
Notable Generic Drug Approvals

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

Patient Safety

- Participated in the Patient Safety Task Force, established within DHHS to integrate medical error data collection efforts, coordinate research and analysis efforts, and to develop strategies to implement patient safety programs;

- Proposed a new prescription drug-labeling rule that will help reduce medical errors. The proposed new labeling will reduce practitioners' time spent looking for information, decrease the number of preventable medical errors, and improve treatment effectiveness;

- Awarded three new three-year contracts that will permit access to drug utilization data from pediatric inpatient, general inpatient, and general longitudinal databases to expand postmarketing drug surveillance capability;

- Cosponsored the nation's first certificate program with Temple University's School of Pharmacy and the Institute for Safe Medication Practices on medication safety as part of Temple's Doctor of Pharmacy program; and,

- Created a Medication Errors Homepage on FDA's website at: www.fda.gov/cder/drug/MedErrors/default.htm.

Postmarket Assurance - Adverse Event Reporting System

- Implemented an Electronic Submission Product Test Pilot for AERS in October 2000 for easier submission and processing of adverse event reports. Over 11,000 individual case safety reports were submitted electronically under the pilot program in FY 2001;

- Enhanced the compliance and Freedom of Information portions of AERS by making it more accessible to compliance staff and improving compliance-related search capabilities; and,

- Implemented new version of AERS, enhancing the ability of the system to accept electronic submissions. Released a draft guidance for industry, "*Providing Regulatory Submissions in Electronic Format - Postmarketing Expedited Safety Reports*".

Prescription Drug User Fee Act (PDUFA)

The Prescription Drug User Fee Act (PDUFA) established performance goals for the evaluation of applications for marketing drug and certain biological products. Review performance monitoring is being done in terms of cohorts, *e.g.*, the FY 2001 cohort includes applications received from October 1, 2000 through September 30, 2001;

- Table 1 below illustrates PDUFA performance for the FY 2000 cohort data; and,

Table 1
Fiscal Year 2000 Cohort (as of 10/31/01)

Submission Type	Number of Submissions Filed	Goal (months)	Number of Reviews "On Time"	Percent of Reviews "On Time"
New Drug Applications (NDAs)				
Priority	29	90% in 6 months	28	97%
Standard	92	90% in 12 months 50% in 10 months	89 73	97% 79%
New Molecular Entities (NMEs)				
Priority	17	90% in 6 months	16	94%
Standard	14	90% in 12 months 50% in 10 months	13 7	93% 50%
NDA Resubmissions-				
Class 1	25	90% in 4 months 70% in 2 months	25 24	100% 96%
Class 2	55	90% in 6 months	54	98%
Efficacy Supplements-				
Priority	18	90% in 6 months	18	100%
Standard	157	90% in 12 months 50% in 10 months	156 142	99% 90%
Manufacturing Supplements-				
CBE	754	90% in 6 months	738	98%
Requiring Prior Approval	684	90% in 6 months 50% in 4 months	662 509	97% 74%

- Met or exceeded all 15 performance review goals for the FY 2000 receipt cohort. In addition, FDA met or exceeded all review goals for New Molecular Entities (NME), a subset of the NDA category. An NME contains an active substance that has never been approved for marketing in any form in the U.S.

New Drug Evaluation

- Initiated 186 actions on NDAs, of which 71 were approvals. The median total approval time in FY 2001 was 12.5 months. Fifteen of the 71 NDA approvals were NMEs. Five of the 15 NMEs were given a priority review (products offering notable improvements over currently marketed drugs);

- Approved 10 priority applications: five NMEs, five NDAs that were not NMEs, and eight priority efficacy supplements; and,

- Significant new drugs approved in FY 2001 are listed in Table 2 below.

Table 2
Significant NDAs Approved in FY 2001

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

Over-the-Counter (OTC) Drug Products

- Approved the following new drug products and/or indications for OTC marketing (see Table 4 below).

Table 4
Notable OTC Drug Approvals

Drug	*Purpose*
Pepcid Complete Antacid/Famotidine/165	Relieves heartburn associated with acid indigestion
Immodium Advanced	Controls diarrhea
Monistat 3 Combination Pack	Vaginal antifungal and cream for external relief of symptoms
Tavist Allergy/Sinus/Headache	Pain reliever/fever reducer/antihistamine/decongestant
Nasalcrom*	Prevents and relieves nasal allergy symptoms down to age 2
Monistat 1*	Vaginal antifungal

*Efficacy supplements

Pediatric Drug Studies

- Issued 43 Written Requests, which address, among other things, the type of studies to be performed, study design, appropriate study age groups, and clinical endpoints. Made 19 Pediatric Exclusivity Determinations, granting exclusivity to those drugs (see Figure 4 below);

- Approved and labeled nine drugs for pediatric use. As of October, 2001, over 47,000 children have participated in clinical trials as a result of the studies FDA requested under the exclusivity provision;

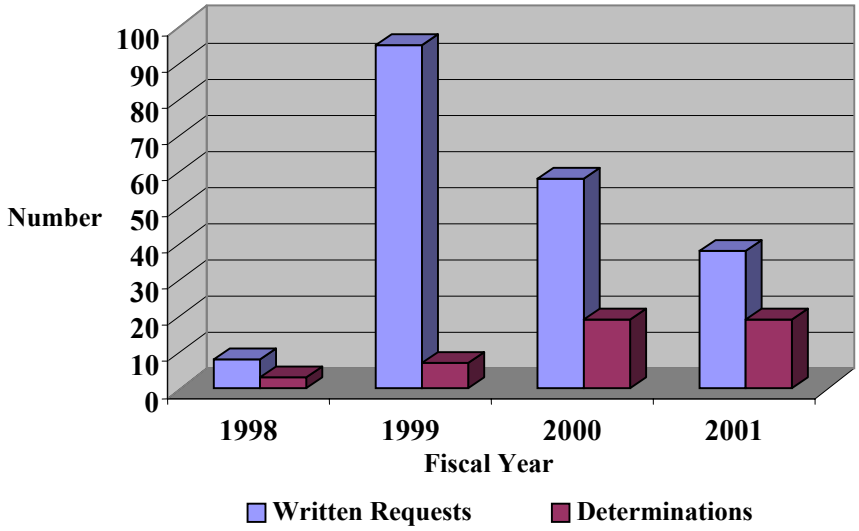
- Contracted for the development of an inpatient pediatric database that will be used to accumulate information on the use of drugs in children in the inpatient care setting, e.g., children's hospitals, community hospitals, and chronic care facilities;

- Prepared and forwarded to Congress the *Report to Congress on Pediatric Exclusivity*. The report concluded that the exclusivity provision has been highly effective in generating pediatric studies in many drugs and in providing useful new information in product labeling. It also concluded that some categories of drugs and some age groups remain inadequately studied, however, despite the new incentives. The report provided suggestions for modifications to the provision that may address these gaps;

- Participated in a working group that prepared the *Report of the Surgeon General's Conference on Children's Mental Health: A National Action Agenda*. The Action Agenda outlines goals and strategies to improve the services for children and adolescents with mental health problems and their families; and,

- Updated the annual list of approved drugs for which pediatric information may produce health benefits in the pediatric population. Issued an interim rule on April 24, 2001 to provide additional safeguards for children enrolled in clinical trials.

Figure 4
Pediatric Exclusivity
Written Requests and Determinations



E-Government Initiative

- Received approximately 75 percent of original NDAs, which included sections that conformed to the electronic submission guidance. Over a third were completely electronic. FDA averaged approximately 100 electronic submissions per month, including full NDAs, supplemental NDAs, and amendments. Since the program began, FDA has seen over a 50 percent reduction in the average number of paper volumes for NDAs. The Electronic Document Room was expanded to manage receipt and handling of full electronic NDAs. Electronic submissions reduce the review time and approval of NDAs;

- Published the draft guidance "*Providing Regulatory Submissions in Electronic Format - Prescription Drug Advertising Material and Promotional Labeling"* for providing advertising and promotional material in electronic format and had a pilot program to receive these submissions electronically;

- Drafted guidance documents for internal comment on "Providing Regulatory Submissions in Electronic Format - Postmarketing Periodic Adverse Drug Experience Reports," "Providing Regulatory Submissions in Electronic Format – IND," and "Providing Regulatory Submissions in Electronic Format - Annual Reports." Also drafted guidance on "Providing Regulatory Submissions in Electronic Format - Drug Registration and Listing;" and,

- Finalized a proposed rule that would require NDA applicants to submit final printed labeling content electronically to the Agency for review. FDA anticipates that in the near future it will be able to accept all drug applications in electronic format, including INDs.

Leveraging and Outreach

- Communicated with consumers and patients through seminars on risk management and safe use of drugs; expanded information available via the Internet; and disseminated consumer-focused information on new and innovative drug approvals via a drug web page;

- Presented a discussion on "CDER Live!", a talk show aimed primarily at the pharmaceutical industry co-sponsored by the Drug Information Association. The programs are broadcast live by satellite or by webcast. The broadcast explored the proposed revisions to prescription labeling regulations that are designed to make information easier to find, read and use; and,

- Provided educational information to students, health care professionals, and consumers through the CDERLern seminar program. CDERLern focuses on FDA's mission and discusses its role in the new drug development process.

FDA University

- As a part of FDA University conducted in-house development and implementation of seminars, professional meetings and courses that increased the science-based knowledge of the FDA's review staff, which can help reduce review times and backlogs.

Human Drugs
Program Activity Data

Program Workload and Outputs	FY 2001 Actual	FY 2002 Estimate	FY 2003 Estimate[4/]
Total New Drug Application (NDA) Reviews	186	190	210
NDAs approved	71	80	88
Time from Receipt to Approval (mos.)(mean)	(16.4)	(14.0)	(13.5)
Time from Receipt to Approval (mos.)(median)	(12.5)	(12.5)	(12.0)
NDA Supplemental Reviews	2,852	2,860	2,900
Abbreviated New Drug Application (ANDA) Actions	1,333	1,400	1,470
ANDA Approvals	241	256	268
Average Review Time from ANDA Receipt to Approval (mos.)	20.9	19	18
ANDA Supplemental Actions	4,576	4,708	4,826
INDs (Active)	11,100	10,800	10,600
Clinical Pharmacology/BioPharmaceutic Reviews	1,510	1,525	1,540
OTC Monographs Under Development	13	15	15
Adverse Reactions Reports	275,000	305,000	330,000
Drug Quality Reporting System Report	2,300	2,400	2,500
PROGRAM OUTPUTS - DOMESTIC INSPECTIONS[1/]			
Preapproval Inspections (NDA)	142	190	360
Preapproval Inspections (ANDA)	109	165	170
Bioresearch Monitoring Programs Inspections	540	750	750
Drug Processing (GMP) Program Inspections	930	949	1,450
Compressed Medical Gas Manufacturers Inspections	393	337	330
Adverse Drug Events Project Inspections	63	77	80
OTC Monograph Project Inspections	23	20	20
Health Fraud Project Inspections	80	80	80
State Partnership: Compressed Medical Gas Manufacturers Inspections	156	150	120
Total FDA and State Contract Inspections	2,436	2,718	3,490
Domestic Field Exams/Tests[2/]	200	20	20
Domestic Laboratory Samples Analyzed[3/]	1,802	1,460	1,500
PROGRAM OUTPUTS - IMPORT/FOREIGN INSPECTIONS[1/]			
Foreign Preapproval Inspections (NDA)	133	199	280
Foreign Preapproval Inspections (ANDA)	97	80	100
Foreign Bioresearch Monitoring Program Inspections	52	100	100
Foreign Drug Processing (GMP) Program Inspections	219	111	240
Foreign Adverse Drug Events Project Inspections	17	25	30
Total Foreign FDA Inspections	518	515	750
Import Field Exams/Tests[2/]	1,487	1,500	3,700
Import Laboratory Samples Analyzed[3/]	132	295	200
Import Line Entry Decisions	111,631	125,027	131,278

1/An inspection is any visit to a firm during which all or part of one or more phases of that establishment's operation is evaluated against appropriate agency r
2/Field Exam is the on-site examination of a product that is sufficient in itself to determine whether the product is in compliance with agency requirements. Examples of exams include visual, organoleptic, quick color, and rapid abrasion.
3/Laboratory Samples Analyzed are product samples physically analyzed by the laboratory to determine whether or not the product is in compliance with agency requirements.
4/When fully implemented, the FY 2003 requested increase for all Field programs will provide additional domestic inspections performed by FDA depending on progress in hiring, training, and equipping new staff.

Office of Orphan Products Development

	FY 2001 Actual Obligations	FY 2002 Current Estimate	FY 2003 +/- FY 2002 Current Estimate	FY 2003 Baseline Estimate
Total Program Level	**$15,031,000**	**$16,031,000**	--	**$16,031,000**
Grants	$12,542,000	$13,392,000	--	$13,392,000
Administration 1/	$2,489,000	$2,639,000	--	$2,639,000

1/Administrative expenses are funded in Other Activities.

Historical Funding

Fiscal Year	*Grant Level*
1999 Actuals	$11,248,000
2000Actuals	$11,542,000
2001 Actuals	$12,542,000
2002 Current Estimate	$13,392,000
2003 Estimate	$13,392,000

MISSION

Since it was created in 1982, the Office of Orphan Products Development (OOPD) has been dedicated to promoting the development of products that demonstrate promise for the diagnosis and/or treatment of rare diseases or conditions.

JUSTIFICATION OF BASE

OOPD administers the orphan products development program. This program identifies orphan products and facilitates their development. Although the OOPD Grants Program has been expanded to include clinical studies for medical foods and devices that meet the "orphan" criteria established by Congress, the Orphan Drug Act pertains primarily to drug and biological products.

The 1983 Orphan Drug Act guarantees the developer of an orphan product seven years of market exclusivity following the approval of the product by FDA. The following procedures are administered by the Office of Orphan Products Development:

- Reviewing and approving requests for orphan product designation;
- Overseeing the orphan product program that gives sponsors seven years of exclusive marketing for orphan products;
- Coordinating research study design assistance for sponsors of drugs for rare diseases;
- Encouraging sponsors to conduct open protocols, allowing patients to be added to ongoing studies; and,
- Awarding grant funding to defray costs of qualified clinical testing incurred in connection with the development of drugs for rare diseases and conditions.

Since the passage of the Orphan Drug Act, OOPD has designated 1,100 products to treat rare diseases. Two hundred twenty four of these orphan products have received FDA market approval, and are now available to treat a potential patient population of more than 11 million U.S. citizens. In contrast, the decade prior to 1983 saw fewer than 10 such products come to market. Twenty-seven of these approved orphan products were developed with funding from the orphan product grant program.

SELECTED FY 2001 ACCOMPLISHMENTS

- Received 119 applications for orphan designation. Based on reviews conducted by OOPD medical, and pharmaceutical review staff, 67 products received designation as orphan products. Eleven orphan products received FDA market approval for the treatment of rare diseases;

- During the grant 2001 cycle, OOPD received 64 applications for funding; 24 applicants received grants. Since 1983, the orphan grant program has funded a total of $150 million in rare disease research. Grant funding was $12.5 million;

- Reviewed all Humanitarian Device Exemption (HDE) applications within the statutory timeframe. Following establishment of FDA's 1996 final rule to carry out the humanitarian use devices (HUD) provisions of the Safe Medical Devices Act, OOPD staff assumed responsibility for reviewing applications for a HDE required for HUD approval; and,

- Continued to facilitate the development of treatments for rare diseases worldwide. Consulted with interested European Community legislators, and spent considerable time briefing and mentoring members of the Committee on Orphan and Medicinal Products (COMP) of the European Agency for the Evaluation of Medicinal Products (EMEA). Hosted visits from representatives of foreign legislative organizations currently investigating new strategies for orphan product development.

List of Orphan Product Approvals in FY 2001

Generic Name/ Trade Name	***Date Designated = DD Date Approved= MA***	***Indication***	***Sponsor and Address***
Alemtuzumab *Campath*	DD: 10/20/97 MA: 5/7/01	Treatment of chronic lymphocytic leukemia.	Millennium and ILEX Partners, LP 75 Sidney Street Cambridge MA 02138
Antivenin, crotalidae Polyvalent immune Fab (ovine) *CroFab*	DD: 1/12/94 MA: 10/2/00	Treatment of envenomations inflicted by North American crotalid snakes.	Protherics, Inc. 1207 17th Ave. S. Suite 103 Nashville TN 37212
Botulinum toxin type A *Botox*	DD: 8/20/86 MA: 12/21/00	Treatment of cervical dystonia.	Allergan, Inc. 2525 Dupont Drive P.O. Box 19534 Irvine CA 92623-9534

Botulinum toxin type B *NeuroBloc*	DD: 1/16/92 MA: 12/8/00	Treatment of cervical dystonia.	Elan Pharmaceuticals 800 Gateway Blvd. South San Francisco CA 94080
Fomepizole *Antizole*	DD: 12/22/88 MA: 12/8/00	Treatment of methanol or ethylene glycol poisoning.	Orphan Medical, Inc. 13911 Ridgedale Drive Suite 250 Minnetonka MN 55305
Imatinib *Gleevec*	DD: 1/31/01 MA: 5/10/01	Treatment of chronic myelogenous leukemia.	Novartis Pharmaceuticals 59 Route 10 East Hanover NJ 07936
Mitoxantrone *Novantrone*	DD: 8/13/99 MA: 10/13/00	Treatment of progressive-relapsing multiple sclerosis.	Immunex Corporation 51 University St. Seattle WA 98101
Mitoxantrone *Novantrone*	DD: 8/13/99 MA: 10/13/00	Treatment of secondary-progressive multiple sclerosis.	Immunex Corporation 51 University St. Seattle WA 98101
somatropin [rDNA] *Genotropin*	DD: 12/27/00 MA: 7/25/01	Treatment of growth failure in children who were born small for gestational age.	Pharmacia and Upjohn Company 7000 Portage Road Kalamazoo MI 49001
Topiramate *Topamax*	DD: 11/25/92 MA: 8/28/01	Treatment of Lennox-Gastaut syndrome.	R. W. Johnson Pharmaceutical Research Institute Route 202, P.O. Box 300 Raritan NJ 08869-0602
Zoledronate *Zometa, Zabel*	DD: 8/18/00 MA: 8/20/01	Treatment of tumor induced hypercalcemia.	Novartis. Pharmaceuticals Corp 59 Route 10 East Hanover NJ 07936

Total orphan approvals FY 2001= 11

Biologics

	FY 2001 Actual Obligations	FY 2002 Current Estimate	FY 2003 +/- FY 2002 Current Estimate	FY 2003 Baseline Estimate
Total Program Level	**$147,230,000**	**$175,675,000**	**+ $33,648,000**	**$209,323,000**
Center	*$122,432,000*	*$146,922,000*	*+ $31,988,000*	*$178,910,000*
FTE	*809*	*935*	*+ 75*	*1,010*
Field	*$24,798,000*	*$28,753,000*	*+ $1,660,000*	*$30,413,000*
FTE	*232*	*255*	*+ 6*	*261*
Current Law BA	**$108,303,000**	**$140,331,000**	**+ $6,518,000**	**$146,849,000**
Counter Terrorism	3,113,000	23,066,000	*+ $2,512,000*	25,578,000
Pay Increase 1/			*+ $3,102,000*	*$3,102,000*
Medical Errors	2,503,000	4,703,000	*+ $1,300,000*	*6,003,000*
Mgmt. Efficiencies			*(396,000)*	*(396,000)*
Current Law BA Accrual Costs2/	**$4,930,000**	**$5,496,000**	**+ $555,000**	**$6,051,000**
Total Current Law BA with Accrual Costs2/	**$113,233,000**	**$145,827,000**	**+ $7,073**	**$152,900,000**
FTE	**786**	**937**	**+ 40**	**977**
Current Law User Fees				
PDUFA II	**$38,927,000**	**$35,344,000**	**($35,344,000)**	**$0**
FTE	**255**	**253**	**(253)**	**0**
Current Law User Fee Accrual Costs2/	**$1,559,000 2/**	**$1,662,000**	**$0**	**$0**
Total Current Law User Fees with Proposed Accruals	**$40,486,000**	**$37,006,000**	**$0**	**$0**
FTE	**255**	**253**	**0**	**0**
Proposed User Fees				
PDUFA III	**$0**	**$0**	**+ $62,474,000**	**$62,474,000**
FTE	**0**	**0**	**+ 294**	**294**
Proposed Law User Fee Accrual Costs	**$0**	**$0**	**+ $1,850,000**	**$1,850,000**
Total Proposed Law User Fees with Proposed Accruals	**$0**	**$0**	**+ $64,234,000**	**$64,324,000**
FTE			**+ 294**	**294**

1*/Pay increases shown on separate line, and not reflected in individual initiative areas.*
2/Reflects 2001 and 2002 comparable estimates.

Historical Funding and FTE Levels

Fiscal Year	Program Level	Budget Authority	User Fee	Program Level FTE
1999 Actuals	$126,165,000	$96,823,000	$29,342,000	989
2000 Actuals	$140,717,000	$106,133,000	$34,584,000	991
2001 Actuals	$147,230,000	$108,303,000	$38,927,000	1,041
2002 Current Estimate **3/**	$175,675,000	$140,331,000	$35,344,000	1,190
2003 Estimate	$209,323,000	$146,849,000	$62,474,000	1,271

3/*Includes FDA's FY 2002 Appropriation and the Counter Terrorism Supplemental.*

MISSION

- Ensure the safety, efficacy, potency and purity of biological products including vaccines, therapeutics, and related drugs and devices intended for use in the treatment, prevention or cure of diseases in humans;

- Ensure the safety of the nation's supply of blood and blood products;

- Evaluate the safety and effectiveness of biological products before marketing, and monitors the pre-clinical and clinical testing of new biological products;

- License biological products and manufacturing establishments, including plasmapheresis centers, blood banks, vaccine and biotechnology manufacturers;

- Conduct regulatory research to establish product standards and develop improved testing methods; and,

- Assure the safety of marketed biological products through monitoring adverse experiences, lot release testing and postmarket surveillance.

PROGRAM RESOURCE CHANGES

The FY 2003 request builds upon funding FDA received from the FY 2002 appropriation plus the FY 2002 emergency supplemental for Counter Terrorism. As a result, while FDA has received increased funding to support counter terrorism, some of the programs are showing either no funding increase, or a slight decrease. The FY 2003 request annualizes those dollars received as one-time money in the supplemental -- a significant increase to the Agency of $152,276,000 in total. The funding changes shown below are the differences once these annualized dollars are removed.

For the Biologics program, in FY 2003, FDA will continue to utilize $19,800,000 provided in the supplemental, plus an additional $2,512,000 to develop safe and effective vaccines and

biological products in preparation for defense against biological weapons. The Agency will also continue to guide these products through the regulatory process, which includes the manufacturing process, pre-clinical testing, and license application review process determines the speed with which these products will be available for use.

Counter Terrorism – Safe and Effective Medical Products: + $2,512,000 and 38 FTE ($19,800,000 annualized from the CT Supplemental)

The authority to operate the program is found under Title 42 CFR Subchapter II Part F Subpart 1.

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

- Expedite the product evaluation process, including lot release activities, inspection of manufacturing facilities, assessment of product availability, and surveillance and compliance activities. Current activities are focused on anthrax vaccine, smallpox vaccine, and the accompanying vaccinia immune globulin to treat adverse events associated with the smallpox vaccine;

- Continue development of biologic products including anthrax vaccine and smallpox vaccine needed in numerous other areas such as: botulism anti-toxin, plague vaccine, tularemia vaccine, filoviruses, and arenaviruses;

- Continue a variety of other treatments of therapeutic interventions that are under development such as skin, bone, fascia, and ligamentous tissues needed for replacement and repair; bone marrow and cord blood for hematopoetic reconstitution for victims with injury through physical (radiation), chemical and biological means to the bone marrow and immune system; as well as non-hematopoetic stem cells which offer the potential for creating cell and tissue based products that can ameliorate or cure metabolic diseases; and gene therapies to specially tailor cells to meet specialized functions such as local expression of antidotes to threat agents;

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

- Develop staff expertise to determine the types of non-clinical data that may be acceptable for product licensure if pre-licensure clinical studies are not feasible or ethical to treat human diseases caused by exposure to a biological weapon. These do not occur naturally or only occur with limited frequency. A mechanism must be developed at state and local user levels for data collection and follow-up on individuals who require medical intervention in a bioterrorist event. Particularly those interventions that involve investigational medical products;

- Ensure the availability of safe blood and blood products at the time of an emergency. Victims will need immediate access to blood and blood products in the aftermath of an attack. FDA leads the development of policies that determine the practices of blood establishments and sets the criteria for blood donor selection, as well as evaluates applications for the licensure of blood establishments, for blood products and for devices that both manufacture and test blood. FDA reviews applications for plasma derivatives and products analogous to blood derivatives that are manufactured by recombinant technology; and,

- Increase staff expertise to expedite and expand lot release activities and expedite review of investigational blood products; as well as address: supply issues (including the availability of testing reagents and resources to perform testing and blood typing). Conditions for use of blood and blood products collected for intrastate use; safety of imported product including proper storage, labeling and testing. FDA would also review applications for changes in normal procedures for establishments to address use and storage of blood and blood products including issues such as changes in freezing and storage conditions.

  Expedite review of product specific lot release and extension of dating submissions for the Anthrax Vaccine Absorbed (AVA). (Performance Goal)

  Provide guidance to the CDC, DOD and the AVA manufacturer regarding clincial studies to support proposed changes in the immunization schedule and routes of administration. (Performance Goal)

  Facilitate expedited development and review of new vaccines for protection and/or treatment against bioterrorism related thread disease (e.g. smallpox and anthrax vaccines.). (Performance Goal)

  Facilitate expedited development and review of new gamma globulins for protection and/or treatment against bioterrorism related threat diseases. (Performance Goal)

  Evaluate the need for guidance documents to assist in the development of products such as immunoglobulins and select vaccines. (Performance Goal)

Pay Increase: + $3,102,000

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 people-intensive. Payroll accounts for over 60 percent of the total FDA budget. This has a significant impact on all activities in FDA. FDA is requesting $28,552,000 to cover pay-related increases. The Biologics program piece of this increase is $3,102,000.

Medical Errors: + $1,300,000 and 2 FTE

The authority to operate the program is found under Title 42 CFR Subchapter XIX.

- Conduct product safety biomedical research in areas such as new cells used to produce drugs and biologics. Rapid advances in technology and the evolving HIV pandemic are stimulating a need in the field of biologicals to use new types of cell substrates and to develop new assays and assess the reliability of current assays used to monitor product safety. This is coupled with other public health crises of global proportions, such as hepatitis B/C infections, the constant threat of pandemic influenza, and the treatment of genetic defects;

- Develop new, specific and sensitive techniques and assays for validation and the detection of a greater variety of known potentially infectious viruses. A prime objective of safe biological products is detection, identification, and elimination of adventitious agents. One of the chief concerns inherent in biologicals is the potential for the presence of adventitious agents (infectious for humans) in the approved product;

- Enhance Vaccines and Biologics Safety Surveillance. Develop and maintain ongoing programs for safety surveillance of cutting edge technology and its appropriate implementation;

- Establish contracts for safety monitoring data links that include data on product exposure and extensive patient information. Develop access to external databases with other government agencies, States, academia and independent health organizations such as hospitals, to enhance FDA's ability to monitor the public health impact of FDA regulated products; and,

- Maintain and expand the gene therapy database to track individual patient's short and long term health status. The gene therapy database will support collection and analysis of effects of gene transfer products. It is imperative that clinical trial participants are not exposed to unreasonable risks and the experimental products are as safe as possible.

> *Reduce the risk of biologics products on the market through assuring product quality and correcting problems associated with their production and use. (Biologics Program Strategic Goal #2).*

Management Efficiencies: - $396,000 and -4 FTE

FDA's budget assumes savings of $2,578,000 associated with efficiency improvements and consolidations related to the President's Management Plan. The Biologics program piece of this total is $396,000 and four FTE.

PROPOSED LAW USER FEES

Prescription Drug User Fee Act III (PDUFA) III Proposed Law User Fees: + $64,324,000 and 41 FTE

The FDA Modernization Act of 1997 reauthorized the collection of user fees to enhance the review process of new human drugs and biological products and established fees for applications, establishments, and approved products. PDUFA expires at the end of 2002. FDA is working on a proposal to reauthorize PDUFA and make enhancements to it. FDA strongly

believes in the success of PDUFA and that it serves as a model for reinventing government with Congress, the Agency, the industry, and consumer groups all working together providing necessary resources, setting performance goals, and establishing accountability. Biologics would receive $64,324,000 of the FY 2003 budget request of $272,038,000 in new user fees to reauthorize PDUFA.

JUSTIFICATION OF BASE

Activities Related to Increases for FY 2003

Counter Terrorism-Safe and Effective Medical Products

Ensure the safety and efficacy of biological products, support the development, maintenance and deployment of stockpiles of medical counter-measures, assist in assuring that sufficient quantities of medical products are available, and support post-event follow-up and data collection initiatives for these products; some of which may be investigational.

Review the over 100 active investigational new drug applications on products under development for use either to mitigate or prevent the pathological effects of counter terrorism-related pathogens in humans, and products under development to treat adverse events associated with the smallpox vaccine. FDA also has numerous product applications for licensing and approval;

- Participate in activities to facilitate the availability of the currently approved vaccine for anthrax. The regulatory activity includes review of IND and BLA as well as the supplements to modify the potency test, extend the dating period, and renovate the establishment;

- Continue counter terrorism activities associated with the development of new smallpox and anthrax vaccines;

- Continue counter terrorism activities associated with improved vaccines for plague, tularemia, and Venezuelean Equine Encephalitis (VEE) as well as other encephalitis-causing viruses;

- Monitor production of biologics from the early stages all the way through post marketing with lot release testing to ensure the individual lots continue to meet safety, purity, potency and efficacy requirements. New vaccines must be reviewed and approved prior to use in humans. Biologic products are derived from living organisms and are sometimes made in living organisms, therefore, their manufacture presents difficulties not encountered in drug manufacturing. Traditional drug products usually consist of pure chemical substances that are easily analyzed after manufacture to determine safety, purity, potency and effectiveness. Biologics, however, consist of delicate substances or cells that are sensitive to heat, light, and to being shaken when in liquid form, and are easily susceptible to contamination;

- Guide products through the regulatory process, including the manufacturing process, pre-clinical testing, clinical trials, and the licensing application review process; and,

- Engage in compliance, lot release, surveillance and standards development activities. Manufacturers are required to follow good manufacturing practices (GMPs) in the production of biologic products, and must submit samples of each vaccine lot and results of their own tests for potency, safety and purity to the Agency before release of the product. Tests applicable include those for bacterial and fungal sterility, general safety, purity, identity, suitability of constituent materials, and potency. Adverse events are monitored to identify patterns of significant reactions to these new vaccines.

Payroll

- FDA's Biologics program ensures the safety, purity, potency and effectiveness of biological products (primarily vaccines, blood and blood products, and therapeutics), most of which represent the leading edge of technology. The Agency also monitors over 5,000 biological firms to ensure they are in compliance with quality and safety regulations; and,

- The field component of Biologics inspects regulated industry, and collects and analyzes samples. Other activities that often arise are review and management of enforcement actions, and consumer complaints, trace back efforts, and review of import entries for admissibility decisions. These functions are inherently governmental and highly personnel intensive.

Import Monitoring and Inspections

- Improve the safety of imported and domestic biological products through the surveillance of imported human tissues and other imported biological products and coordinate domestic field investigational analytical compliance activities.

  Meet the biennial inspection statutory requirement by inspecting 50 percent of registered blood bans, source plasma operations and biologics manufacturing establishments. (Performance Goal #13012)

Bovine Spongiform Encephalopathy (BSE)

- Continue to emphasize the need to protect the nation's blood supply, and minimize any risk to patients of acquiring BSE or Creutzfeldt-Jakob Disease (CJD), and other blood-borne diseases. No tests for the rapid diagnosis of either BSE or CJD or for detection of infected tissue have been validated as either sufficiently specific or sensitive to be used to screen the blood supply. A reliable blood-screening test for BSE is an extremely important goal and is currently the object of considerable research activity.

Patient Safety - Medical Errors

- Maintain the Agency's system of postmarketing surveillance and risk assessment program to identify adverse event reports (AERS) that did not appear during the product development process by collecting, evaluating and acting on information of AERS associated with marketed products; and,

- Maintain reporting systems to collect biological product deviation events that occur during manufacturing processes or storage of all biological products, including blood product manufacturers and blood-banking facilities.

Gene Therapy

- Develop a database application, the Genetic Modification Clinical Research Information System (GeMCRIS), to facilitate the evaluation and analysis of human gene therapy clinical information; and,

- Developing a gene therapy patient tracking system to supplement and/or replace current systems for assessing and promoting the safety of gene therapy human patients.

Blood Safety

Provide regulatory oversight of the U.S. blood supply. The Agency promulgates and enforces standards for blood collection and for the manufacturing of blood products, including both transfusible components of Whole Blood, pharmaceuticals derived from blood cells or plasma, and related medical devices and screening tests. FDA also inspects blood establishments; monitors reports of product deviations and adverse clinical events; and, works closely with other parts of the Public Health Service (PHS) to establish blood standards, and to identify and respond to potential threats to blood safety or supply.

- Continue to implement the Blood Action Plan to update the blood regulations, reinvent blood regulations, address emerging infectious diseases, ensure compliance of plasma fractionation establishments, blood donor/recipient notification and look back, and FDA emergency and Class I recalls affecting blood safety response procedures. Continue to reduce the number of exemptions to outdated blood regulations and the number of guidance documents lacking enforceability. The Blood Action Plan has greatly enhanced the regulatory oversight and safety of the nation's blood supply and increased the blood industry's compliance with standards; and,

- Respond to emerging potential threats to the blood supply in a timely and coordinated approach. Examples of the emerging threats include new HIV variants; new hepatitis agents; human herpes virus-type 8; and Creutzfeldt-Jakob Disease. A specific scientific and regulatory strategy must be developed for each identified threat. The Agency, in collaboration with the CDC and the NIH, engages in scientific investigations of emerging infectious agents. Actions include an assessment of the risk to the blood supply, diagnostic methods, standards development and regulatory controls.

Human Subject Protection

- Expedite development and licensing of safe and effective biological products and ensure patient safety through an effective, comprehensive bioresearch monitoring (BIMO) program in the Biologics program. Recent and highly publicized developments have highlighted the need for constant FDA vigilance as well as several critical changes in the program to address this rapidly changing product development environment;

- Bolster the protection of clinical study participants and the integrity of high risk clinical trials including gene therapy trials;

- Conduct inspections to increase oversight of high-risk Investigational New Drug (IND) applications including gene therapy;

- Provide guidance documents to industry and other interested parties on gene therapy products and take action to build upon existing guidance; and,

- Convene a conference of investigators whereby the most experienced professionals in the field discuss the appropriate monitoring practices.

Prescription Drug User Fee Act II (PDUFA) II Current Law User Fees

The Prescription Drug User Fee Act of 1992 (PDUFA) authorized the assessment and collection of user fees for drug applications, establishment registrations, and product listings to enhance and expand FDA's existing review process.

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 Act established fees for applications, establishments, and approved products. PDUFA is a model for reinventing government with Congress, the Agency, the industry and consumer groups working together to provide necessary resources, to set performance goals, and to hold the Agency accountable. Review performance monitoring is done in terms of fiscal year cohorts, e.g., the FY 1998 cohort includes applications received from October 1, 1997 through September 30, 1998. Fiscal year cohort performance is not immediately measurable at the end of the fiscal year. The measurable outcome will occur either 6 or 12 months after the last submission received during the fiscal year, depending upon the category of submission. FDA has met or exceeded all its performance goals. The fees collected in FY 2002 will enable the FDA to continue to meet its PDUFA II performance goals including:

- Review and act on 90 percent of standard original NDA and PLA/BLA submissions filed during FY 2002 within 10 months of receipt;

- Review and act on 90 percent of priority original NDA and PLA/BLA submissions filed during FY 2002 within six months of receipt;

- Review and act on 90 percent of standard efficacy supplements filed during FY 2002 within 10 months of receipt;

- Review and act on 90 percent of priority efficacy supplements filed during FY 2002 within six months of receipt;

- Review and act on 90 percent of manufacturing supplements filed during FY 2002 within six months of receipt and review and act on 90 percent of manufacturing supplements requiring prior approval within four months of receipt;
- Review and act on 90 percent of Class 1 resubmitted original applications filed during FY 2002 within two months of receipt; and,

- Review and act on 90 percent of Class 2 resubmitted original applications received during FY 2002 within six months of receipt.

Other Activities Related to High Priority Areas

Xenotransplantation

- Regulate xenotransplantation clinical trials conducted within the United States and establish public health policy in xenotransplantation. Although the potential benefits are considerable, the use of live animal materials raises concerns regarding the potential infection of recipients with both recognized and unrecognized infectious agents and the possible subsequent transmission to their close contacts and into the human population. Potential cross-species infection with persistent viruses, such as retroviruses, is of particular public health concern because they may be latent and lead to disease years after infection. Moreover, new or emerging infectious agents may not be readily identifiable with current techniques.

Regulation of Human Tissue Intended for Transplantation

- Establish comprehensive risk-based oversight of communicable disease transmission from human tissues and cells intended for implantation, transplantation, infusion or transfer. FDA has finalized the proposed rule for tissue establishment registration, and listing of human cells, tissues, and cellular and tissue-based products. The Agency has published proposed rules on current good manufacturing practice regulations that apply to establishments of human cell, tissues, and cellular and tissue-based products as well as on donor-suitability procedures.

Pandemic Influenza

- Collaborate with public health experts to determine the strains of virus to be used to manufacture the influenza virus vaccine that to be administered each fall. The recommendations are based on the data provided from laboratories worldwide as the strains are continuously evolving or mutating. As soon as the strains are recommended, manufacturers begin to grow virus strains in fertile hen's eggs. The parent strains of vaccine, know as "seed strains," used by each manufacturer are tested to assure they are the same as the recommended strains; and,

- Expedite lot release of influenza virus vaccine through the manufacturing time period. The process of manufacturing the influenza virus vaccine is a very complex one, complicated by the large number of doses administered in a very short time frame.

Therapeutic Products

- Review and evaluate biological therapeutic products, including establishing standards, conducting mission related research, participating in inspections, developing policy and procedures, and evaluating clinical experience and reports of adverse events. Biological therapeutic products include such products as growth factors, enzymes, monoclonal antibodies, products prepared by genetic engineering and synthetic procedures, and biological gene therapy products.

Diabetes

- Review Investigational New Drugs (INDs) for the treatment of diabetes including the use of human islet cells that have shown promising results in recent clinical studies as a possible cure for diabetes; and,

- Conduct research regarding human islet cell transplantation. FDA's role has been to perform safety tests for porcine endogenous retovirus (PERV) in an animal model for xenotransplantation. Quality control of the production of pancreatic islet cells, and the development of newer methods for characterization of the quality of the cells themselves are emerging issues.

SELECTED FY 2001 ACCOMPLISHMENTS

Countering Terrorism-Safe and Effective Medical Products

- Expedited development and licensing of products to diagnose, treat or prevent outbreaks from exposure to the pathogens that have been identified as bioterrorist agents. These products must be reviewed and approved prior to the large-scale productions necessary to create and maintain a stockpile-- a process that is extremely complex and early involvement by staff is crucial to the success of the expedited review process;

- Collaborated with other government agencies on anti-bioterrorism activities and participates in bioterrorism response interagency working groups. For example, FDA, CDC, DOD and NIH continue efforts toward development of a new smallpox vaccine, evaluation of currently outdated VIG (vaccinia immune globulin, used to treat certain serious but rare adverse events caused by the smallpox vaccine) and development of new VIG to support a wide-scale smallpox vaccination program;

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

- Drafted a proposal that could obviate the requirement for human efficacy studies of therapeutics intended to treat diseases that either do not occur naturally or occur with very low frequency. Controlled efficacy studies in humans cannot be undertaken due to ethical and safety concerns that would rule out challenging human subjects with a deadly organism to show the efficacy of the product;

- Published the proposed rule "Evidence Needed to Demonstrate Efficacy of New Drugs for Use against Lethal or Permanently Disabling Toxic Substances when Efficacy Studies in Humans Ethically Cannot Be Conducted." This proposed rule would amend the new drug and biological product regulations to identify the information needed to provide substantial evidence of the efficacy of new drug and biological products used to reduce or prevent the toxicity of chemical, biological, radiological, or nuclear substances. This proposal would

apply when the traditional efficacy studies in humans are not feasible and cannot be ethically conducted under FDA's regulations for adequate and well-controlled studies in humans;

- Proposed a change to the standards for approving biological products in exceptional instances, where non-clinical studies could serve as replacements for clinical efficacy studies in the approval of medical products against bioterrorism; and,

- Published the guidance document "Recommendations for Assessment of Donor Suitability and Blood and Blood Product Safety in Cases of Possible Exposure to Anthrax". This guidance document applies to whole blood, blood components, including recovered plasma, and source plasma collections intended for use in transfusion or for further manufacturing into injectable products provides the current recommendations of the Agency for assessment of donor suitability and product safety for donors potentially exposed to Bacillus anthracis, the agent of anthrax.

Blood Safety

- Continued implementation of the Blood Action Plan including: updating the blood regulations; the reinvention of blood regulation; addressing emerging infectious diseases; insuring compliance of plasma fractionation establishments; blood donor/recipient notification and lookback; FDA emergency and Class I recalls affecting blood safety response procedures; and monitoring and increasing the blood supply. The plan is being implemented jointly by FDA, the Centers for Disease Control and Prevention (CDC) the National Institutes of Health (NIH), and the Centers for Medicare and Medicaid Services;

- Reduced the number of outdated blood regulations exemptions; the number of guidance documents lacking enforceability; and, increased the blood industry's compliance through enforcement of standards;

- Implemented a simplified Biologics License Application (BLA) instead of the previous Product License Application (PLA) and Establishment License Application (ELA);

- Developed product and manufacturing standards and provided direction to the blood industry on effective compliance actions to ensure adequate quality assurance and compliance with good manufacturing practices by industry;

- Engaged in the scientific investigation of the emerging infectious agents including new HIV variants; new hepatitis agents; human herpes virus-type 8; Creutzfeldt-Jakob Disease and anthrax in collaboration with the Centers for Disease Control and Prevention (CDC) and National Institutes of Health (NIH);

- Conducted risk assessments of the blood supply, diagnostic methods, standards development and regulatory controls;

- During FY 2001, FDA received 676 blood and blood product Biologic License Applications (BLA) and BLA supplements, 29 New Drug Applications (NDA) and Abbreviated New Drug Applications (ANDA) and supplements, 36 510(k) submissions, and 27 Premarket

Applications (PMA) and supplements. Received 167 new blood and blood product Investigational New Drug (IND) applications and 12 new Investigational Device Exemption (IDE) applications; and,

- Approved 594 blood and blood product BLAs and BLA supplements; cleared 19, 510(k)s; approved 2 PMAs and 3 PMA supplements; and, maintained an average of 733 active blood and blood product INDs and 45 IDEs with associated amendments.

Patient Safety

- Co-sponsored with the National Institute of Allergy and Infectious Diseases, the Centers for Disease Control and Prevention, the Health Resources and Services Administration and the National Vaccine Program Office a workshop entitled "Evaluation of Vaccine Safety: How Much Safety Data?" addressing the methods and information needed to evaluate the safety of new vaccines; and,

- Participated in the HHS Patient Safety Task Force working to reduce the current gap that exists between the quality of care people receive and the quality of care that the health-care system is capable of providing, focusing on reduction of medical errors including medications, devices and hospital-acquired infections. FDA is developing plans to utilize existing vaccine and blood event reporting systems to reduce medical errors and improvement of patient safety.

Postmarket Assurance – Vaccine Adverse Event Reporting

- Completed preliminary study of Empirical Bayesian Data Mining, a computer algorithm for signal screening in VAERS;

- Completed a study that developed case definitions for acute encephalopathy, encephalitis, and multiple sclerosis based on reports to VAERS;

- Collaborated with CDC to evaluate the risk of serious events after yellow fever vaccine in the elderly and of rheumatoid arthritis after hepatitis B vaccine;

- Participated in the overall Vaccine Safety Datalink (VSD) project research collaboration, a study conducted at four west coast health-maintenance organizations (HMOs). Projects included investigations of possible associations between vaccination and infant mortality and neonatal mortality, as well as preliminary investigations of vaccination and alopecia, aplastic anemia, thrombocytopenia. In addition, VSB staff participated in workgroups focusing on varicella zoster and the safety of influenza vaccine in children;

- Reviewed more than 17,290 adverse event reports for therapeutic biological products and 10,918 reports for vaccines during FY 2001; and,

- Provided post-licensure adverse event data from AERS for multiple BLA supplements, including those for infliximab, etanercept, beta interferons, alpha interferons, Lyme vaccine, and other products.

Prescription Drug User Fee Act (PDUFA)

The Prescription Drug User Fee Act (PDUFA) established performance goals for the evaluation of applications for marketing drug and certain biological products. Review performance monitoring is being done in terms of cohorts, *e.g.*, the FY 2001 cohort includes applications received from October 1, 2000 through September 30, 2001.

- Reviewed and acted on 90 percent of standard original NDA and PLA/BLA submissions filed during FY 2001 within 12 months of receipt, and review and act on 70 percent within 10 months of receipt;
- Reviewed and acted on 90 percent of priority original NDA and PLA/BLA submissions filed during FY 2001 within 6 months of receipt;
- Reviewed and acted on 90 percent of standard efficacy supplements filed during FY 2001 within 12 months of receipt, and review and act on 70 percent within 10 months of receipt;
- Reviewed and acted on 90 percent of priority efficacy supplements filed during FY 2001 within 6 months of receipt;
- Reviewed and acted on 90 percent of manufacturing supplements filed during FY 2001 within 6 months of receipt, and review and act on 70 percent of manufacturing supplements requiring prior approval within 4 months of receipt;
- Reviewed and acted on 90 percent of Class 1 resubmitted original applications filed during FY 2001 within 2 months of receipt, and act on 70 percent within 2 months of receipt; and,
- Reviewed and acted on 90 percent of Class 2 resubmitted original applications received during FY 2001 within 6 months of receipt.

The table below shows FDA's performance on the PDUFA FY 2000 cohort. The data provided are as of September 30, 2001.

FY 2000 Cohort

Application Type	Number Submitted	Number Filed	RTF,UN or WF	First Action w/in Goal (%)		Submissions Overdue (%)
New Product Standard	11	10	1	10 mo.	100	0
				12 mo.	100	0
New Product Priority	4	4	0	6 mo.	100	0
Efficacy Supplements Standard	12	11	1	10 mo.	100	0
				12 mo.	100	0
Efficacy Supplements Priority	2	2	0	6 mo.	100	0
Manufacturing Supplements Prior Approval	242	241	1	4 mo.	100	0
				6 mo.	100	0
Manufacturing Supplements CBE & CBE 30	349	349	0	6 mo.	97	3
Resubmissions Class 1	1	NA	NA	2 mo.	100	0
				4 mo.	100	0
Resubmissions Class 2	8	NA	NA	6 mo.	100	0

RTF = Refuse to File; UN = Unacceptable for filing (User Fee not paid); WF = Withdrawn before filing; CBE = Change being effected immediately; CBE = Change being effected after 30 days; NA = Not applicable.

Gene Therapy

FDA, in coordination with the National Institutes of Health (NIH), Office of Biotechnology Activities (OBA), are developing a database application, the Genetic Modification Clinical Research Information System (GeMCRIS), to facilitate the evaluation and analysis of human gene therapy clinical information. FDA is also developing a gene therapy patient tracking system to supplement and/or replace current systems for assessing and promoting the safety of gene therapy human subjects/patients. The system will consist of many components including databases, procedures, policies, and guidances.

- Recommended long-term patient monitoring for retroviral vectors and these safety requirements previously described in various guidances;

- Issued a 'Dear Gene Therapy IND or Master File Sponsor' letter to all active IND sponsors of files classified as gene therapy products requesting additional information including written clinical monitoring programs and to submit it to FDA for review;

- Conducted telephone interviews to assess compliance with long-term patient monitoring recommendations for gene-transfer INDs. These interviews were to gain insight into the barriers and practical limitations that exist in conducting the proposed long-term follow-up for clinical studies; and,

- Established the Gene Therapy Monitoring Analysis Working Group to devise and conduct analyses of the clinical monitoring programs. The primary goal of the group is to define, categorize, and risk-stratify types clinical monitoring programs; identify common variables indicative of inadequate programs; characterize the quality of clinical trials with respect to the type of sponsorship and hosting institution; and identify sponsors and/or investigators that may have had financial or other significant conflict-of-interest.

FDA University

- As a part of FDA University conducted in-house development and implementation of seminars, professional meetings and courses that increased the science-based knowledge of the FDA's review staff which can help reduce review times and backlogs.

BIOLOGICS
PROGRAM ACTIVITY DATA

Program Workload and Outputs	FY 2001 Actual	FY 2002 Estimate	FY 2003 Estimate[4/]
Total Original License Application (PLA/ELA/BLA) Reviews[1/]	145	145	145
PLA/BLA Approvals	60	65	65
Mean/BLA Approval Time (months)	8.0	8.0	8.0
Median PLA/BLA Approval Time (months)	4.0	4.0	4.0
License Supplement (PLA/ELA/BLA) Reviews[1/]	1,950	1,950	1,950
NDA & NDA Supplement Approvals	40	40	40
ANDA & ANDA Supplement Approvals	5	5	5
PMA & PMA Supplement Reviews[1/]	30	30	30
510(k) Reviews[1/]	110	160	160
Commercial IND/IDE Receipts	300	325	350
IND/IDE Amendments Receipts[2/]	15,200	16,300	17,500
Active INDs/IDEs[2/]	3,600	3,700	3,800
Adverse Event Report Receipts[3/]	22,300	22,300	22,500
Biological Product Deviation Reports Received	25,000	27,000	27,000

PROGRAM OUTPUTS - DOMESTIC INSPECTIONS[5/]	FY 2001 Actual	FY 2002 Estimate	FY 2003 Estimate
Bioresearch Monitoring Programs Inspections	88	189	190
Blood Bank Inspections	1,441	1,439	1,500
Source Plasma Inspections	269	265	270
Pre-Approval (Pre-Market) Programs Inspections	7	10	10
Pre-License Inspections	16	12	20
GMP Inspections	63	41	50
GMP (Device) Inspections	12	36	40
Human Tissue Inspections	132	183	200
Total FDA Inspections	2,028	2,175	2,280

PROGRAM OUTPUTS - IMPORT/FOREIGN INSPECTIONS[5/]			
Inspections	13	12	10
Blood Bank Inspections	16	34	40
Source Plasma Inspections	3	10	10
Pre-Approval (Pre-Market) Programs Inspections	1	5	5
Pre-License Inspections	2	5	5
GMP Inspections	20	20	20
GMP (Device) Inspections	1	5	5
Total Foreign FDA Inspections	**56**	**91**	**95**
Import Field Exams/Tests[6/]	6	10	10
Import Line Entry Decisions	24,067	26,955	28,302

1/Total of approval, and complete decisions. Does not include refuse-to-file decisions or withdrawals.
2/Includes IND, IDE, Master File and license master file receipts.
3/Includes MedWatch, Foreign reports and VAERs reports.
4/When fully implemented, the FY 2003 requested increase for all Field programs will provide additional domestic inspections performed by FDA depending on progress in hiring, training, and equipping new staff.
5/An inspection is any visit to a firm during which all or part of one or more phases of that establishment's operation is evaluated against appropriate agency requirements.
6/A Field Exam is the on-site examination of a product that is sufficient in itself to determine whether the product is in compliance with Agency requirements. Examples of exams include visual, organoleptic, quick color, and rapid abrasion.

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Animal Drugs and Feeds

	FY 2001 Actual Obligations	FY 2002 Current Estimate	FY 2003 +/-FY 2002 Current Estimate	FY 2003 Baseline Estimate
Total Program Level	**$64,070,000**	**$86,467,000**	**+$2,505,000**	**$88,972,000**
Center	*$48,440,000*	*$56,041,000*	*+1,834,000*	*$57,875,000*
FTE	*290*	*320*	*+5*	*325*
Field	*$15,630,000*	*$30,426,000*	*+$671,000*	*$31,097,000*
FTE	*152*	*274*	*+13*	*287*
Current Law BA	**$64,070,000**	**$86,467,000**	**+$2,505,000**	**$88,972,000**
Counter Terrorism	*$408,000*	*$3,928,000*	*+$948,000*	*$4,876,000*
Pay Increase 1/			*+$1,953,000*	*$1,953,000*
Mgmt. Efficiencies			*($396,000)*	*($396,000)*
Current Law BA Accrual Costs2/	**$2,710,000**	**$3,484,000**	**+$306,000**	**$3,790,000**
Current Law BA with Accrual Costs2/	**$66,780,000**	**$89,951,100**	**+$2,811,000**	**$92,762,000**
FTE	**442**	**594**	**+18**	**612**

1/Pay increases shown on separate line, and not reflected in individual initiative areas
2/Reflects 2001 and 2002 comparable estimates.

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Historical Funding and FTE Levels

Fiscal Year	Program Level	Budget Authority	User Fee	Program Level FTE
1999 Actuals	$43,253,000	$43,253,000	$0	393
2000 Actuals	$49,593,000	$49,593,000	$0	406
2001 Actuals	$64,070,000	$64,070,000	$0	442
2002 Current Estimate 2/	$86,467,000	$86,467,000	$0	594
2003 Estimate	$88,972,000	$88,972,000	$0	612

2/Includes FDA's FY 2002 Appropriation and the Counter Terrorism Supplemental.

MISSION

- Protect the health and safety of all animals that serve either as companions, or other animals for mankind and assure that food from animals is safe for human consumption;

- Process premarket applications as quickly as possible to increase the availability and diversity of safe and effective veterinary products that relieve animal pain and suffering while ensuring the resulting products are safe, wholesome, and free of drug residue when they reach the consumer; and,

- Monitor marketed products for all animal drugs and feeds to minimize harm to humans or animals that might arise from the use of these products. This is accomplished through science-based review of drug experience reports, nationwide monitoring systems, and compliance programs implemented by the FDA field offices through inspections, sample collections and analysis, and investigations, and appropriate regulatory actions to control violating goods and firms.

PROGRAM RESOURCE CHANGES

The FY 2003 request builds upon funding FDA received from the FY 2002 appropriation plus the FY 2002 emergency supplemental. As a result, while FDA has received increased funding to support counter terrorism, some of the programs are showing either no funding increase, or a slight decrease. The FY 2003 request annualizes those dollars received as one-time money in the supplemental -- a significant increase to the Agency of $152,276,000 in total. The funding changes shown below are the differences once these annualized dollars are removed.

For the Animal Drugs and Feeds program, in FY 2003, in addition to the activities discussed below, FDA will continue to utilize $3,500,000 provided in the supplemental, plus an additional $948,000 to continue the effort of increasing oversight and inspections of imports and other related activities.

Counter Terrorism – Food Safety: + $948,000 and 22 FTE

- Review, assess and take appropriate enforcement action as a result of inspections conducted/samples collected. This includes follow-up actions as a result of intentional contamination;

- Assure immediate assessment and identification of GMP compliant facilities to ensure continued availability of veterinary drug products and increase supply of pivotal drug products to meet emergency needs;

- Develop a database containing a comprehensive inventory of registered animal drug establishments, and listed animal drug products. Use this database to assess the availability or anticipated shortage of animal drugs products that would be needed to deal with terrorist attacks;

- Facilitate sharing information between databases and organizations that already exist and fill in any gaps that we identified;

- Implement a state university contract to develop analytical methods to detect the presence of prohibited animal substances that could be introduced into U.S. animal feed supplies by bioterrorists. Once they are developed and optimized, these methods would be provided to FDA diagnostic laboratories for testing of prohibited substances in routine animal feed surveys; and

- Conduct a threat analysis of possible terrorist actions that could be taken to contaminate animal feed.

Increase the availability and diversity of safe and effective animal drugs and feeds. (Strategic Goal #1)

Pay Increase: + $1,953,000

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 people-intensive. Payroll accounts for over 60 percent of the total FDA budget. This has a significant impact on all activities in FDA. FDA is requesting $28,552,000 to cover pay-related increases. The Animal Drugs and Feed piece of this increase is $1,953,000.

Management Efficiencies: - $396,000 and 4 FTE

FDA's budget assumes savings of $2,578,000 associated with efficiency improvements and consolidations related to the President's Management Plan. The Animal Drugs program portion of this total is $396,000 and four FTE.

JUSTIFICATION OF BASE

Counter Terrorism

- Assist state diagnostic laboratories to acquire the scientific and analytical expertise and capability to handle a feed contamination incident;
- Educate State veterinary offices about FDA's technical role in intentional or accidental contaminated animal feed incidents;
- Modernize the OASIS import data process system so import reviewers will have more rapid and direct access to information necessary for entry decisions;
- Begin to develop an internet web-site to share information concerning animal feed contaminants potentially used as bioterrorism agents; and
- Develop rapid analytical methods for screening imports at the border and increase the number of import line entries reviewed for admissibility into domestic commerce.

Payroll

- Protect the health and safety of all animals that serve either as companions or food sources for mankind. This is accomplished through processing premarket applications to increase the availability and diversity of safe and effective veterinary products that relieve animal pain and suffering, while ensuring the resulting products are safe, wholesome, and free of drug residue when they reach the consumer; and through the surveillance of marketed products for all animal drugs and feeds to minimize harm to humans or animals which might arise from the use of these products.

Bovine Spongiform Encephalopathy (BSE)

- Prevent the establishment and amplification of BSE through animal feed, by enforcing the rule "Animal Proteins Prohibited From Use in Animal Feed", that prohibits the use of certain proteins derived from mammalian tissue in feeding ruminant animals;

- Enforce the rule by conducting targeted BSE inspections of all known renderers and feed mills handling prohibited material, such as meat and bone meal on a yearly basis. As of November 19, 2001, there have been 12,206 inspections conducted. Of those inspections, 2,190 firms were found to be handling prohibited material, and will be targeted for inspection annually. In addition, any firm found to be in violation of the requirements of the regulation will be inspected, and as many other potentially affected firms will be inspected to be assured they are in compliance with the regulation if they have initiated handling of prohibited material;

- Maintain relationships with industry using telecommunication and conferences to provide information on regulatory compliance and share inspection data;

- Modernize the existing information technology infrastructure to facilitate electronic inspection reporting and information collection and distribution;

- Develop and validate detection methods for BSE collaborating with experts and foreign scientists to assist in developing BSE methods; and

- Review and evaluate field inspection data and take enforcement action when necessary.

Conduct targeted BSE inspections of 100 percent of all known renderers and feed mills handling prohibited material. (Performance Goal 14006).

Reduce the risks associated with marketed animal products. (Strategic Goal #2)

Imports and Inspections

- Develop laboratory analytical methods to permit analyses of products for chemical and microbiological hazards, and perform laboratory validation of analytical methods submitted to support pre-market product applications;

- Maintain statutory requirements by inspecting 50 percent of registered animal drug and feed establishments and FDA licensed feed mills, which handle medicated feeds;

Maintain biennial inspection coverage by inspecting 50 percent of registered animal drug and feed establishments. (Performance Goal #14009)

- Continue the sampling program for animal feeds domestically and those detained at U.S. ports of entry that contain ingredients possibly derived from contaminated animals; and,

- Conduct bioresearch-monitoring inspections, which assure that product sponsors are in compliance with regulations and good laboratory practices.

. **Premarket Review**

- Increase the availability of safe and effective animal products, by reviewing animal drug applications in a timely manner for safety and effectiveness, and continue to work with regulated industry to minimize drug development time; and,

- Continue pre-submission conferences, meeting, and workshops with industry, and support electronic submission of applications.

Increase the availability and diversity of safe and effective animal drugs and feeds. (Program Strategic Goal #l)

Reduce pending overdue Animal Drug Applications by 15 percent. (Performance Goal)

Maintain the level of requested pre-submission conferences conducted with industry sponsors at 80 percent. (Performance Goal #14007)

Food Safety - Antimicrobial Resistance

- Continue to develop the framework for evaluating and managing the human health impact of microbial effects of antimicrobial new animal drugs intended for use in food producing animals;

- Conduct research to identify food animal species causing human drug resistance;

- Reduce the transfer of resistant animal pathogens to humans by conducting research studies and risk assessments that will yield future benefits, and begin to reverse the trend of foodborne pathogen antibiotic resistance development; and

- Deliver the food safety message to livestock producers, veterinarians, industry and consumers via trade shows, videotapes, and pamphlets to educate them on the risk of antimicrobial resistance of bacteria following the use of antimicrobial drugs in food animals.

Develop an antibiotic risk assessment model using fluoroquinolone, chickens and Campylobacter. (Performance Goal #14003)

National Antimicrobial Resistance Monitoring System (NARMS)

- Identify emerging resistance in foodborne pathogens through an early warning system, NARMS. This has improved our ability to detect emerging resistance among foodborne pathogens;

- Use NARMS data to initiate field investigations of outbreaks of illness marked by pathogens which display an unusual antimicrobial resistance pattern; and

- Assess the human health impact of fluoroquinolone use in poultry through NARMS data as well as trigger broader research projects of prudent antimicrobial use in animals and the role of the environment in the emergence and spread of antimicrobial resistance.

  Maintain isolate testing rate for Salmonella in the National Antimicrobial Resistance Monitoring System (NARMS) at 12,000. (Performance Goal #14005).

International Expansion of NARMS

- Support for an advanced World Health Organization training course in Mexico on the surveillance of Salmonella and antimicrobial resistance in foodborne pathogens; and,

- Continue the pilot project cooperative agreement with four sites in Mexico to determine prevalence of Salmonella species and quinolone-resistant E.coli in asymptomatic humans.

Food Safety

- Leverage FDA's Tissue Residue Information Management System with the USDA's Residue Violation Information System to maintain feed contaminants and tissue residue compliance programs and to detect chemical and microbial contaminants in the animal feed supply;

- Maintain early warning systems by collecting information from Drug Experience Reports and Adverse Event Reports;

- Participate on a Presidential task group to encourage the development of safe and effective aquaculture in the United States. Assist in the development of approved aquaculture drugs through participation in the National Research Support Project #7 (NRSP #7);

- Continue training programs for federal and state inspectors on the concept of HACCP audit inspections and follow-up on pilot initiative with one or two manufacturing plants;

- Conduct method validation studies required before applications for new drugs for food producing animals can be approved; and,

- Outreach with the public on the education of biotechnology products and assist developers through the regulatory process.

Selected FY 2001 Accomplishments

Counter Terrorism

- Participated in meetings to communicate and coordinate activities in counter terrorism with other Federal and State agencies;

- Established and maintain a Feed Contaminants and Tissue Residue Compliance Program which plays an important role in early detection of chemical and biological contaminants in the animal feed supply;

- Determined how to assess veterinary diagnostic laboratories capabilities (e.g. visit a state university which has developed software and a search engine to access availability of methods to analyze specific contaminants); and,

- Organized a Center-wide Counter Terrorism Workgroup to plan and implement the Agency's counter terrorism activities. Protection of agricultural animals from bioterrorism attack is important because food producing animals supply about two-thirds of the protein nutrient needs of the American consumer.

Premarket Review

- Decreased the backlog of overdue documents in order to move FDA back on track towards meeting statutory and stakeholder requirements for new animal drug application reviews. FDA reduced its backlog of pending overdue documents by 1,334, from 2,234 to 900;

- Processed 5,600 submissions for new animal drug applications (NADAs), abbreviated new animal drug applications (ANADAs), investigational new animal drug files (INADs), generic investigational new animal drug (JINADs) files and master files, and general related correspondences. Included were:

    a) 65 submissions for NADAs and ANADAs (original and reactivations) and 1,444 for supplements (originals and reactivations) to previously approved NADAs and ANADAs;
    b) 264 phased data review submissions under INADs and JINADs to support approvals; and,
    c) 40 documents published in the Federal Register regarding significant NADA and ANADA approvals

- Announced 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 FDA plans to use to grant Expedited Review Status (ERS) for applications for new animal drugs intended to reduce human pathogens in food-producing animals.

Antimicrobial Resistance

- Finalized the quantitative risk assessment entitled "The human health impact of fluoroquinolone resistant Campylobacter associated with the consumption of chicken." FDA determined that the use of fluoroquinolones in poultry causes the development of fluoroquinolone-resistant Campylobacter, which can be transferred to humans and is a significant cause of the development of fluoroquinolone-resistant Campylobacter infections in humans;

- Published "An Approach for Establishing Thresholds in Association with the Use of Antimicrobial Drugs in Food-Producing Animals" that reflects the criteria for establishing resistance thresh-holds for antimicrobial drugs used in food-producing animals. A public meeting was held and input was obtained from a broad range of experts, consumer representatives, and other stakeholders;

- Completed a feasibility study for a risk assessment on the link between the use of virginiamycin in animals and Synercid™ resistance in humans. Based on the feasibility study, the FDA determined that sufficient data did exist or was forthcoming to support a quantitative risk assessment of the human health impact from the use of virginiamycin in food-producing animals;

- Designed, coordinated and administered an emergency survey to inspect a nationally representative sample of chicken and turkey hatcheries in the U.S. to investigate whether ceftiofur and gentamicin were present and how they were used. This survey was initiated due to the emergence of domestically acquired ceftriaxone-resistant *Salmonella* in humans in the US, which was detected by the routine surveillance of the NARMS; and,

- Developed consumer-oriented training material about antimicrobial resistance, published brochures on judicious use of antimicrobials for pork and poultry producers, and began planning for two public meetings on antimicrobial resistance.

National Antimicrobial Resistance Monitoring System (NARMS)

- Completed annual interagency agreements with the U.S. Department of Agriculture's Animal Research Service (USDA/ARS) and Centers for Disease Control and Prevention's National Center for Infectious Diseases (CDC/NCID) to provide funding for conduct of animal and human isolate testing;

- Coordinated the implementation of a USDA/ARS NARMS Web page for posting of NARMS animal data, as well as other general information on the NARMS program. Prior to this, the animal data was located on the FDA NARMS page and the human data was located on the CDC NARMS site;

- Worked with CDC, to add to NARMS an animal feed component. The new phase will monitor animal feeds for enteric organisms that cause foodborne illness with sampling protocol approval; and,

- Added a third testing site for susceptibility testing to handle samples from the retail meat component of the pilot study designed to determine the prevalence and antimicrobial resistance patterns of foodborne bacteria in commonly consumed meats. Five FoodNet sites will begin to collect retail meat and send the isolates to the three testing sites for susceptibility testing.

International Expansion of NARMS

- Supported a World Health Organization (WHO) training course in Mexico on the surveillance of *Salmonella* and antimicrobial resistance in foodborne pathogens;

- Continued the pilot project with Mexico on a monitoring system for antimicrobial resistance in *Salmonella.* The increase in international trade in food has increased the risk from cross-border transmission of foodborne pathogens and underscores the need to use international

surveillance systems to monitor the prevalence of resistance to antimicrobials of importance to human medical therapy; and,

- Expanded the pilot project into a three-year cooperative agreement, signed September 29, 2001, with four sites in Mexico to determine prevalence of *Salmonella* species and quinolone-resistant *E.coli* in asymptomatic humans.

Bovine Spongiform Encephalopathy (BSE)

- FDA and State investigators performed 2,505 inspections for compliance with BSE feed regulations which completes our original efforts to bring about 100 percent compliance with the rule;

- Awarded 34 BSE/medicated feed contracts to the States for 3,353 inspections, and 18 state tissue residue contracts for 699 inspections;

- Investigated and issued 15 recalls due to lack of ruminant warning labels on animal feeds manufactured using prohibited bovine protein;

- Designed new database and data entry procedures for BSE inspections as well as a new BSE inspection checklist to better target firms for re-inspections and for collection of better data from both FDA and state inspectors;

- Continued development of methods for testing animal feed for prohibited mammalian protein. Several different methods of testing are being researched: detection of genetic material from several species as a marker for the presence of prohibited proteins, use of immunological methods for detection of prohibited material, and a microchip application for testing of DNA material from various species in feed;

- Enhanced coordination and communication with State regulators and State Feed Inspection contracts and expanded partnerships to include more inspections of animal feed mills; and,

- Developed an inventory of establishments that process BSE prohibited materials and conducted annual inspections of these establishments to refine and update the inventory in subsequent years.

Dioxin Contamination

- Evaluated the results of the national survey of dioxin-like compounds in animal fats, animal meals, oilseed deodorizer distillates, and molasses and planed for follow up sampling of these products, and;

- Partnered with Arkansas Regional Laboratory (ARL) to investigate the usefulness of a dioxin screening method that uses the Ah (aromatic hydrocarbon) receptors.

Animal Drug Availability Act (ADAA) Implementation

- Published a final rule to implement the Veterinary Feed Directive Drugs on December 8, 2000, and issued Guidance 120, Veterinary Feed Directive Regulation on March 1, 2001;

and, published an advanced notice of proposed rulemaking on August 10, 2001 (66 FR 42167) on issues related to the implementation of the import tolerances provision in section 4 of the ADAA.

Biotechnology

- Authored a case study on genetically engineered salmon that was posted for public comment on the Office of Science and Technology Policy (OSTP) website, along with a number of other case studies in biotechnology; and,

- Contracted with the National Academy of Sciences/National Research Council (NAS/NRC) to conduct a workshop on "Scientific Basis for Determining Ecological Effects of Aquaculture Biotechnology" as a follow up to the OSTP case study on genetically engineered salmon.

Aquaculture

- Contracted for development of a database and risk assessment of drugs used in foreign aquaculture. Information will be collected, assessed for possible hazards as drug residues in food, and prioritized for analytical method development and tissue monitoring.

FDA University

- As a part of the FDA University conducted in-house development and implementation of seminars, professional meetings and courses that increased the science-based knowledge of the FDA's review staff, which can help reduce review times and backlogs.

Animal Drugs and Feeds
Program Activity Data

Program Workload and Output	FY 2001 Actual	FY 2002 Estimate	FY 2003 Estimate[5/]
New Animal Drug Applications (NADAs) Processed Originals:[1/]			
Received	20	30	30
Completed	26	32	32
Approved	14	24	24
Pending [2/]	17	15	13
Average (median) months from receipt to approval, original NADAs and re-activations	(10)	(12)	(12)
New Animal Drug Application Supplements: [3/]			
Received	1,307	1,276	1,276
Completed	1,282	1,173	1,379
Approved	214	250	319
Pending	687	790	687
Original Abbreviated New Animal Drug Applications:			
Received	47	43	43
Completed	39	36	36
Approved	8	8	8
Pending	43	50	57
Average (median) months from receipt to approval, Original ANADAs	(18)	(16)	(16)
Abbreviated New Animal Drug Application Supplements:			
Received	221	164	164
Completed	162	147	181
Approved	37	32	32
Pending	168	185	168
Investigational New Animal Drug (INAD) Files: [4/]			
Received	2,771	2,716	2,716
Completed	3,056	2,607	2,825
Pending	591	700	591
Generic Investigational New Animal Drug Files: [4/]			
New Receipts	101	100	100
Final Actions	120	98	98
Pending	31	33	35

[1/] Includes originals and reactivations. If application is not approvable, the sponsor may submit additional information until the Agency is able to approve the application.
[2/] All applications received during a fiscal year are not reviewed during the same fiscal year. Pending applications indicates the number of applications in our backlog.
[3/] A supplemental application is a sponsor request to change the conditions of the existing approval. They can be significant (a new species or indication), or routine (product manufacturing changes).
[4/] An INAD or JINAD file is established at the request of the sponsor to archive all sponsor submissions for a phased drug review including: request for interstate shipment of an unapproved drug for study, protocols, technical sections, data sets, meeting requests, memos of conference and other information.
[5/]When fully implemented, the FY 2003 requested increase for all Field programs will provide additional domestic inspections performed by FDA depending on progress in hiring, training, and equipping new staff.

Animal Drugs and Feeds
Program Activity Data

Program Workload and Output	FY 2001 Actuals	FY 2002 Estimate	FY 2003 Estimate
PROGRAM OUTPUTS-DOMESTIC INSPECTIONS[6/]			
Investigational Food Additive Petitions	39	50	50
Food (Animal) Additive Petition	14	20	20
Preapproval/Bioresearch Monitoring Programs Inspections	73	110	110
Drug Process and New ADF Programs Inspections	178	800	800
BSE Inspections	892	2,673	2,700
Illegal Tissue Residue Program Inspections	210	150	150
Feed Manufacturing Program Inspections	278	890	900
Feed Contaminants Program Inspections	27	1,210	1,500
State Contract Inspections: BSE	1,503	4,000	4,000
State Contract Inspections: Feed Manufacturers	337	453	600
State Contract Inspections: Illegal Tissue Residue	438	600	700
State Partnership Inspections: BSE	110	623	800
Domestic Field Exams/Tests[7]	24	50	50
Domestic Laboratory Samples Analyzed[8]	3,120	4,800	6,000
PROGRAM OUTPUTS-IMPORT/FOREIGN INSPECTIONS[6/]			
Foreign Preapproval/Bioresearch Monitoring Programs Inspections	34	40	40
Foreign Drug Process and New ADF Program Inspections	11	10	20
Foreign BSE Inspections	5	10	20
Foreign Feed Manufacturing Program Inspections	6	10	10
Import Field Exams/Tests[7/]	120	300	700
Import Laboratory Samples Analyzed[8/]	229	770	900
Import Line Entry Decisions	155,089	173,699	182,384
Manufacturers Drug Experience Reports (DERs)			
Received	4,574	4,800	4,800
Reviewed	4,436	4,800	4,800
Adverse Experience Reports (AERs)			
Received	18,601	30,000	30,000
Reviewed	20,086	24,000	24,000
Animal/Medicated Feed Partnership Agreements	28	28	28
NARMS Salmonella Isolates Tested	12,000	12,000	12,000

[6/] An inspection is any visit to a firm during which all or part of one or more phases of that establishment's operation is evaluated against appropriate Agency requirements.

[7/] A Field Exam is the on-site examination of a product that is sufficient in itself to determine whether the product is in compliance with Agency requirements.

[8/] Laboratory Samples Analyzed are product samples physically analyzed by the laboratory to determine whether or not the product is in compliance with Agency requirements.

Devices and Radiological Health

	FY 2001 Actual Obligations	FY 2002 Current Estimate	FY 2003 +/-FY 2002 Current Estimate	FY 2003 Baseline Estimate
Total Program Level	**$177,565,000**	**$196,425,000**	**+ $10,215,000**	**$206,640,000**
Center	$125,872,000	$136,978,000	+ $5,369,000	$142,347,000
FTE	1,016	1,028	+ 4	1,032
Field	$51,693,000	$59,447	+ $4,846,000	$64,293,000
FTE	457	497	+ 20	517
Current Law BA	**$165,306,000**	**$181,021,000**	**+ $9,699,000**	**$190,720,000**
Counter Terrorism	1,043,000	2,594,000	+ $3,422,000	6,016,000
Pay Increase 1/		-	+ $5,173,000	5,173,000
Medical Errors	9,950,000	12,250,000	+ $1,500,000	13,750,000
Mgmt. Efficiencies	-	-	($396,000)	(396,000)
Current Law BA Accrual Costs2/	**$8,045,000**	**$7,932,000**	**+ $32,000**	**$7,964,000**
Total Current Law BA with Accrual Costs	**$173,351,000**	**$188,953,000**	**+ $9,731,000**	**$198,684,000**
FTE	**1,428**	**1,477**	**+ 24**	**1,501**
MQSA	**$12,259,000**	**$15,404,000**	**+ $516,000**	**$15,920,000**
FTE	**45**	**48**	**0**	**48**
Accrual Costs2/	**$296,000**	**$315,000**	**($13,000)**	**$302,000**
Total User Fees with Accruals	**$12,555,000**	**$15,719,000**	**+ $503,000**	**$16,222,000**
FTE	**45**	**48**	**0**	**48**

1/Pay increases shown on separate line, and not reflected in individual initiative areas.
2/Reflects 2001 and 2002 comparable estimates.

Historical Funding and FTE Levels

Fiscal Year	Program Level	Budget Authority	User Fees	Program Level FTE
1999 Actuals	159,008,000	145,790,000	13,218,000	1,480
2000 Actuals	170,257,000	157,656,000	12,601,000	1,472
2001 Actuals	177,565,000	165,306,000	12,259,000	1,472
2002 Current Estimate *3/*	196,425,000	181,021,000	15,404,000	1,525
2003 Estimate	206,640,000	190,720,000	15,920,000	1,549

3/Includes FDA's FY 2002 Appropriation and the Counter Terrorism Supplemental.

MISSION

- Meet all statutory responsibilities for review of new medical devices;
- Assure medical product safety by monitoring the use of all medical devices, and the function and use of radiological products;
- Manage emerging hazards to prevent widespread health and safety threat and ensure safe and effective new technologies;
- Apply the Total Product Life Cycle model across the range of Devices and Radiological Health activities, by covering products from concept to obsolescence;
- Connect to the global public health community, and partner with stakeholders;
- Use science in the regulatory process to the maximum extent;
- Attract and retain a diverse and high quality workforce; and,
- Measure and set targets to assess our continuing impact on public health.

PROGRAM RESOURCE CHANGES

The FY 2003 request builds upon funding FDA received from the FY 2002 appropriation plus the FY 2002 emergency supplemental. As a result, while FDA has received increased funding to support counter terrorism, some of the programs are showing either no funding increase, or a slight decrease. The FY 2003 request annualizes those dollars received as one-time money in the supplemental -- a significant increase to the Agency of $152,276,000 in total. The funding changes shown below are the differences once these annualized dollars are removed.

For the Devices program, in FY 2003, FDA will continue to utilize $1,500,000 provided in the supplemental, plus an additional $3,422,000, to maintain the level of effort and the frequency and quality of imported medical device inspections. The Agency will also continue to modernize the import data system to better detect tainted medical device products or those in which tampering may have occurred.

Counter Terrorism –Safe and Effective Medical Products: + $3,422,000
Statutory authority/requirement for conducting biennial inspections of Class II and III device manufacturers is in Section 510(h) of the FFD&C Act and general statutory authority for conducting inspections is found in Section 704 of the Act.

- Develop new diagnostic tests for field and import examinations of imports to help our field investigators determine if a product has been tampered with or is otherwise tainted;
- Predict and manage potential device shortages, such as rubber gloves, so there are enough critical commonly used devices to aid in the rescue effort;

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

- Evaluate diagnostic test kit performance that detect warfare agents that are being marketed to the public and the government;

- Develop field expertise to sample high-risk products, such as rubber gloves or surgical masks, for contamination and consider automatic detention of medical devices imported from the Middle East;

- Work with U.S. Customs to increase surveillance and detention of products that are at high risk for tampering and contamination outside the U.S., such as syringes and rubber gloves and evaluate high-risk imports labeled "for export only";

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

- Expand technical assistance to industry and DOD, expedite review, and expand outreach to civilian emergency medical professionals to give them more information about new devices in their field; and,

- Upgrade field laboratory capabilities to rapidly detect bio-terrorism contamination.

Provide the medical community with faster access to important, life-saving and health-enhancing medical devices, while assuring their safety and effectiveness. (Strategic Goal #1).

Expedite review for 100 percent of Bioterrorism Diagnostic Medical Device Applications. (Performance Goal)

Implement Emergency Counter Terrorism Preparedness and Response Plan for radiation. (Performance Goal)

Begin to develop radiation standards for the safety of novel or new technology used to scan people in airports and other places. (Performance Goal)

Pay Increase: + $5,173,000

FDA's request for funds to cover pay 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 people-intensive. Payroll accounts for over 60 percent of the total FDA budget. This has a significant impact on all activities in FDA. FDA is requesting $28,552,000 million to cover pay-related increases. The Device program piece of this increase is $5,173,000.

Patient Safety/Medical Errors: +$1,500,000 and 1 FTE

FDAs Medical Device User Facility Reporting authority is Section 519(b) of the FFD&C Act.

- Continue the development of the Medical Device Surveillance Network (MedSuN). MedSuN, when fully implemented, will reduce the occurrence of medical device related events; serve as an advanced warning system; and greatly improve real-time public health communication among FDA and user-facilities. The MedSuN program significantly enhances the effectiveness of postmarketing surveillance of medical products as they are used in clinical practice and to rapidly identify critical health hazards associated with these products;

- Recruit more hospitals and other health care facilities for the MedSuN program and train the facilities in the mechanics of the program. In FY 2003, FDA expects to recruit an additional 100 facilities, which will include hospitals and nursing homes, which will raise the total of network facilities to180; and,

- Continue to develop MedSuN education and training materials. Examples include the following: provide training that describes how to recognize when an adverse event is related to medical devices to maintain high quality reporting from facilities; review all reports sent to MedSuN for completeness, and follow-up with the reporting facilities to create higher quality and more thorough reports; create and distribute monthly newsletters to provide education and feedback to the participating facilities; conduct annual meetings and workshops for participating facilities; and increase the number of FDA analysts and human-factors experts who attend facility training and workshops so they may train the facilities to recognize and report device-specific problems.

Reduce the risk of medical devices and radiation-emitting products on the market by assuring product quality and correcting problems associated with their production and use. (Strategic Goal #2)

Build the MedSuN System by expanding the network to 180 facilities. (Performance Goal #15012)

Management Efficiencies: + $396,000 and 4 FTE

FDA's budget assumes savings of $2,578,000 million associated with efficiency improvements and consolidations related to the President's Management Plan. The Devices Program piece of this total reduction is $396,000 and four FTE.

USER FEES

Mammography Quality Standards Act (MQSA): + $516,000

The Mammography Quality Standards Act (MQSA) of 1992 was reauthorized in 1998 for an additional five years (P.L. 105-298). MQSA requires that mammography facilities be certified (by October 1, 1994) and inspected annually to ensure compliance with national quality and safety standards. FDA requests an increase of $516,000 for the medical devices program in

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

Ensure at least 97 percent of mammography facilities meet inspection standards, with less than three percent with Level I (serious) problems. (Performance Goal #15007)

JUSTIFICATION OF BASE

Activities Related to Increases for FY 2003

Counter Terrorism – Safe and Effective Medical Products

- Provide expedited review of diagnostic products that detect/identify biologic threat agents for use in directing patient treatment and investigating outbreaks;

- Recruit and train expert reviewers and scientific staff to address the expected increase in new diagnostic products that have intended uses not previously evaluated by FDA;

- Participate in the development and/or recognition of standards developed by other Federal agencies such as CDC and DOD and outside organizations for use in reviewing and defining performance for test kits and mail irradiation equipment;

- Conduct research to give scientific staff an understanding of the technology used with *in vitro* diagnostic devices that help detect/identify biothreat agents. Research will advance the diagnostic technology, and improve techniques for testing decontamination systems;

- Educate health professionals and consumers on the use of medical device biowarfare products;

- Assess the *in vitro* diagnostic market to determine the number and type of test kits that are being marketed to either the public or the government. FDA should be able to identify the manufacturers that promote the diagnostic devices, monitor their activities, and act appropriately when unsafe practices are detected;

- Use field resources to monitor, evaluate, and follow-up on medical devices and radiological products used in counter terrorism response;

- Prepare field staff to safely seize, remove, and dispose of contaminated products by developing procedures and providing appropriate facilities and equipment;

- Identify and address potential device shortages associated with a public health response before a terrorist attack occurs. A coordinated public health response to a counter terrorist attack will require the use of many commonly used devices such as *in vitro* diagnostic devices, portable ventilators, syringes, gloves, and other standard equipment, which may not be available in sufficient quantity to aid in the rescue effort;

- Implement the Emergency Counter Terrorism Preparedness and Response Plan for the device program, which allows FDA to respond quickly to all types of emergencies related to devices and radiation-emitting products;

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

- Provide technical assistance where needed to use irradiation to kill anthrax spores in the mail and in mail-handling equipment; and,

- Develop radiation safety standards for the safe use of people scanners in airports and other places.

Medical Errors

- Continue to partner with other Federal agencies, States and private-sector organizations to develop and communicate information that will encourage safer use of medical devices and avert risks to patients. For example, support finding methods to reduce hazards associated with hospital beds. FDA has partnered with Centers for Medicare and Medicaid Services, manufacturers of medical beds, the Joint Commission on the Accreditation of Healthcare Organizations, and other interested parties to look at bed-related injuries to develop a standard-of-care for use of bed rails in hospitals, long term care facilities, and home health settings;

- Provide increased health education to U.S. consumers and healthcare workers about FDA regulated products that may pose adverse health risks;

- Continue to provide technical assistance to small medical device manufacturers, and provide accessible, timely feedback to industry, health professionals, and consumers. FDA will provide industry, health professionals, and consumers with feedback via: (1) Device Advice: the CDRH self-service site for medical device and radiation emitting information: www.fda.gov/cdrh/devadvice/11.html; (2) E-mail: Director@cdrh.fda.gov; (3) Internet Comments and Feedback; (4) links for submitting comments on proposed regulations; and (5) use of automation to provide the public with the latest information; and,

- Continue implementing MedSuN. FDA projects recruiting up to 80 facilities by the end of FY 2002. This reflects a downward adjustment to FDA's FY 2002 performance goal from 125 facilities. In FY 2001 FDA delayed implementing feasibility testing due to extended software development issues and unanticipated program changes, as well as increased information technology security requirements. Thus, in FY 2001, FDA began feasibility studies with only 25 facilities instead of the 75 facilities originally projected.

Implement the MeDSuN System by expanding the network to 180 facilities. (Performance Goal #15012)

Radiation Safety

- Continue to prioritize and leverage FDA's radiation protection efforts with State governments, professional societies, and other Federal agencies. Advances in new technologies and expansion of overseas manufacturing facilities increase the likelihood that new products used by American consumers will require radiation to perform their intended function. FDA continues to detect increasing numbers of electronic product radiation emissions that far exceed radiation safety standards. FDA will provide inspection and product testing coverage of 10 percent to the radiological health industry.

Bovine Spongiform Encephalopathies (BSE)

- Develop and maintain databases of devices containing/exposed to animal-derived materials;

- Initiate reviewer training and establish linkages to the Operational and Administrative System for Import Support (OASIS) to enhance import controls; and,

- Evaluate decontamination/sterilization of medical/surgical instruments, and assess policy regarding reuse.

Other Activities Related to High Priority Areas

Import Monitoring and Inspections

- Inspect 1,000 of 5,000 (20 percent) of high-risk device domestic statutory inventory. Inspect nine percent of the foreign high-risk statutory inventory, which consists of over 2,500 firms. FDA's statutory performance requirement is to inspect 50 percent of high-risk device manufacturers every year;

- Inspect a sample of 7,000 Class I lower risk firms to monitor Quality Systems performance. The remainder of the Class I manufacturers will be inspected for cause;

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

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

- Review approximately 2,080,000 million devices import lines for admissibility into domestic commerce.

Conduct 290 BIMO inspections with an emphasis on vulnerable populations (e.g., Mentally impaired, pediatric, etc.) (Performance Goal #15025)

Provide inspection coverage for Class II and Class III foreign medical device manufacturers at nine percent for FY 2003. (Performance Goal #15005.02)

Statutory Device Review Times

- Complete 95 percent of first actions within 180 days, per FDA's FY 2002 performance target. The FDAMA statutory requirement is to complete 100 percent of Premarket Approval Applications (PMAs) review actions within 180 days. PMAs are high-risk devices with the highest likelihood of significantly improving the treatment of patients; and,

- Complete 95 percent of PMA supplement final actions within 180 days, which is another FY 2002 premarket objective. The FDAMA requirement is to complete 100 percent of PMA supplement review actions within 180 days. Supplemental applications are generally submitted for changes in already approved applications. Such changes might include technology changes or the addition of a new indication.

Review and complete 95 percent of Premarket Approval Application (PMA) supplement final actions within 180 days. (Performance Goal #15009)

Third Party Review Program

- Continue to encourage industry's use of third party reviews. Seventy percent of all 510(k)s are now eligible for third party review. FDA has a web site which provides information on the Accredited Persons Program (www.fda.gov/cdrh/thirdparty.) This is an alternative premarket notification (510(k)) process that allows 510(k) submitters to use FDA-accredited third party review organizations (Accredited Persons) in place of FDA's review. FDA will also explore other areas where it may be appropriate to use third party inspectors or reviewers.

Least Burdensome Initiative

- Continue to make progress at implementing this provision through training, meetings with sponsors, and guidance development and to effectively meet the challenge to reduce regulatory burdens without compromising safety and effectiveness.

Genetic Testing

- Continue to develop scientific expertise and regulatory strategies for evolving medical device areas such as genetic testing;

- Collaborate with other DHHS agencies as part of an inter-agency working group and as a participant with the CDC on genetics testing; and,

- Continue with internal training efforts and informal outreach efforts to address issues dealing with reviews and the development of guidance and standards.

Clinical Laboratory Improvement Amendments (CLIA)

- Continue with FDA's responsibility to categorize commercially marketed *in vitro* diagnostic test systems. FDA is developing guidance that will streamline the process and provide an alternative to the Center for Disease Control criteria in the 1995 proposed rule that is currently used to review waiver requests. This activity is funded by a portion of the CLIA user fees collected by the Centers for Medicare and Medicaid Services.

International Activities

- Continue FDA's commitment to implement the U.S. - European Union (EU) Mutual Recognition Agreement (MRA);

- Continue to develop information about EU-based medical device manufacturers and provide more information about the status of those manufacturers to help expedite product approval. This involves training, assessing the work performance of third-party, and Conformance Assessment Bodies (CABs) for inspections of device manufacturers; and,

- Continue to maintain FDA's international inspection program as one of the Agency's top priorities as more FDA regulated products originate from foreign sources. Maintaining a strong FDA 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.

Science and Standards Activities

- Use high scientific standards to promote and protect the public health and to expedite premarket reviews. The Agency will continue to issue standards for industry use.

Antimicrobial Resistance

- Continue to develop and streamline review of quick, easy to use test kits for identifying microbes and for determining susceptibility to treatments;

- Issue an advanced notice of proposed rulemaking concerning how to regulate devices that contain antimicrobials in light of public health concerns regarding antimicrobial resistance;

- Draft a guidance document for industry concerning how FDA intends to regulate devices containing antimicrobials, and what information regarding efficacy and resistance FDA wants to see in premarket applications; and,

- Gather information from experts on developing test methods that could be used to demonstrate efficacy of antimicrobials on devices for use in guidance and rulemaking.

Human Subject Protection

- Ensure prompt follow-up to bona fide complaints of research misconduct that may compromise the safety of human research subjects or subvert regulatory review;

- Enhance the quality and integrity of investigational device research by maintaining a regulatory presence in the research community, and by working with non-compliant firms to develop corrective and preventative actions to improve their human subject protection or research integrity systems;

- Continue to educate the device research community; and,

- Maintain and update the knowledge, skills, and abilities of FDA staff to keep pace with clinical research in evolving or breakthrough device technologies.

Device Reuse

- Extend date for obtaining FDA approval for Class III single use devices (SUDs), i.e., cardiac ablation catheter PMA under current review, from August 14, 2001 to February 14, 2002. All other Class III SUDs may be only available under the Investigational Device Exemption (IDE) regulation; and,

- Continue FDA's commitment to inspect 200 hospitals annually to evaluate their compliance with premarket clearance requirements and the requirements of the Quality System regulation. In FY 2002, inspections of hospitals reprocessing Class I devices will be educational in nature. Formal GMP inspections will be reserved for those hospitals reprocessing higher risk Class II and III devices.

Diabetes

- Regulate a wide variety of devices used to diagnose and treat diabetes;

- Work with the diagnostics industry, health professionals, and diabetics to assure that safe and effective diagnostics are available to check the blood level of diabetics so they can manage their home treatments; and,

- Develop and maintain a diabetes web page with other Agency components that will provide the consumer with information on FDA regulated products.

Obesity

- Regulate several devices that enable doctors to help their patients control obesity;

- Work interactively with several sponsors on new, promising, investigational weight loss devices for the severely obese; and,

- Monitor Internet marketing activities for fraudulent weight loss devices to ensure that the medical device information displayed is truthful, and meets the requirements of the Federal Food, Drug, and Cosmetic Act.

Asthma

- Regulate a wide variety of inhalers used by asthmatics to administer their medicines. These inhalers are often regulated as combination products in conjunction with the Human Drugs program, which regulates the drugs that the inhalers deliver; and,

- Regulate diagnostics used to screen patients for asthma and to monitor their therapy.

MQSA

- Certify annually mammography facilities to ensure compliance with national quality and safety standards;

- Fund approximately 7,900 State contract MQSA inspections to ensure compliance with the standards; and,

- Continue with the Demonstration Project, which is a Congressionally mandated program designed to assess the results of less frequent inspections for high performing facilities. It is anticipated that the selected facilities will maintain the same level of mammography quality without annual inspections.

SELECTED FY 2001 ACCOMPLISHMENTS

Counter Terrorism – Safe and Effective Medical Products

- Developed an Emergency Counter Terrorism Preparedness and Response Plan for the medical device program. The plan defines FDA's response to all types of emergencies that involve medical devices and radiation-emitting products, and identifies other Agencies to clarify their responsibilities. It will also focus on counter terrorism activities that may involve product availability, battlefield/emergency medicine, surveillance and detection capabilities, radiation safety, and coordination and communication of public health information;

- Updated the Radiation Emergency Response Plan for liaison and assistance activities in the event of a nuclear materials disaster or terrorist event. Worked with other Federal and State agencies to clarify their responsibilities;
- Worked on a priority basis with academicians, manufacturers, and agencies such as the DOD and CDC to develop marketing applications for the detection/identification of biothreat agents;

- Evaluated new products for military decontamination in the field such as packs worn by troops to remove chemical and biological agents; and discussed updating testing standards to make sure battlefield and emergency devices work in spite of electronic interference;

- Evaluated new products for environmental decontamination such as UV radiation, air filtering systems, and electron beam irradiation of mail; and

- Provided expert advice and safety standards relating to safe and effective mail irradiation procedures.

Patient Safety/Medical Errors

- Continued to look for ways to reduce preventable deaths and injuries associated with the use of medical device products through access to a sufficient amount of quality information regarding device events;

- Continued developing the necessary software to implement MedSuN feasibility testing and met all of the FDA information technology security requirements. Facility reports of deaths, serious injuries, and "close-calls" associated with medical devices are now sent to FDA through the Internet to a secure webserver; and,

- Began MedSuN feasibility studies with 25 hospital facilities instead of the 75 originally projected. FDA did not meet the goal of recruiting 75 hospitals because most of the year's effort was focused on software development for the pilot phase of the program, unanticipated program changes beyond FDA's control, as well as increased information technology security requirements.

MQSA

- Determined that 97 percent of mammography facilities met inspection standards, with 3.4 percent with Level I (serious) problems. The slight increase above the GPRA goal of 3 percent for this element was likely due to the fact that under the final regulations, which became effective in April, 1999, several citations were elevated to Level I, and some new Level I citations were added.

Antimicrobial Resistance

- Worked with scientific and industrial communities to facilitate development of rapid diagnostics/susceptibility tests. FDA routinely meets with the industry/clinical laboratory community to keep this project on track; and,

- Drafted Advanced Notice of Proposed Rule Making (ANPRM) on the review and labeling of devices that contain antimicrobial agents. The proposed rule is currently awaiting clearance from DHHS.

Obesity

- Regulated several devices that doctors can use to help their patients control obesity. FDA approved a new medical device called the LAP-BAND system, designed to help patients lose excess body weight.

Asthma

- Regulated a wide variety of inhalers used by asthmatics to administer their medications. These inhalers are often regulated as combination products in conjunction with FDA's Center for Drugs.

Significant Medical Device Approvals/Clearances

- Approved and cleared many novel and medical breakthrough devices that will provide significant improvements in patient care:

- **GlucoWatch Biographer**: The new technology for monitoring glucose levels in diabetics is a wristwatch-like device that provides adult diabetics with more information for managing their disease. It is intended for use along with, not as a replacement for, finger-prick blood tests to monitor glucose. Glucose levels are measured every 20 minutes for 12 hours even during sleep. The device sounds an alarm if a patient's glucose reaches dangerous levels, thus helping patients manage a potential problem;

- **Implanted Stomach Band**: The Lap-Band Adjustable Gastric Banding System, made by BioEnterics Corporation of Carpinteria, California, is a new surgically implanted device to help severely obese people lose weight. An inflatable band is placed around the upper

stomach to create a small gastric pouch. This limits food consumption and creates a feeling of fullness. Previously the only surgical treatments available for severe obesity were more invasive procedures such as stomach stapling and gastric bypass;

- **Implantable Middle Ear Hearing Device**: The Direct, Soundtec, Inc., is a surgically implanted hearing device intended to help adults with moderate to severe hearing loss. This device is an alternative to traditional hearing aids. Adults who choose this device should have already tried traditional hearing aids and found them unsatisfactory;

- **First automatic external defibrillator system for use on infants and young children**: The new device, made by Agilent Technologies, Inc., of Palo Alto, Calif., can be used on infants and children up to age eight and/or weighing up to 55 lbs. Automatic External Defibrillator Systems (AEDs) are life saving devices used when the heart is beating irregularly and ineffectively (fibrillating). The AED administers an external electric shock through the chest wall to the heart via conductive adhesive pads in an effort to restore normal heart rhythm. The AEDs currently marketed are restricted to use on adults and children over eight years of age. This device widens the availability of life-saving technology; and
- **First pacemaker for congestive heart failure**: The new device is the InSync Biventricular Cardiac Pacing System made by Medtronic, Inc., of Minneapolis. Specially timed electrical impulses are sent to the heart's lower chambers to treat the symptoms of moderate to severe congestive heart failure. The InSync system is the first pacemaker approved for treating the symptoms of congestive heart failure, a condition in which the heart can not adequately pump blood around the body. Standard pacemakers are used to treat rhythm disturbances in the heart, a different condition.

Bringing New Medical Device Products to Market

- Received almost 10,000 major submissions, and, for the fifth consecutive year, there were no overdue submissions. The additional funding for premarket review received in FYs 2000 and 2001 allowed FDA to maintain performance while continuing to review increasingly complex medical device technologies;

- Approved a record 53 premarket approvals (PMAs);

- Approved four Humanitarian Device Exemptions (HDEs). A HDE application is similar in both form and content to a PMA application but is exempt from the effectiveness requirements of a PMA. Included in the four approvals are a coronary stent graft and a joint implant finger prosthesis; and,

- Started developing a device center database to aid in the consistent processing of inquiries about the need for an Investigational Device Exemption (IDE) application.

Third Party 510(k) Reviews

- Encouraged greater use of the Third Party Program, and implemented an expansion pilot in 2001 that allows Accredited Persons to review many Class II devices that were not previously eligible. Determined that 510(k)s reviewed by Accredited Persons are 29 percent faster than comparable 510(k)s reviewed entirely by FDA;

- The pilot allows, subject to certain conditions, Accredited Persons to review Class II devices for which there are no device-specific guidance documents;

- Issued a guidance document entitled Guidance for Staff, Industry and Third Parties: Implementation of Third Party Programs Under the FDA Modernization Act of 1997 (PDF). This program has the potential to improve the efficiency and timeliness of FDA's 510k review process. Most Accredited Persons have specialized expertise in areas that may be helpful to 510(k) submitters, such as device testing, standards, or foreign regulatory requirements; and,

- Received 107 510(k)s reviewed by third parties.

Genetic Testing

- Prepared a template that serves as an outline for collecting administrative, analytical, and clinical data on genetic tests. Templates will be completed by each facility offering genetic testing services;

- Interacted with other HHS agencies, such as CDC and the Centers for Medicare and Medicaid Services, who also have roles in the oversight of genetic testing; and,

- Developed an extensive in-house training program specifically geared toward pharmacognenomic test applications and related use of DNA chip technology.

Reuse of Single Use Devices

- Established an FDA policy on reuse of single-use to protect the health of the public by assuring that the practice of reprocessing and reusing single-use devices (SUDs) is safe and effective and based on good science;

- Requested the Association for the Advancement of Medical Instrumentation (AAMI) to initiate standards development. No standardized protocol is available for the cleaning of devices after use but prior to sterilization. When completed, this protocol will be useful to hospitals and others who clean medical devices prior to their being placed back into service;

- Issued four guidance documents to assist hospital and third party (commercial) reprocessors to comply with FDA's regulatory requirements. The guidance documents addressed adverse event reporting for hospital reprocessors, submission of premarket applications and notifications, frequently asked questions about reprocessing and reprocessors, and labeling of reprocessed SUDs;

- Received five premarket applications (PMAs) for cardiac ablation catheters on February 14, 2001, which was the deadline for submission of PMAs for reprocessed Class III (high-risk) SUDs. Four of the five PMAs were filed and they are currently undergoing review;

- Received 90 premarket notifications 510(k)s for a variety of reprocessed Class II non-exempt (moderate risk) SUDs. Several of the 510(k)s that were submitted have received FDA clearance for marketing; and,

- Initiated the regulatory requirement that all U.S. hospitals that reprocess SUDs must register their establishments and list their devices with the Agency.

Human Subject Protection

- Conducted 224 domestic and foreign inspections under the bioresearch monitoring program. FDA relies heavily on the integrity of data generated from clinical trials in making many of its review decisions. FDA inspects sponsors, contract research organizations, monitors, and institutional review boards to ensure that the rights and welfare of human subjects who participate in research or clinical trials are protected, and to verify that data collected by the regulated industry are accurate and reliable.

Clinical Laboratory Improvement Amendments (CLIA)

- Established a CLIA database, which contains commercially marketed *in vitro* diagnostic test systems categorized by FDA and those characterized by CDC. The database searches the records for Test System, Specialty/Subspecialty, Document Number, Qualifier, Effective Date, or Complexity enabling the user to efficiently determine the CLIA complexity of a test with minimal information; and,

- Categorized 1,839 tests: 1,558 moderate complexity, 149 waived and 132 high complexity. Congress passed CLIA in 1988 establishing quality standards for all laboratory testing to ensure the accuracy, reliability, and timeliness of patient test results regardless of where the test was performed. The CLIA statute requires laboratory regulation on the basis of test complexity instead of test site, and defines waived tests as being simple, low risk tests. The CLIA regulation, published in 1992, established criteria for categorizing tests on the basis of complexity for moderate and high tests.

Postmarket Inspections

- Exceeded the FY 2001 performance target (17 percent) by inspecting 20 percent of 4,900 domestic higher risk Class II and Class III manufactures. FDA's statutory performance requirement is 50 percent. With the exception of those inspected for cause, many manufacturers of low risk Class I devices have never been inspected. To develop a better understanding of the compliance rate of low risk Class I devices, a small number of such firms were inspected; and,

- Conducted 266 foreign inspections compared to 261 foreign inspections.

Radiological Health Activities

- Organized and participated in the development of a voluntary consensus standard for x-ray personnel security screening systems, and advised Federal agencies on their safety of use in counter terrorism activities;

- Continued to address oversight concerns with the expanding overseas facilities, which contribute to roughly 335 million foreign made products imported into the U.S.;

- Initiated activities to prioritize and leverage radiation protection efforts with State governments, professional societies, and other Federal agencies; and,

- Continued to develop an electronic reporting system for laser products, which account for three-quarters of the reports submitted on radiation-emitting electronic products.

Transmissible Spongiform Encephalopathies (TSEs)

- Helped to develop the working draft of the FDA Proposed Bovine Spongiform Encephalopathy (BSE) Rule which would make bovine and bovine materials from BSE-positive or BSE high-risk countries prohibited materials in the manufacture of FDA-regulated products;

- Prepared a draft document on the risk of transmitting TSEs through medical devices and products with components of bovine origin;

- Developed guidance for industry on preventive measures to reduce the possible risk of transmission of CJD and variant Creutzfeldt-Jakob disease (vCJD) by human cells, tissues, and cellular and tissue-based products.

Devices and Radiological Health
Program Activity Data

Program Workload and Outputs	FY 2001 Actual	FY 2002 Estimate	FY 2003 Estimate[4/]
PMAs Received (includes PMAs/PDPs)	70	75	80
PMAs Approved	53	40	45
Average Elapsed Time (FDA days-approval)	257	255	255
Total PMA Actions[1/]	282	300	300
HDEs Received	5	12	15
HDEs Approved	4	12	15
Average FDA Review Time (FDA days approval)	142	75	75
PMA Supplements Received	641	650	700
PMA Supplements Approved	442	550	550
Average Elapsed Time (FDA days-approval)	78	95	95
PMA Supplement Panel Tracks[2/] (Received/Approved)	14/10	16	16
510(k)s Received (includes Trad., Spec. Abbrev., 3rd party	4,248	4,800	4,800
510(k)s Completed (All Decisions)	4,150	4,750	4,750
Average Elapsed Time (FDA days-decision)	75	75	75
IDEs Received	284	330	350
IDEs Approved/Total	284	330	350
Average Elapsed Time (FDA days-approval)	28	30	30
IDE Supplements Received	4811	4,450	4,500
IDE Supplements (Approved/Total Decisions)	4803	4,450	4,500
Avg FDA Review Time (FDA days-approval)	21	20	20
MDR Initial Reports Received	50,966	53,000	53,000
MDR Line Item Summary Reporting	49,059	50,000	50,000
Total MDR Incidents (mandatory)	100,025	100,000	100,000
MDR Voluntary Reports Received	3,134	3,000	3,000
Export Certificates and Permits	3,015	3,000	3,000
MQSA Facility Certifications[3/]	3,170	2,409	2,953
MeDSuN Facility Network	25	80	180

[1/]Includes filing decisions, review determinations, and approval decisions.
[2/]A "Panel-Tracked" PMA supplement is a supplement to an already approved PMA and is usually for a change in the indications for use statement. The change in indications statement is usually for a new use of the already approved device (not change to the device), for use in a different disease condition, for use in a different anatomical site, or for use in a different patient population. A summary of safety and effectiveness information is prepared and made available to the public.
[3/]These numbers represent certifications only and do not include certificates issued to facilities who are new, reinstated, or have changed their addresses.
[4/]When fully implemented, the FY 2003 requested increase for all Field programs will provide additional domestic inspections performed by FDA depending on progress in hiring, training, and equipping new staff.

Devices and Radiological Health
Program Activity Data (Continued)

Program Workload and Outputs	FY 2001 Actual	FY 2002 Estimate	FY 2003 Estimate
Field Program Outputs-Domestic			
Bioresearch Monitoring Inspections[5/]	224	270	270
Inspections Pre-Approval	123	125	130
GMP Inspections	996	1,000	1,150
Inspections (MQSA) FDA Domestic (non-VHA)	565	427	427
Inspections (MQSA) FDA Domestic (VHA)	41	39	39
Inspections (MQSA) by State Contract [6/]	8,113	7,900	7,900
Inspections (MQSA) by State non-Contract	543	543	543
Total Domestic MQSA	9,262	8,909	8,909
Domestic Radiological Health Inspections	117	160	200
Domestic Field Exams/Tests	1,572	1,520	1,520
Domestic Lab Samples Analyzed	137	300	340
Field Program Outputs-Import/Foreign			
Foreign Bioresearch Monitoring Inspections[5/]	14	20	20
Foreign Pre-Approval Inspections	41	40	40
Foreign GMP Inspections	266	250	250
Foreign MQSA Inspections	16	13	13
Foreign Radiological Health Inspections	33	40	40
Import Field Exams/Tests	625	750	1,100
Import Laboratory Samples Analyzed	1,297	1,440	1,500
Import Line Entry Decisions	1,761,992	1,980,000	2,080,000

[4/]When fully implemented, the FY 2003 requested increase for all Field programs will provide additional domestic inspections performed by FDA depending on progress in hiring, training, and equipping new staff.
[5/]Bioresearch Monitoring Inspections involve the inspection of sponsors of premarket applications (PMAs), clinical investigators, Institutional Review Boards (IRBs), and non-clinical laboratories.
[6/]The estimate of the total number of Inspections (MQSA) performed by State Contract (non-federal, non-VHA, and non-SAC facilities) reflects a decrease in the actual facility inventory and hence a slight reduction in the number of inspections.

National Center for Toxicological Research

	FY 2001 Actual Obligations	FY 2002 Current Estimate	FY 2003 +/-FY 2002 Current Estimate	FY 2003 Baseline Estimate
Total Program Level				
Center	**$36,248,000**	**$42,882,000**	**($2,194,000)**	**$40,688,000**
FTE	**206**	**237**	**+ 1**	**238**
Current Law BA	**$36,248,000**	**$42,882,000**	**($2,194,000)**	**$40,688,000**
Counter Terrorism	*438,000*	*6,259,000*	*($2,842,000)*	*3,417,000*
Pay Increase 1/			*+ $945,000*	945,000
Mgmt. Efficiencies			*($297,000)*	(297,000)
Current Law BA Accrual Costs2/	**$2,011,000**	**$1,983,000**	**+ $6,000**	**$1,989,000**
Current Law BA with Accrual Costs2/	**$38,259,000**	**$44,865,000**	**($2,188,000)**	**$42,677,000**
FTE	**206**	**237**	**+ 1**	**238**

1/Pay increases shown on separate line, and not reflected in individual initiative areas.
2/Reflects 2001 and 2002 comparable estimates.

Historical Funding and FTE Levels

Fiscal Year	Program Level	Budget Authority	User Fees	Program Level FTE
1999 Actuals	$32,109,000	$32,109,000	0	223
2000 Actuals	$36,522,000	$36,522,000	0	217
2001 Actuals	$36,248,000	$36,248,000	0	206
2002 Current Estimate 2/	$42,882,000	$42,882,000	0	237
2003 Estimate	$40,688,000	$40,688,000	0	238

2/Includes FDA's FY 2002 Appropriation and the Counter Terrorism Supplemental.

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 pre-market 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 the 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.

PROGRAM RESOURCE CHANGES

The FY 2003 request builds upon funding FDA received from the FY 2002 appropriation plus the FY 2002 emergency supplemental. As a result, while FDA has received increased funding to support counter terrorism, some of the programs are showing either no funding increase, or a slight decrease. The FY 2003 request annualizes those dollars received as one-time money in the supplemental -- a significant increase to the Agency of $152,276,000 in total. The funding changes shown below are the differences once these annualized dollars are removed.

For NCTR, in FY 2003, FDA will continue to utilize $2,958,000 of the $5,800,000 provided in the supplemental to maintain counter-terrorism efforts begun in FY 2002. NCTR received $5,800,000 to upgrade and outfit laboratory facilities in support of counter terrorism initiatives and improve detection techniques for bioterrorist agents.

Counter Terrorism – Food Safety/Safe and Effective Medical Products: -$2,842,000

- Continue expansion of newly developed bacterial identification techniques started with counter-terrorism supplemental funds to include ability to rapidly identify and characterize biological warfare agents, and other organisms of mass destruction as well as development of a protein structure database that can be used for accurate identifications of biomarkers associated with these organisms; and,

- Purchase additional proteomics equipment essential to support detection and characterization of aberrent protein structures that will serve as biomarkers for terrorism. This instrument is required to ensure availability of dedicated instrumentation within the BSL-3 laboratory for use with these biohazards.

Pay Increase: + $945,000

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 people-intensive. Payroll accounts for over 60 percent of the total FDA budget. This has a significant impact on all activities in FDA. FDA is requesting $28,552,000 to cover pay-related increases. The NCTR program piece of this increase is $945,000.

Management Efficiencies: -$297,000 and -2 FTE

FDA's budget assumes savings of $2,578,000 associated with efficiency improvements and consolidations related to the President's Management Plan. The NCTR portion of this total reduction is $297,000 and two FTE.

JUSTIFICATION OF BASE

Activities Related to Increases for FY 2003

Counter Terrorism

- Upgrade designated laboratory facilities at NCTR (located in the Jefferson Laboratories of the FDA in Jefferson, Arkansas) to a Biosafety Level 3 (BSL-3) to support mad cow disease

(BSE/TSE) and microbial bioterrorism research. BSL-3 facilities have containment capability that allows work with indigenous or designer agents that may cause serious or potentially lethal disease such as anthrax;

- Outfit laboratory facilities to allow rapid detection and identification and assignment of bacterial strains of bioterrorist agents. This includes fitting facilities with equipment including containment hoods, and appropriate filtering and monitoring devices; and,

- Improve rapid detection and assessment of bacterial strains of bioterrorist agents through the purchase of tools necessary to identify bacterial proteins and toxicity markers in foods including a Matrix Assisted Laser Desorption Ionization (MALDI)/Time-of-Flight (TOF) mass spectrometer, a high resolution Fourier Transformed Mass Spectrometer (FTMS), and a Laser Capture Microdissection microscope and microarray reader/printer.

Payroll

- 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. NCTR 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 techniques to identify emerging bacterial and chemical contaminants in the food supply. These techniques can also provide methods of assessment for potential biochemical terrorist threats or foodborne contamination;

- Use chemical analysis and computer assisted data interpretation to identify specific proteins that may be a contaminant in foods, or food related products such as dietary supplements. For example, this technology could be used to find peanut protein, a strong allergen, in a food product where peanut products are not identified as a component;

- Support the Agency's need for a viable nutrition program to improve human health. This program will contain research dealing with: folic acid (commonly found in liver, green vegetables, and yeast) and other nutrient deficiencies; nutrition and cancer prevention; drug nutrient interactions; nutrition and prevention of birth defects; nutrition and cardiovascular disease; nutrition and diabetes; seafood and potential neurotoxicity; and caloric restriction, diet and toxicity;

- Use updated mathematical models to better predict the danger associated with foodborne bacterial exposure;

- Use chemical probes to determine if bacteria in food, food producing animals or their environment have developed resistance to commonly used antibiotics; and,

- Test new technologies, such as competitive exclusion (a bacterial suspension used to treat poultry), to prevent animals from developing antibiotic resistance.

Develop methods and build biological dose-response models to replicate bacterial survival in the stomach. (Performance Goal #16007)

Other Activities Related to High Priority Areas

New Technologies

- Develop methods to measure human exposure to adulterated products, and assess effectiveness and/or safety of a product. NCTR provides the scientific findings used by FDA's program centers for premarket application review and product safety assurance to the scientific community for the betterment of public health;

- Apply new scientific discoveries in genomics and proteomics-new technologies that show promise in the mechanistic understanding of toxicological responses in the human as well as in test rodents-to regulatory decision-making;

- Use state-of-the-art technologies, such as *FreshTag®,* a product developed at NCTR, for determining the freshness of seafood, to monitor food decomposition. On a national level, this product, and products using similar technologies, would allow consumers to make informed decisions on food quality and decrease the need for some food inspections by allowing the consumer to determine if the product is still fresh and possibly reducing the risk of foodborne illness; and,

- Use microchip arrays -- small quantities of genetic material bound to computer chips -- to do a large number of chemical reactions very quickly. This technique would allow doctors to screen their patients for genes that may cause adverse drug reactions, predict cancer susceptibility or determine drug efficacy.

Use new technologies (imaging, proteomics, and metabonomics) for diagnosis of toxicity. (Performance Goal #16013)

Medical Product Safety

- Investigate if photo-active chemicals found in cosmetics increase the risk of cancer from solar radiation using a new Phototoxicity Center developed in collaboration with the National Institute of Environmental Health Sciences;

- Investigate the long-term consequences of using HIV therapeutics and endocrine disrupter products particularly from generation to generation; and,

- Develop transgenic animal models that contain human genes to better predict how animal feeding study data relates to humans.

Develop new strategies and methods to test/predict toxicity and assess/detect risk for FDA-regulated products (new and on the market). (Strategic Goal #1)

SELECTED FY 2001 ACCOMPLISHMENTS

Food Safety

- Developed a new technique to identify minor changes in bacterial and chemical contaminants in foods. These techniques have the potential to crossover and provide methods of assessment for minor changes in bio-warfare agents. Researchers are focusing on mass spectrometry techniques (methods for identifying the chemical constitution of a substance) to detect biomarkers of human risk. After the recent outbreak of anthrax, the American public is concerned about the use of biological agents by a hostile force. These efforts will provide FDA with a means to quickly respond to biological threats and ultimately minimize the impact on human health;

- Began the study of over-the-counter cosmetics and/or drug and cosmetic dyes, emphazing on the potential interaction between artificial sunlight and substances found in cosmetics. Studies demonstrated that alpha hydroxy acids found in many skin cosmetics, when applied to the skin of mice in conjunction with ultraviolet (UV) radiation, induced skin tumors. Results suggest that the compound in sun-skin-care preparations may enhance the damage caused by the sun;

- Performed pre-validation studies that examine the effect of low-level antibiotic residues on the human intestinal microflora. Using this system, three different concentrations of fluoroquinolones, antibiotics such as Ciprofloaxin, were tested. Studies indicate that this method can be a valuable tool to evaluate the risks of antimicrobial contamination in food. The prevalence of antibiotic-resistance in disease causing microorganisms may have a major public health impact by allowing diseases once thought under control to flourish in an unprotected population;

- Developed simple, rapid, sensitive detection techniques to identify disease causing, drug-resistant strains of foodborne bacteria. In addition, NCTR microbiologists have developed a standardized test for determining the effectiveness of competitive exclusion products (bacterial suspensions used to treat poultry), and are developing new *in vitro* systems to assess the safety of drug residues. The results of this research assist FDA in formulating regulations to help contain the spread of drug-resistant microorganisms and ensure antibiotics are available for future use; and,

- Explored new technologies including, bioinformatics, imaging, proteomics, and metabonomics, for the assessment of toxicity. These new technologies show great promise in the understanding of toxicological responses in humans. The techniques developed will expand the knowledge obtained from the human genome project to biologically relevant protein species. Results should assist FDA in improving public health and further insure the safety of marketed products.

Genetic Testing

- Developed a new animal test for the evaluation of genetic change. This test was modeled after a similar rodent lymphoma test already used internationally for hazard identification. The test, which studies the chemical basis of genetic damage, is shown to detect most, if not all, of the mutational events leading to human cancer. The data generated from the animal and cell culture systems provide a more accurate and rapid assessment of the potential risk to the human population; and,

- Developed, through partnerships with state and local organizations, a DNA microarray platform to determine series of gene types for all major enzyme variants. Increasing evidence of adverse drug and chemical reactions in sub-populations (specific classifications such as race, gender, geographic location, common disease inflicted) of humans, point to a need to identify and protect groups of people at higher risk from exposure to specific drugs, contaminated food, or other FDA-regulated products. The human data produced with this technology will provide FDA with a better understanding of how some individuals react adversely to drugs and regulated products.

New Technologies

- Validated a predictive computer model for estrogenic or estrogen-like compounds. Replicate tests are now complete for over 200 chemicals that bind to the male hormone receptor, thus potentially influencing the development of the male reproductive system. Increased emphasis on soy-based products coupled with increased exposure to hormonally active compounds, such as plant-derived food, environmental products, pesticides, and other FDA-regulated products, is of increasing concern to public health. It is important to understand the toxicological and pharmacological properties of these compounds that critically effect infant development and sexually related drug activity.

National Center for Toxicological Research
Program Activity Data

Program Output	FY 2001 Actual	FY 2002 Estimate	FY 2003 Estimate
Research Publications	192	245	275
Scientific Presentations	507	425	430
Patents (Industry)	5	6	5
Interagency Agreements (IAG)*	4	6	4
Cooperative Research & Development Agreements	6	4	4
Total Ongoing Research Projects	215	203	225

*One IAG includes 25 separate projects

Office of Regulatory Affairs

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

	FY 2001 Actual Obligations		FY 2002 Current Estimate		FY 2002 +/- FY 2003 Current Estimate		FY 2003 Baseline Estimate	
	$(000)	FTE	$(000)	FTE	$(000)	FTE	$(000)	FTE
Total Program Level	**$327,754**	**3,158**	**$462,960**	**3,803**	**+ $28,867**	**+ 333**	**$491,827**	**4,136**
Foods	$161,616	1,566	$259,306	1,942	+ $4,679	+ 234	$263,985	2,176
Human Drugs	$74,017	751	$85,028	835	+ $17,011	+ 60	$102,039	895
Biologics	$24,798	232	$28,753	255	+ $1,660	+ 6	$30,413	261
Animal Drugs and Feed	$15,630	152	$30,426	274	+ $671	+ 13	$31,097	287
Medical Devices	$51,693	457	$59,447	497	+ $4,846	+ 20	$64,293	517
Current Law BA	**$309,715**	**3,069**	**$443,596**	**3,713**	**+ $20,010**	**+ 317**	**$463,606**	**4,030**
Current Law BA Accrual Costs 1/	**$18,117**		**$21,631**		**+ $1,992**		**$23,623**	
Total Current Law BA with Proposed Accrual Costs	**$327,832**	**3,069**	**$465,227**	**3,713**	**+ $22,002**	**+317**	**$487,229**	**4,030**
PDUFA II	$9,680	74	$8,728	74	($8,728)	(74)	0	0
MQSA	$8,359	15	$10,636	16	+ $357	0	$10,993	16
User Fee Accrual Costs 1/	**$555**		**$591**		**($490)**		**$101**	
User Fees with Proposed Accrual Costs1/	**$18,594**	**89**	**$19,955**	**90**	**($8,861)**	**(74)**	**$11,094**	**16**
Proposed User Fees								
PDUFA III	0	0	0	0	+$17,228	+ 90	$17,228	90
Proposed Law User Fee Accrual Costs1/	**$0**	**0**	**$0**	**0**	**+ $566**	**0**	**$566**	**0**
Total Proposed Law User Fee with Proposed Accrual Costs					**+ $17,794**	**+ 90**	**$17,794**	**90**

1/ Reflects 2001 and 2002 comparable estimates.

Historical Funding and FTE Levels

Fiscal Year	Program Level	Budget Authority	User Fee	Program Level FTE
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 Actuals	$327,754,000	$309,715,000	$18,039,000	3,148
2002 Current Estimate *1/*	$462,960,000	$443,596,000	$19,364,000	3,803
2003 Estimate	$491,827,000	$463,606,000	$28,221,000	4,136

1/Includes FDA's FY 2002 Appropriation and the Counter Terrorism Supplemental..

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 unforeseen 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; and,

- Perform outreach to consumer groups, health professionals, states and industry to encourage compliance and safe use of FDA-regulated products.

The field supports Agency premarket activities by conducting preapproval inspections and laboratory methods validations when requested by program managers responsible for premarket application decisions. Iinspections, of either foreign or domestic establishments, include bioresearch monitoring inspections of clinical research. 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. Laboratory method validations are conducted to confirm that the methods described in the premarket application work as described.

Field investigators and laboratory analysts conduct foreign inspections for both premarket approval and postmarket compliance purposes. Postmarket foreign inspections in the drug, biologic, animal drug, and device programs are conducted to assess Good Manufacturing

Practices. This is consistent with the biennial inspection requirement that Congress requires of domestic manufacturers in these programs.

In addition to conducting regular surveillance over regulated products, the field workforce also responds to emergencies by immediately mobilizing to investigate reports of product problems including tampering incidents and those due to natural disasters.

To complement the regular field force, the Office of Criminal Investigations (OCI) investigates 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 that 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 for FDA's basic field product testing capability.

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. 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. Outdated facilities would be closed and other laboratories would be renovated or relocated. The Plan identified five large total capacity/multipurpose regulatory laboratories and four specialty laboratories. The five total capacity laboratories would be located in Atlanta, GA, Seattle, WA, Jamaica/Queens, NY, Jefferson, AR and Irvine, CA.

PROGRAM RESOURCE CHANGES
(For Information Only, Field Request is Included within each Program)

The FY 2003 request builds upon funding FDA received from the FY 2002 appropriation plus the FY 2002 emergency supplemental for Counter Terrorism. As a result, while FDA has received increased funding to support counter terrorism, some of the programs are showing either no funding increase, or a slight decrease. The FY 2003 request annualizes those dollars received as one-time money in the supplemental -- a significant increase to the Agency of $152,276,000 in total. The funding changes shown below are the differences once these annualized dollars are removed.

Counter Terrorism – Food Safety and Safe and Effective Medical Products:
+ $8,810, and 306 FTE

- Monitor clinical research and conduct in-plant preapproval inspections to ensure that manufactured products are safe and effective;

- Increase coverage at border, seaport and airport locations;

- Increase import field exams, import sample collections and physical examinations of regulated products;

- Conduct on site testing [chemical, microbiological, organoleptic, etc.] by field laboratory analysts;

- Develop test kits for field use by laboratory analysts;

- Expand eLEXNET, a pilot project that improves communication with state and local authorities about the characteristics of microbiological contaminants found in regulated products;
- Enhance the Operational and Administrative System for Import Support [OASIS] import data processing system to provide import reviewers with more rapid and direct access to other FDA databases that contain the information necessary for entry decisions about food and other FDA regulated products;

- Expand import entry review activities to keep pace with the increase of import line entries;

- Update the criteria that determines which import line entries are selected for an on screen review and increase the frequency of on screen reviews;

- Expand the review of shipping documents associated with entries targeted for in-depth assessment prior to entry decision;

- Increase FDA data audits, import filer training, and liaison activities to improve the integrity of import data submitted by import filers;

- Increase coordination with the U.S. Customs Service to improve the effectiveness of cargo control activities at ports, and monitor food products that have been refused entry pending exportation or destruction;

- Implement enforcement strategies for imported foods and other FDA regulated products to improve compliance with and monitoring of Hazard Analysis Critical Control Points [HACCP] Programs and Current Good Manufacturing Practice [CGMP] Regulations;

- Increase the number of investigators up to 300 at the borders with an additional 100 FTE (compliance officers, laboratory analysts, OCI agents, etc.) to support the increased volume of activity;

- Utilize "Quickhire" an automated hiring system that quickly receives applications to ensure that the minimum qualifications for the advertised positions are met. The Agency is making optimal use of this system to quickly identify applicants and reduce the time to hire; and,

- Continue to work with states to backfill inspectional activity requirements.

Pay Increase: + $10,035,000

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 people-intensive. Payroll accounts for over 60 percent of the total FDA budget. This has a significant impact on all activities in FDA. FDA is requesting $28,552,000 to cover pay related increases. ORA's piece of this increase is $10,035,000.

Medical Errors: +$500,000 and 6 FTE

- Review adverse event and complaint files at manufacturers during inspections for compliance with FDA reporting regulations and to conduct follow up inspections on adverse event reports when information from the manufacturer is needed to evaluate the risks involved.

Generic Drugs: +1,146,000 and 10 FTE

- Hire additional inspectors to increase inspections of domestic and foreign firms by 15 percent. This is critical to reducing total approval times for generic drug applications. The resources will also be used to provide for team inspections (reviewer and inspector) to increase efficiency; and,

- Increase coverage of imported generic drugs by 10 percent so that FDA can better monitor the quality of finished drug products and bulk drug substances entering the U.S. from overseas.

Management Efficiencies: -$474,000 and -5 FTE

FDA's budget assumes savings of $2,578,000 associated with efficiency improvements and consolidations related to the President's Management Plan. The Field Activity portion of this total is $474,000 and five FTE.

JUSTIFICATION OF BASE

Activities Related to Increases for FY 2003

Counter Terrorism – Food Safety and Safe and Effective Medical Products

- Participated in the planning and coordination of exercises simulating responses to terrorist attacks;

- Developed a notification system for terrorism 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 a FDA regulated product; and,

- Inspect drug and vaccine manufacturers whose products may be stockpiled as part of the Governments counter terrorist efforts.

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.

Imports and Inspections

- Inspect drug and vaccine manufacturers whose products may be stockpiled as part of the Governments counter terrorist efforts;

- Conduct inspections of high-risk domestic food establishments. 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 and 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;

- Protect the food supply by continuing with Federal, State and local partners to share data through the field data systems. The FACTS (Field Accomplishment and Compliance Tracking System) data system has been enhanced so that States will enter data directly in the system in FY 2002;

- 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 domestic products;

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

- Conduct inspections by either FDA staff or by States under contract to FDA. FDA is required to audit State inspections. There were a total of 13,900 State contract inspections in FY 2001. Of these, approximately 8,900 were inspections of mammography facilities; 1,000 were of feed mills; another 350 were tissue residue; and 3,700 were food inspections. FDA

performed 16,000 inspections in various program areas;

- Develop rapid analytical methods for screening imports at the border and increase the number of import line entries reviewed for admissibility into domestic commerce;

- Increased inspection of foreign establishments;

- Evaluated the accuracy of information import filers provide to the FDAs automated entry review system regarding regulated products offered for entry into domestic commerce; and,

- Collaborated with the U.S. Customs Service to monitor the importation of regulated products and follow up on the status of products refused entry.

Medical Errors

- Provided training for field staff to improve the information gathered through investigation of consumer complaints and reports of medical errors;

- Conducted more investigations of reported errors to collect information program managers need to assess the error, and develop error reduction strategies with manufacturers and the medical community; and,

- Inspect hospital device reprocessors to determine compliance with regulatory requirements.

Other Activities Related to High Priority Areas

Bovine Spongiform Encephalopathy (BSE)

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

- Increase domestic protection by conducting 1,000 more domestic inspections than in FY 2001;

- Leverage with State agencies by funding contract inspections of feed mills and renderers, and conduct compliance, follow-up, and audit inspections to state contracts. Collect and analyze domestic and import feed and feed component samples for BSE related contaminants to ensure proper labeling of animal feeds and feed components; and,

- Provide intensive line entry and label review of Animal Drug and Feed product import line entries for use in domestic commerce.

Premarket Activities

- Improve the quality and timeliness of product reviews by monitoring pre-approval inspections and expanding inspectional expertise in emerging technologies; and,

- 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 timeframes.

Internet Drug Sales

- Monitor 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; and,

- Provide oversight of mail and courier packages entering from foreign sources - e.g., personal importation of drugs and medical products.

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;

- 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; and,

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

SELECTED FY 2001 ACCOMPLISHMENTS

Counter Terrorism - Food Safety and Safe and Effective Medical Products

- During FY 2001, FDA worked on many counter terrorism initiatives with the Department and within the Agency including Counter Terrorism Steering Committee; Device Storage Working Group; BSE/Bioterrorism Working Group; CDC Preparedness Planning/Core Capacity Meetings; DHHS FY 2002-2006 Plan for Combating Terrorism; and, the DHHS Counter Terrorism Concept of Operations Plan;

- Participated in the U.S. Office of Foreign Disaster Assistance tabletop exercise with other federal, state and local governments. Contracts for a series of exercises to test and evaluate internal bioterrorism response capabilities were awarded. Improved communications and educated employees within the Agency by designating bioterrorism coordinators in each district; creating a bio-terrorism coordinator position within the Emergency Operations Staff; and, distributing a monthly Bioterrorism News Update;

- Continued to send representatives to groups and develop policy and guidance to improve emergency response activities. FDA has served as a project lead for the National Food Safety System Outbreak Coordination Work Group. The multi-agency work group recently completed guidance regarding, "Multi-State Foodborne Outbreak Investigations: Guidelines for Coordination and Communication" and published the document on the Internet;

- Coordinated the development of FDA's BSE Contingency Plan; published the Revised Guide to Traceback of Fresh Fruits and Vegetables; and, working with Batelle, developed and presented the results from the FDA Emergency Response System Re-Engineering Task Force. In addition, ORA published the first electronic publication of the Investigations Operations Manual (IOM) on the internet, and developed the protocol with CDC for joint investigations of domestic cruise ships due to the transfer of Quarantine Authority to CDC; and,

- Working through an Interagency Agreement (IAG) with the Department of Defense (DOD), established a contract with New Mexico State University for the "Rapid Test Kit Evaluation Project." The cost of the contract with DOD oversight is $1.5 million. Under this contract, the University will evaluate commercially available "rapid test kits" for suitability of use for testing FDA regulated products for various contaminants or adulterants. The project goal is to identify "rapid methods" that can be used to quickly evaluate imported products.

Science Initiatives

- **Electronic Laboratory Exchange Network – eLEXNET.** Oversaw the development of eLEXNET, the nation's first seamless data exchange system for food safety testing information, and facilitated data exchange between local, state, and federal agencies. After a successful pilot with E. coli 0157:H7, the program is being expanded to include data concerning other microorganisms including Salmonella, Listeria and Campylobacter;

- **Implementation of a High-Productivity Microbiology Laboratory.** Established a microbiology laboratory especially designed for rapid throughput of imported food samples collected for microbiological analysis at FDA's Northeast Regional Laboratory in New York. Using specialized methods and equipment, this lab was able to cut analysis time from over 20 hours to less than 8 hours per sample. FDA intends to expand this concept to other field microbiology laboratories;

- **New Capabilities in Pesticide Analysis.** Installed new mass spectrometry equipment in its field pesticide laboratories, and trained its analysts in the use of a method developed by an FDA scientist. Using this new technique, FDA laboratories can detect over 100 pesticides, which were undetectable by older methods;

- **Shelf Life Program.** Redirected resources so expired drugs procured by the military can be tested as quickly as possible;

- **Pre-Approval Method Validation**. Established an ORA Scientific Coordinator contact for Abbreviated New Drug Application (ANDA) Method Validation packages as part of the

ANDA Pilot Program. This central coordinator improves the timeliness and efficiency of the ANDA Pre-Approval Program;

- **Toxic Residue Analysis.** Expanded FDA's dioxin analysis to about 2,500 samples per year. The Arkansas Regional Laboratory expanded resources, and the Kansas City District Laboratory began conducting dioxin analyses. This will enable FDA to be more proactive in identifying and reducing human exposure to this family of toxic chemicals; and,

- **FDA Lab Accreditation Initiative.** Received training on International Standards Organization (ISO) Laboratory management systems and auditing. This will result in improved quality systems and eventually lead to accreditation of FDA regulatory laboratories.

Investigation Initiatives

- **Domestic Inspections.** Evaluate regulated establishment operations against appropriate Agency requirements. Inspections evaluated 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;

- **Foreign Inspections.** Increase FDA inspectional presence in the international arena for all program areas. The Agency continues to pursue international relationships with foreign governments that contribute to FDA's understanding about foreign firms that export products to the U.S.;

- **Imported Product Safety.** Coordinated new import procedures for the destruction of refused goods and controlled storage procedures; developed an interim plan for the examination of perishable products after the September 2001 terrorist incident; initiated the co-location of U.S. Customs and FDA facilities in New York District; and, participated in the pilot project to evaluate packages at the U.S. mail facility in Carson City, California;

- Designed industry partnerships to assure food safety and provided training supported certification of procedures for the reconditioning of imported spices; and sponsored training of industry in product security and safety. Collaborated with U.S. Customs Service to develop joint procedures for Notices of Redelivery and Refusal; participation in bimonthly operational meetings; updating the Memorandum of Understanding; and, training on U.S. Customs laws and regulations;

- **Systems Based Pilot Inspection Program.** Evaluated the Agency's inspection approach in various program areas, and in an effort to streamline inspections and cover multiple profile classes, the agency has moved to a systems based approach in certain program areas. This systems based approach is currently being piloted in the drug program;

- **Human Tissue Establishment Inspections.** Evaluated the impact of, and preparing for the implementation of new regulations that govern human tissue establishments. These

regulations not only grant the FDA additional authority, but serve to increase the number of firms that would be subject to FDA's inspectional coverage; and,

- **BSE Prevention and Control.** Responded to increased concern over BSE by expanding current programs and implementing a number of new activities to support the Department's and FDA's BSE/TSE Action Plan. FDA trained laboratory analysts and purchased new equipment to conduct feed microscopy as a means of identifying animal proteins in feed samples. In conjunction with USDA, FDA increased review of food and feed from BSE positive countries to deter entry of products potentially containing the BSE agent. Coordination and communication with State regulators was enhanced and State Feed Inspection contracts and partnerships were expanded to include more inspections of animal feed mills. FDA and State investigators inspected 1122 firms for compliance with BSE feed regulations. FDA developed an inventory of establishments that process BSE prohibited materials and conducted annual inspections of these establishments to refine and update the inventory in subsequent years. A contract to conduct a BSE emergency exercise was awarded during September 2001.

Enforcement Activities

- **Internet Drug Sales.** Continued to take regulatory and enforcement actions against violative Internet drug firms. There are several reviews for regulatory action underway, and numerous active criminal investigations;

- **Cyber Letters**. Issued 75 "cyber" letters. These letters were sent electronically via the Internet to Websites that offer to sell prescription drugs to U.S. citizens without a prescription. Many prescription drugs available from foreign sources are either products for which there is no U.S. approved counterpart or foreign versions of FDA-approved drugs;

    - Renewed two cooperative agreements for internet enforcement with the Federation of State Medical Boards and the National Association of Boards of Pharmacy; and,

    - Pursued criminal charges against violative Internet Drug firms. There are currently 128 open Internet investigations, of which 112 involve drug products. A total of 20 arrests (16 drug products), and 15 convictions (11 drug products) have been made thus far this year.

Recalls

- **Counterfeit Drug Recalls.** Worked to remove the counterfeit drugs from the market and determine the source of the counterfeiting. These drugs included Serostim, Neupogen, and Neutropin AQ;

- **Animal Feed Recall.** Investigated and processed recall recommendations for thirteen (13) recall actions due to lack of ruminant warning labels on animal feeds manufactured using some prohibited bovine protein. FDA is strengthening efforts to keep BSE out of the American cattle herd and to keep it from amplifying in the herd were it ever to be found in American cows. The agency's first priority is to attain full compliance with regulations

regarding banned cattle feeding practices. Part of this effort is strengthening enforcement activities including recalls;

- **Bioengineered Corn Recalls.** Initiated under the food additive provisions of the Act for the bioengineered corn that is considered to contain an unapproved food additive and to have the potential for allergenic properties in humans. Four major sample collection assignments were issued to 16 field offices and four analyzing laboratories. A total of 261 samples were collected, with additional eight consumer complaint samples collected as follow-up to this situation;

- **Bovine Spongiform Encephalopathy (BSE) Recalls**. Investigated and issued 15 recalls due to lack of ruminant warning labels on animal feeds manufactured using some prohibited bovine protein. FDA is strengthening efforts to keep BSE out of the American cattle herd and to keep it from amplifying in the herd were it ever to be found in American cows. The Agency's first priority is to attain full compliance with regulations regarding banned cattle feeding practices. Part of this effort is strengthening enforcement activities including recalls; and,

- **BSE Warning Letters**. Issued 47 Warning Letters for violations of FDA regulations for animal Proteins Prohibited in Ruminant Feed. These Warning Letters alert manufacturers of animal feeds that FDA intends to fully enforce FDA regulations affecting animal feeds. These regulations require that feeds that contain, or may contain, prohibited materials must be labeled with the required cautionary statement: "Do not feed to Cattle or Other Ruminants."

Outreach

- **FDA Guidance.** Published in the Federal Register, notices of availability for public comment on 21 C.F.R. Part 11 draft guidance's to industry on validation and a glossary of terms. Currently there are three additional "Guidance to Industry" documents in their final stages of review. These are Retention of Electronic Records, Electronic Copies, and Time Stamps. Audit Trail guidance is in the early stages of development. ORA is also assisting other government agencies, such as EPA, with similar regulations. In addition, ORA provided Part 11 training to two FDA field offices.

Partnerships and Support for States

- Awarded Innovative Food Safety Grants to13 State and Local regulatory agencies in the amount of $505,000; and, $140,000 was awarded to 28 States in Small Conference Grants to support Food Safety Task Force Meetings;

- Awarded 38 State food contracts for over 6,443 food inspections costing a total of $3,450,000; 34 BSE/medicated feed contracts for 3,353 inspections costing $1,013,247; 18 tissue residue contracts for 699 inspections costing $373,464 and 47 MQSA contracts for 9,671 inspections costing $7,833,579; and,

- Monitored over 172 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 2000. Two partnership agreements were signed with the Department of Agriculture in Nebraska and Missouri to work together on BSE inspections, regulatory follow-up, and training.

Foreign Government Agreements and Other Cooperative Efforts

- Developed provisions and negotiating language with leading Mexican officials for a cooperative agreement that will improve the safety of the food supplies in both countries. The arrangement, which relies on mutual assurances to protect confidentiality of non-public information, will help reduce the incidence of foodborne illnesses (including contamination) in both countries;

- Developed, negotiated, and successfully obtained from Australia's Therapeutic Goods Administration (general), Japan's Ministry of Health, Labour and Welfare (general), and the Canadian Food Inspection Agency (limited purpose) written agreements to maintain the confidentiality of FDA's non-public information shared to promote cooperate efforts in the areas of drug application review and food safety and investigation; and,

- Conducted responsibilities under the 1999 Mutual Recognition Agreement ratified by the European Community (EC) and the United States. As a result of OE and ORO's assistance to other FDA components, during the reporting period FDA obtained letters of assurance from France, Greece, Sweden, United Kingdom, and Italy. The letters set forth each government Agency's intention to protect the confidentiality of FDA information shared during the confidence exercise building phase of implementation of the MRA in the sectoral annex on GMP's for medicinal products.

Training Initiatives to Keep Pace With Scientific Advances

- **ORA University**. Launched a combination of traditional face-to-face training and web-based learning. ORA University supports the Investigator Certification Program, an initiative started several years ago to certify investigators at both a basic or general level and an advanced level of competency in specific areas of regulatory responsibility. As of September 2001, all Regions and Headquarters employees have access to web based courses. Competency areas have been developed for product specific certification programs. On the Job training will reinforce the web based and face-to-face courses providing a level of consistency across the programs. A pilot program will be started with three states by the end of the year to allow state and local health employees take courses on line;

- **Cooperative Research and Development Agreement (CRADA).** Continued to work with a CRADA partner to develop courses to be delivered on line. The Tour of the FDA is available to FDA, as well as the general public on the FDA Internet site. Additional courses that will be available include Food Drug Law, Food Microbiology, Basic Investigator Training and Basic Sanitation. EduNeering, ORA's CRADA partner, has developed and "seeded" ORA U with approximately 100 courses;

- **Training for FDA Staff.** Trained approximately 2,500 employees in 93 courses to promote efficient and effective inspection and analytical services. These include courses in Basic

Medical Devices, Import Investigations, Critical Thinking in Analytical; Laboratory Procedures, Industrial Sterilization of Drugs;

- **Distance Learning Programs.** Presented 13 satellite or videoconference programs in the last year. These include Preparing for Foreign Assessments B What You Need to Know, Introduction to the FDA Laboratory Accreditation Initiative and the International Organization of Standardization (ISO) Standard 17025 for Testing and Calibration Laboratories, Import Enforcement Training Overview and Update, Conducting Food Allergen Inspections, and several programs on Information Disclosure. The broadcasts reached a wide viewing audience of employees across the nation;

- **TURBO Establishment Inspection Report (EIR).** Linked to adverse inspectional findings relevant regulations, generated in standardized language, and stored electronically using the Turbo EIR. This database program used for inspectional findings generates forms that list an investigators'observations; firm violations (FDA-483s); and, print an Establishment Inspection Report (EIR) at the conclusion of an inspection. The data will categorize violations in great detail, and will be available throughout the agency for trending, analysis and reference, and allows for the automatic synchronization of EIR data on the investigator's notebook computer with a network server; and,

- Provided turbo EIR training to field investigators, trainers and computer support staff. This program will eventually include every field employee who independently conducts establishment inspections that could result in the issuance of an FDA-483.

Emergency Operations

- Managed, tracked, and investigated 216 significant incidents and emergencies and has received and investigated more than 6,100 consumer complaints. This included 146 food emergencies (outbreaks, tampering reports, and adverse reactions); 21 drug emergencies; 4 incidents related to biologics; 13 veterinary product issues; 18 medical device problems; and, 14 other emergencies (natural disasters and emergency interagency training exercises);

- Initiated and conducted 24 food product tracebacks during the same timeframe. This includes pathogen-related incidents. Examples of food borne pathogens tracked which affected a multi-state area include a salmonella-Thompson outbreak in tomatoes; a shigella sonnei in salsa; hepatitis A found in green onions and tomatoes; s. typhimurium found in pericardial membranes in Japan and the United States; salmonella poona found in cantaloupes; and, vibrio vulnificus found in oysters;

- Investigated non-pathogen related incidents, examples of which are adverse reactions; injuries; chemical contaminants; tampering; recalls; natural disasters; counterfeit labeling, drug residues; and, death. For instance, an example of an adverse reaction incident involves a reaction to an antibiotic that resulted in death; or, tampering with bottled water in the State of North Carolina. Other types of non-pathogen related incidents happen in natural disasters such as a tornado in Tennessee, or an earthquake in Washington State; or, flooding in Minnesota, North Dakota, Wisconsin and Iowa; or terrorist attacks in Washington, D.C. and New York;

- Signed a Confidentiality Commitment with Canada. In addition, Mexico and the United States signed an agreement to promote cooperation in food safety response and information sharing. Both agreements will facilitate response to multi-state, multi-national foodborne outbreaks; and,

- Completed the design phase for ORA's Emergency Operations Center and began construction. This initiative will provide the Agency with a state-of-the-art facility to house emergency operations.

Criminal Investigations

Made 412 arrests that led to 342 convictions. This number could increase as some arrests are are still in judicial status. During FY 2001, fines and forfeitures totaled $99,329,228.

- Expanded efforts to address domestic websites exploiting loopholes in state and federal laws resulting in the promotion and sale of prescription drugs through exploitation of public fear of bioterrorism.

Office of Regulatory Affairs

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

Foods

Program Workload and Output	FY 2001 Actual	FY 2002 Estimate	FY 2003 Estimate[4/]
PROGRAM OUTPUTS - DOMESTIC INSPECTIONS[1/]			
Domestic Food Safety Program Inspections	4,666	5,000	6,000
Imported and Domestic Cheese Program Inspections	392	300	400
Domestic Low Acid Canned Food/Acidified Foods Inspections	809	1,435	2,000
Domestic Fish & Fishery Products (HAACP) Inspections	3,283	4,715	5,000
Import (Imported Seafood Program including HAACP) Inspections	650	700	800
Interstate Travel Sanitation (ITS) Inspections	1,446	1,894	2,500
State Food Safety (Non HAACP) Inspections	4,365	8,300	9,000
State Contract Domestic Seafood HAACP Inspections	673	700	1,000
State Partnership Inspections	1,870	1,900	2,000
Total FDA and State Contract Inspections	**18,154**	**24,944**	**28,700**
Domestic Field Exams/Tests[2/]	2,016	3,000	5,000
Domestic Laboratory Samples Analyzed[3/]	10,889	14,090	14,090
PROGRAM OUTPUTS - IMPORT/FOREIGN INSPECTIONS[1/]			
All Foreign Inspections	209	250	250
Import Field Exams/Tests[2/]	12,169	24,000	48,000
Import Laboratory Samples Analyzed[3/]	14,863	21,200	21,200
Import Line Entry Decisions	4,589,081	5,139,770	5,396,759

FIELD COSMETICS

PROGRAM OUTPUTS - DOMESTIC INSPECTIONS[1/]			
All Inspections	128	100	100
Domestic Field Exams/Tests[2/]	25	75	75
PROGRAM OUTPUTS - IMPORT/FOREIGN INSPECTIONS[1/]			
Import Field Exams/Tests[2/]	282	700	700
Import Laboratory Samples Analyzed[3/]	129	125	125
Import Line Entry Decisions	505,849	566,551	594,879

1/An inspection is any visit to a firm during which all or part of one or more phases of that establishment's operation is evaluated against appropriate agency requirements.
2/A Field Exam is the on-site examination of a product that is sufficient in itself to determine whether the product is in compliance with agency requirements. Examples of exams include visual, organoleptic, quick color, and rapid abrasion.
3/Laboratory Samples Analyzed are product samples physically analyzed by the laboratory to determine whether or not the product is in compliance with agency requirements.
4/When fully implemented, the FY 2003 requested increase for all Field programs will provide additional domestic inspections performed by FDA depending on progress in hiring, training, and equipping new staff.

Human Drugs
Program Activity Data

Program Workload and Outputs	FY 2001 Actual	FY 2002 Estimate	FY 2003 Estimate[4/]
Program Outputs - Domestic Inspections[1/]			
Preapproval Inspections (NDA)	142	190	360
Preapproval Inspections (ANDA)	109	165	170
Bioresearch Monitoring Programs Inspections	540	750	750
Drug Processing (GMP) Program Inspections	930	949	1,450
Compressed Medical Gas Manuf. Inspections	393	337	330
Adverse Drug Events Project Inspections	63	77	80
OTC Monograph Project Inspections	23	20	20
Health Fraud Project Inspections	80	80	80
State Partnership: Comp. Medical Gas Manuf. Inspections	156	150	120
Total FDA and State Contract Inspections	**2,436**	**2,718**	**3,490**
Domestic Field Exams/Tests[2/]	200	20	20
Domestic Laboratory Samples Analyzed[3/]	1,802	1,460	1,500
Program Outputs - Import/Foreign Inspections[1/]			
Foreign Preapproval Inspections (NDA)	133	199	280
Foreign Preapproval Inspections (ANDA)	97	80	100
Foreign Bioresearch Monitoring Program Inspec.	52	100	100
Foreign Drug Preocessing (GMP) Program Inspec.	219	111	240
Foreign Adverse Drug Events Project Inspec.	17	25	30
Total Foreign FDA Inspections	518	515	750
Import Field Exams/Tests [2/]	1,487	1,500	3,700
Import Laboratory Samples Analyzed [3/]	132	295	200
Import Line Entry Decisions	111,631	125,027	131,278

1/An inspection is any visit to a firm during which all or part of one or more phases of that establishment's operation is evaluated against appropriate agency requirements.
2/Field Exam is the on-site examination of a product that is sufficient in itself to determine whether the product is in compliance with agency requirements. Examples of exams include visual, organoleptic, quick color, and rapid abrasion.
3/Laboratory Samples Analyzed are product samples physically analyzed by the laboratory to determine whether or not the product is in compliance with agency requirements.
4/When fully implemented, the FY 2003 requested increase for all Field programs will provide additional domestic inspections performed by FDA depending on progress in hiring, training, and equipping new staff.

Biologics
Program Activity Data

PROGRAM OUTPUTS - DOMESTIC INSPECTIONS[1/]	FY 2001 Actual	FY 2002 Estimate	FY 2003 Estimate[3/]
Bioresearch Monitoring Programs Inspections	88	189	190
Blood Bank Inspections	1,441	1,439	1,500
Source Plasma Inspections	269	265	270
Pre-Approval (Pre-Market) Programs Inspections	7	10	10
Pre-License Inspections	16	12	20
GMP Inspections	63	41	50
GMP (Device) Inspections	12	36	40
Human Tissue Inspections	132	183	200
Total FDA Inspections	**2,028**	**2,175**	**2,280**
PROGRAM OUTPUTS - IMPORT/FOREIGN INSPECTIONS[1/]			
Inspections	13	12	10
Blood Bank Inspections	16	34	40
Source Plasma Inspections	3	10	10
Pre-Approval (Pre-Market) Programs Inspections	1	5	5
Pre-License Inspections	2	5	5
GMP Inspections	20	20	20
GMP (Device) Inspections	1	5	5
Total Foreign FDA Inspections	**56**	**91**	**95**
Import Field Exams/Tests[2/]	6	10	10
Import Line Entry Decisions	24,067	26,955	28,302

1/An inspection is any visit to a firm during which all or part of one or more phases of that establishment's operation is evaluated against appropriate agency requirements.
2/A Field Exam is the on-site examination of a product that is sufficient in itself to determine whether the product is in compliance with Agency requirements. Examples of exams include visual, organoleptic, quick color, and rapid abrasion.
3/Laboratory Samples Analyzed are product samples physically analyzed by the laboratory to determine whether or not the product is in compliance with Agency requirements.

Animal Drugs and Feeds
Program Activity Data

Program Workload and Output	FY 2001 Actuals	FY 2002 Estimate	FY 2003 Estimate[4/]
PROGRAM OUTPUTS-DOMESTIC INSPECTIONS[1/]			
Investigational Food Additive Petitions	39	50	50
Food (Animal) Additive Petition	14	20	20
Preapproval/Bioresearch Monitoring Programs Inspections	73	110	110
Drug Process and New ADF Programs Inspections	178	800	800
BSE Inspections	892	2,673	2,700
Illegal Tissue Residue Program Inspections	210	150	150
Feed Manufacturing Program Inspections	278	890	900
Feed Contaminants Program Inspections	27	1,210	1,500
State Contract Inspections: BSE	1,503	4,000	4,000
State Contract Inspections: Feed Manufacturers	337	453	600
State Contract Inspections: Illegal Tissue Residue	438	600	700
State Partnership Inspections: BSE	110	623	800
Domestic Field Exams/Tests[2/]	24	50	50
Domestic Laboratory Samples Analyzed[3/]	3,120	4,800	6,000
PROGRAM OUTPUTS-IMPORT/FOREIGN INSPECTIONS			
Foreign Preapproval/Bioresearch Monitoring Programs Inspections	34	40	40
Foreign Drug Process and New ADF Program Inspections	11	10	20
Foreign BSE Inspections	5	10	20
Foreign Feed Manufacturing Program Inspections	6	10	10
Import Field Exams/Tests[2/]	120	300	700
Import Laboratory Samples Analyzed[3/]	229	770	900
Import Line Entry Decisions	155,089	173,699	182,384
Manufacturers Drug Experience Reports (DERs)			
Received	4,574	4,800	4,800
Reviewed	4,436	4,800	4,800
Adverse Experience Reports (AERs)			
Received	18,601	30,000	30,000
Reviewed	20,086	24,000	24,000
Animal/Medicated Feed Partnership Agreements	28	28	28
NARMS Salmonella Isolates Tested	12,000	12,000	12,000

1/An inspection is any visit to a firm during which all or part of one or more phases of that establishment's operation is evaluated against appropriate Agency requirements.
2/The estimate of the total number of Inspections (MQSA) performed by State Contract (non-federal, non-VHA, and non-SAC facilities) reflects a decrease in the actual facility inventory and hence a slight reduction in the number of inspections.
3/Laboratory Samples Analyzed are product samples physically analyzed by the laboratory to determine whether or not the product is in compliance with Agency requirements.

Devices and Radiological Health
Program Activity Data

Program Workload and Outputs	FY 2001 Actual	FY 2002 Estimate	FY 2003 Estimate
Field Program Outputs-Domestic			
Bioresearch Monitoring Inspections 1/	224	270	270
Inspections Pre-Approval	123	125	130
GMP Inspections	996	1,000	1,150
Inspections (MQSA) FDA Domestic (non-VHA)	565	427	427
Inspections (MQSA) FDA Domestic (VHA)	41	39	39
Inspections (MQSA) by State Contract 2/	8,113	7,900	7,900
Inspections (MQSA) by State non-Contract	543	543	543
Total Domestic MQSA	9,262	8,909	8,909
Domestic Radiological Health Inspections	117	160	200
Domestic Field Exams/Tests	1,572	1,520	1,520
Domestic Lab Samples Analyzed	137	300	340
Field Program Outputs-Import/Foreign			
Foreign Bioresearch Monitoring Inspections 1/	14	20	20
Foreign Pre-Approval Inspections	41	40	40
Foreign GMP Inspections	266	250	250
Foreign MQSA Inspections	16	13	13
Foreign Radiological Health Inspections	33	40	40
Import Field Exams/Tests	625	750	1,100
Import Laboratory Samples Analyzed	1,297	1,440	1,500
Import Line Entry Decisions	1,761,992	1,980,000	2,080,000

1/Bioresearch Monitoring Inspections involve the inspection of sponsors of premarket applications (PMAs), clinical investigators, Institutional Review Boards (IRBs), and non-clinical laboratories.
2/The estimate of the total number of Inspections (MQSA) performed by State Contract (non-federal, non-VHA, and non-SAC facilities) reflects a decrease in the actual facility inventory and hence a slight reduction in the number of inspections.

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Other Activities

	FY 2001 Actual Obligations	FY 2002 Current Estimate	FY 2003 +/-FY 2002 Current Estimate	FY 2003 Baseline Estimate
Total Program Level	**$80,126,000**	**$91,267,000**	**+ $557,000**	**$91,824,000**
FTE	*799*	*793*	*(82)*	*711*
Current Law BA	**$67,985,000**	**$77,137,000**	**+ $551,000**	**$77,688,000**
Counter Terrorism	*$300,000*	*$1,065,000*	*+ $352,000*	*$1,417,000*
Pay Increase 1/			*+ $2,296,000*	*$2,296,000*
Administrative Consolidation			*(6,997,000)*	*($6,997,000)*
Mgmt. Efficiencies				*(300,000)*
UFMS		*$3,100,000*	*+ $5,200,000*	*$8,300,000*
Current Law BA Accrual Costs2/	**$3,637,000**	**$3,590,000**	**+ $392,000**	**$3,982,000**
Current Law BA with Accrual Costs2/	**$71,629,000**	**$80,727,000**	**+ $943,000**	**$81,670,000**
FTE	**674**	**664**	**(82)**	**582**
User Fees	**$12,141,000**	**$14,130,000**	**(13,938,000)**	**$192,000**
PDUFA II	*$11,961,000*	*$13,944,000*	*(13,944,000)*	*0*
FTE	*123*	*127*	*(127)*	*0*
MQSA	*$180,000*	*$186,000*	*+$6,000*	*$192,000*
FTE	*2*	*2*	*0*	*2*
User Fee Accrual Costs2/	**$794,000**	**$847,000**	**($834,000)**	**$13,000**
User Fee with Accrual Costs2/	**$12,936,000**	**$14,977,000**	**($14,772,000)**	**$205,000**
FTE	**129**	**129**	**(127)**	**2**
Proposed User Fees				
PDUFA III	**$0**	**$0**	**+$13,944,000**	**$13,944,000**
FTE	**0**	**0**	**+127**	**127**
Proposed PDUFA Accrual Costs2/	**$0**	**$0**	**+ $800,000**	**$800,000**
Proposed PDUFA with Accrual Costs2/	**$0**	**$0**	**+ $14,744,000**	**$14,744,000**
FTE	**0**	**0**	**+ 127**	**127**

1/ Pay increases shown on separate line, and not reflected in individual initiative areas.
Note: FY's 2001/2002 does not reflect comparable adjustments of $6,260,000 and 82 FTE and $6,670,000 and 82 FTE, respectively, for the FY 2003 Administrative Consolidation of public and legislative affairs to DHHS.
2/Reflects 2001 and 2002 comparable estimates.

Historical Funding and FTE Levels

Fiscal Year	Program Level	Budget Authority	User Fee	Program Level FTE
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 Actuals	$80,126,000	$67,985,000	$12,141,000	799
2002 Current Estimate *3/*	$91,267,000	$77,137,000	$14,130,000	793
2003 Estimate	$91,824,000	$77,688,000	$14,136,000	711

3/ Includes FDA's FY 2002 Appropriation and the Counter Terrorism Supplemental.

MISSION

- Provide centralized program direction and management services for Agency programs to ensure FDA's Public health hazard prevention efforts are effectively managed within its regulatory framework;

- Provide management expertise and direction to support standards development for regulated products as well as the management of transparent processes that merit the trust of stakeholders;

- Develop Agency wide policy in legislation, consumer communications, public information, scientific coordination and regulatory requirements; and,

- Provide direction in the management of Agency resources that support the science based regulatory work of FDA. This includes financial, human and information systems resources, knowledge management and other critical infrastructure needs. Other more specific programs include: Freedom of Information Act activities; and the administration of internal management controls consistent with the Federal Managers' Financial Integrity Act.

PROGRAM RESOURCE CHANGES

The FY 2003 request builds upon funding FDA received from the FY 2002 appropriation plus the FY 2002 emergency supplemental for Counter Terrorism. As a result, while FDA has received increased funding to support counter terrorism, some of the programs are showing either no funding increase, or a slight decrease. The FY 2003 request annualizes those dollars received as one-time money in the supplemental -- a significant increase to the Agency of $152,276,000 in total. The funding changes shown below are the differences once these annualized dollars are removed.

For the Other Activities program, in FY 2003, FDA will continue to utilize $750,000 provided in the supplemental, plus an additional $352,000, to develop safe and effective vaccines and biological products in preparation for defense against biological weapons.

The Agency will also continue to guide these products through the regulatory process, which includes the manufacturing process, pre-clinical testing, and license application review process determines the speed with which these products will be available for use.

Counter Terrorism - (Food Safety/Safe and Effective Medical Products):
+ $352,000 and 1 FTE ($300,000 Annualized from CT Supplemental)

A combination of public health and law enforcement responsibilities requires Agency involvement in a number of aspects of the response to a terrorism event. Many facets of counter terrorism link to the Agency's legislative mandate to protect the public health by ensuring the availability of safe and effective drugs, vaccines, blood products, medical devices, and animal health products, and by ensuring a safe food supply. FDA's team of specialists will work to prepare the nation for current and future biological or chemical terrorist attacks, including the services of the Office of Chief Counsel (OCC). OCC will provide advice and counsel on legal matters, render opinions, and support rulemaking proceedings, legislative matters, policy deliberations, and domestic and international negotiations.

Pay Increase: + $2,296,000

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 2002, FDA is requesting $28,552,000 to cover pay-related costs. The Other Activities program piece of this increase is $2,296,000.

Management Efficiencies: -$300,000 and 3 FTE

FDA will support the President's management objectives to create a streamlined, citizen-centered government agency delayering the bureaucracy and restructuring agency functions so that they are more supportive of mission-critical activities. FDA's budget assumes savings of $2,578,000 associated with efficiency improvements and consolidations related to the President's Management Plan. The Other Activities Program portion of this total reduction is $300,000 and 3 FTE.

> *Provide for a streamlined and efficient hierarchy within the Agency that is more efficient and effective and ties in with Department goals. (Strategic Goal)*
>
> *Increase supervisory ratio to increase the span of control among management personnel. (Performance Goal 19001)*

Administrative Consolidation: -$6,997,000 and 80 FTE

During FY 2003, legislative and public affairs will be consolidated at the Department level. FDA's portion of this transfer will be 80 FTE and $7,317,000. To ensure an orderly, logical, and rational transition, FDA awarded an administrative services contract to Booz-Allen Hamilton, Inc. to study all of our administrative functions and to provide recommendations on what makes good business sense. The results of the study will be a comprehensive plan to meet all of the requirements of the President's Management Agenda and the Secretary's desire to implement management improvements. Organizational structures will be designed that effectively serve internal and external constituencies which includes a flattened hierarchical structure, cost-effective processes and knowledge management to support Agency decisions. FDA has also submitted an action plan for the consolidation of its Personnel Offices as part of its overall consolidation plan for administrative services. These initiatives will enable the FDA to more effectively carry out its mission of protecting the health and safety of U.S. citizens.

Unified Financial Management System: + $5,200,000

Continue implementation of the Agency's component of the DHHS Unified Financial Management System (UFMS). This enterprise-wide system will provide qualitative and quantitative benefits to FDA because it will achieve improved business processes and provide more accurate and timely information to better support FDA's and DHHS' mission. FDA will continue its considerable efforts to retain its clean audit opinion, while meeting the additional challenge of the accelerated time frames established by the Reports Consolidation Act. The UFMS provides the following benefits:

- Reduce cost and complexity of doing business;
- Increase service levels;
- Improve operational efficiency;
- Improve reporting and information sharing between organizational entities;
- Standardize procedures and internal controls; and,
- Comply with Federal legislation and regulations.

Maintain a clean (or unqualified) audit opinion with no material weakness. (Performance Goal 19005)

Mammography Quality Standards Act: + $6,000

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 $6,000 for Other Activities in MQSA authorized inspection user fees to cover inflation, for a total of $186,000 and 2 FTE in FY 2003. The fees collected will pay for the costs of inspections. The current MQSA legislation expires October 28, 2002 and will need to be reauthorized. The Administration will be sending a bill to Congress in the coming months.

Proposed Law User Fees

Prescription Drug User Fee Act III (PDUFA) III: + $14,744,000 and 127 FTE

The FDA Modernization Act of 1997 reauthorized the collection of user fees to enhance the review process of new human drugs and biological products and established fees for applications, establishments, and approved products. PDUFA expires at the end of 2002. FDA is working on a proposal to reauthorize PDUFA and make enhancements to it. FDA strongly believes in the success of PDUFA and that it serves as a model for reinventing government with Congress, the Agency, the industry, and consumer groups all working together providing necessary resources, setting performance goals, and establishing accountability. Other Activities will receive $14,744,000 of the FY 2003 budget request of $272,038,000 in new user fees to reauthorize (PDUFA).

JUSTIFICATION OF BASE

Activities Related to Increases for FY 2003

Counter Terrorism

- Maintain a 24-hour notification system for counter terrorism incidents, including hoaxes, in cooperation with the FBI;

- Facilitate the rapid production and licensure of vaccines and approval of medicines related to counter terrorism agents;

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

- Provide increased physical security at FDA facilities nationwide, including physical barriers, enhanced guard services, and improved security systems.

Payroll

- 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. 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.

Medical Errors

- Continue to develop and enhance an Agency-wide system 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;

- Respond to internal FDA requests for consultation on patient issues of interest. For example, to support development of agency initiatives related to pregnancy and lactation labeling, completed a review of product labeling for nursing mothers;

- Initiate/support activities that are designed to help reach international consensus on regulatory requirements, helping to improve public health;

- Improve the Agency's ability to prevent illness and adverse events by evaluating gender- and culturally-specific perceptions of risk and benefit information for the development of new policies, standards, guidelines and rules that promote participation of women in clinical trials, analyzing data by sex/gender, age, and ethnicity and communicating information in a format understandable to these women;

- Maintain and operate a data bank of information, in collaboration with the NIH, on clinical trials for drugs for serious or life-threatening diseases and conditions (Clinical Trials Data Bank). This bank is used as a central resource, providing current information on clinical trials to individuals with serious or life-threatening diseases, to other members of the public, and to health care providers and researchers. Also, continue to develop and maintain an Agency-wide, OWH-based clinical trials database designed to track the inclusion of women in clinical trials and the analysis of clinical data by sex, age and ethnicity and to determine signals that impact future clinical trial design. Developing and maintaining a single coordinated clinical trials database will improve FDA's ability to track the inclusion of women and minorities in clinical trials and to collect product safety information. Data analysis will allow the Agency to develop, revise and implement policy and standards for data collection during product development and to disseminate risk information on medical products used by women; and,

- Fund research through the National Centers of Excellence in Women's Health to fill gaps in safety and efficacy information for vulnerable populations of women including continued funding of projects investigating the pharmacokinetic and pharmacodynamic changes in drugs used to treat chronic conditions in pregnant women. Extend project beyond pregnancy into lactation and beyond drugs to biologics and dietary supplements. This could lead to improved labeling of medications for pregnant women, assisting *both* providers and patients and reducing adverse events during pregnancy;

- Identify priority regulatory research problems to prevent illness in women and propose and fund research to address these areas. Results of Office of Women's Health (OWH)-funded research promote health through development of industry wide standards for regulated products and providing guidance to the industry on how to meet standards. OWH funded research directly benefits women by incorporating knowledge into product label and educational campaigns; and,

- Provide outreach to consumers in a way that easily explains the science behind FDA's activity. For example, participate in Agency activities that improve the health of women by conducting workshops, disseminating important health information, developing regulations, guidance and implementing label changes to promote the health of women.

Other Activities Related to High Priority Areas

Food Safety

- 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.

Bovine Spongiform Encephalopathy (BSE)

- Provide assistance for BSE issues to assist with coordination of the FDA's role in the DHHS Transmissible Spongiform Encephalopathies (TSE) Action Plan.

Human Subject Protection

- Improve the system for industry reporting of fraud and scientific misconduct in clinical trials by revising agency regulations;

- Improve the quality and integrity of clinical trial data underlying the Agency's decisions to approve new medical products; and,

- Develop and present education and training programs on good clinical practice and human subject protection to major Academic Medical Institutions. Deliver speeches and conduct workshops about FDA, clinical trials, and drug development to patient advocacy groups.

Imports and Inspections

- 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.

Information Management

Financial Management

- Continue implementation of the Agency's component of the DHHS Unified Financial Management System (UFMS);

- Reduce erroneous payments by developing and implementing web-based payments which will help ensure increased accountability to vendors in order to meet Prompt Payment Act requirements and reduce FDA's interest penalties; and,

- Improve financial management systems and business process by streamlining financial management operations, and integrating financial and accounting systems which will facilitate the generation of timely, more frequent financial statements.

Information Technology

- Continue to manage firewall technology to detect and deter unauthorized network access, strengthen defenses from cyber terrorism, including the development of an Agency Critical Infrastructure Protection Plan. The Critical Infrastructure Protection (CIP) program will conduct physical and system security audits to evaluate access controls to ensure FDA's information is not compromised by internal or external threats and the Agency is in compliance with the Government Information Security Reform Act (GISRA);

- Expand existing automated facilities management system to an Agency-wide system through the web capabilities;

- Develop and implement a comprehensive secure remote access system; and,

- Promote the complete implementation of the Information Systems Architecture components by the entire Agency.

Facilities

- Continue support for facilities improvements (e.g. the administration of the Los Angeles Irvine Laboratory contract will continue over the next two years and Phase ! and Phase II of the White Oak Project Planning have received appropriations for design and construction from Congress); and,

- Continue to implement commercial activities for cost comparison studies relative to OFACS real property management.

Human Resources

- Continue implementation of the total consolidation of personnel offices to DHHS by the end of 2003. FDA has submitted an action Plan for the consolidation of FDA's Personnel Offices from eight to one by September 30, 2002 as part of our overall consolidation of administrative services plan. We will continue to move along the timeline by accomplishing the first DHHS goal of 40 personnel offices to 4; and,

- Continue to implement commercial activities for cost comparison studies relative to personnel management and support, and administrative support for the Office of Regulatory Affairs.

International Activities

- Leverage outside entities to provide benefits and incentives for all participants, while accomplishing the Agency's mission. Help to disseminate information to the public

about FDA's international activities, providing useful information to consumers, regulated industry and trade organizations;

- Work to ensure that FDA's finite resources are leveraged to achieve maximum benefit from the collaborative efforts of the agency and its partners;

- Meet with industry representatives on issues related to expanded access to unapproved drugs and facilitate meetings between industry and patient advocacy groups;

- Serve as a focal point for communication and collaboration between the Agency and foreign governments on a variety of public health issues that influence global food safety policy such as arranges for policy and program discussions with foreign scientists and regulators under FDA's International Programs, to ensure that goods imported to the U.S. meet Agency standards;

- Guide FDA's program centers toward the development of agency-wide strategies for all FDA-supported international harmonization programs and coordinate FDA's submissions for U.S. Policy development. Also support worldwide research on new drug and biologic products by seeking evaluation for, and issuing authorizations to, export unapproved drugs and biologics for use in clinical trials; and,

- Supplement FDA's regulatory enforcement activities by managing international agreements based on the cooperation of the exporting countries' governments. Assess the efficacy of bilateral and multilateral agreements, and work with the Department of State, the U.S. Trade Representative (USTR), and other Federal agencies to negotiate additional agreements. Protect FDA's interests and assert leadership by participating in USTR initiatives affecting public health issues such as intellectual property, pharmaceutical access, interagency activities related to trade and environment, the Free Trade Agreement of the Americas, and other interagency efforts.

Education and Outreach

- Develop regulatory based action plans across FDA's different product centers in collaboration with other agencies in areas with great threat to public health, such as antimicrobial resistance and Bovine Spongiform Encephalopathy (BSE), and ensure these actions are successfully implemented across the Agency;

- Recruit, retain, and adequately compensate the highest caliber scientist and health professionals needed to keep pace with the explosion of technological and scientific breakthroughs;

- Recruit and train patient advocates for participation in FDA advisory committee meetings and other FDA meetings, such as the deliberations on drugs, biologics, and devices to treat AIDS, cancer, diabetes, Crohn's Disease, Hepatitis C, Parkinson's disease, TMJ, Cerebral Palsy, Lupus and others;

- Provide opportunities for scientists and professors to learn about FDA's multi-disciplinary processes for addressing public health issues involving drugs, biologics, and medical devices. For example, through the FDA Volunteer Pharmacy Student Experiential Program, FDA's program for pharmacy students which serves as a tool for FDA pharmacist recruiting, helps future scientists and professors to acquire knowledge, skills, and impressions of FDA beneficial to their professional career;

- Increase and expand the use of hiring programs for minority and disabled student interns, and established formal partnership agreements with Historically Black Colleges and Universities (HBCU) and Hispanic Serving Institutions (HSI).

SELECTED FY 2001 ACCOMPLISHMENTS

Counter Terrorism

- Enhanced strategies to disseminate current information to the public regarding the protection of citizens from anthrax laden letters that have been introduced into our mail system;

- Continued efforts to enhance security software to update computerized systems; and,

- Coordinated efforts across organizational components to identify potentially dangerous products; and, promptly evaluate health hazards and classify recalls.

Cyber Terrorism (Presidential Decision Directive 63)

- Completed development of an Agency Critical Infrastructure Protection Plan;

- Implemented a secure remote dial-in solution for the Agency, which will allow for secure connectivity to the Agency network by utilizing technologies such as Virtual Private Networks;

- Identified and deployed secure e-mail and encryption software to allow for the transmission of confidential and trade secret data; and,

- Enhanced the Agency's firewall infrastructure to increase capacity and response times to the Internet.

Management Activities

- Initiated a comprehensive project to update, reorganize and propose renumbering of FDA's delegations, by functional categories (i.e., drugs, biologics, foods, devices, etc.). The long-range goal is to discontinue publishing the delegations under Title 21, Code of Federal Regulations (CFR), Part 5 and to utilize the existing 1410 series of the Agency's on-line Staff Manual Guide System for publication. This would eliminate the cost of publishing the information in the Federal Register and CFR; allow for more timely updates; and improve access to the most "up-to-date" information;

- Moved to award an administrative services study contract. The plan is to have a contractor study all of our administrative functions starting with human resources, but also include financial management IT and facilities. The study will generate a comprehensive plan to meet all of the requirements of the President's Management Agenda and the Secretary's desire to implement management improvements. The plan addresses the consolidation of FDA's Personnel Offices from eight to one by September 30, 2002 as part of our overall consolidation of administrative services.

- Continued support for facilities improvements. The Agency was involved in a number of large, complex facility improvement projects:

    - *Los Angeles (Irvine) Laboratory.* A contract for this project was negotiated, and construction begun on the first phase of the project that involved site work, construction of the building's structure, and exterior walls. As an FDA-funded project, the administration of the contract will continue over the next two years;

    - *White Oak Project Planning.* The FDA consolidation at White Oak is a five-phase project requiring over $580 million in appropriations. Phase I and Phase II of the project have received appropriations for design and construction from Congress. Construction for phase I and design of phase II will occur concurrently. The design and construction activities will result in the development of nearly 600,000 gross square feet for over 1,900 FDA employees;

    - *College Park Move*. The construction of CFSAN's College Park facility was completed in October 2001. FDA is continuing the orderly transition of relocating CFSAN staff to this facility;

    - Explored ways to redesign and streamline the way we do business with our customer communities, including:

        - Grants management systems that could support FDA's grant management work functions such as electronic imaged record storage; and,

        - Collaborated with NIH's ongoing interagency development of the Federal Commons. (The Federal Commons is an Internet-based point of entry for grant prepares and recipients to conduct business electronically with Federal grant making agencies).

Financial Management

- Continued to position the Agency to meet the 21st century state-of-the-art technology, redesigned cost management systems, streamlined business processes, and innovative approaches with fewer resources;

- Realigned staff resources to ensure FDA will meet the requirements of the FY 2000 Chief Financial Officers Act audit by establishing a branch dedicated to the CFO

Audit requirements. The reorganization closely aligns accounting and financial system development resources;

- Revised procedures so that accounting records are updated nightly rather than three times a week to allow for more timely access to financial information and reduced risk of errors or omissions;

- Completed Spiderman Hyperion rollout of the FTE and Payroll applications to all Centers and offices. This completed the rollout of the Hyperion software capability to all components for various budget applications, and also provided on –line access to a variety of payroll information applications;

- Completed follow-up actions to finalize the FY 1999 reorganization of the Office of the Commissioner. Provided training and technical support to the Office of the Commissioner offices to assist them in establishing improves financial control systems for the newly established offices, including payroll management improvements;

- Leveraged a department-wide financial systems workgroup effort to review financial system models for consideration by FDA and other operating divisions whose core accounting system was being replaced. The Department believes that participating agencies should realize cost savings;

- Developed a project plan on financial systems activities and integration, and a preliminary estimate of out-year costs for a new financial management system;

- Converted approximately 69 state contracts under $100,000 to simplified acquisition procedures. Invoices and progress reports will now bypass the contact office and go directly to the finance and program office. This will require fewer staff hours necessary for the administration and close-out process for these actions;

- Expanded existing facilities management system to and Agency-wide systems with web capabilities. The new system will allow FDA to maintain a comprehensive database of all FDA facilities; and,

- Continued to explore and encourage leveraging FDA assets through enhanced education and outreach programs, and identifying new ways for using exiting mechanisms to defer costs.

Information Technology

- Implemented an Electronic Submission Form and Registration Form on the Internet to allow the pubic to electronically submit responses to the Agency and an Intranet–based electronic document management application to provide Agency staff with immediate on–line access to records;

- Facilitated a series of reviews and deliberations by the FDA's Information Technology Investment Review Board (ITIRB) and developed a proof-of-concept web-based capital planning tool to capture existing investment information and help produce standardize routine reports for external distribution of DHHS and OMB;

- Developed a new database application and integrated it with Documentum-document management and workflow. Developed an application for creating and tracking changes to the CFRs. This application provides access to all current CFRs and proposed changes to FDA personnel via the FDA Intranet; and,

- Created a secure Internet environment that fosters collaboration and allows electronic collecting and exchange of data directly from sources outside of FDA (public, states and industry). This was achieved through the implementation of an infrastructure with its own dedicated network, firewall system, high-end encryption capabilities, and a secure end-to-end connection between FDA and the hosting company.

Policy and Planning

- Ensured effective and efficient completion of reporting requirements, including reports to Congress on a wide range of topics under E.O. 12866 and other requirements; and,

- Developed regulations to further the Agency's mission that were high quality and done in a timely fashion. Significant time and attention was given not only to promulgating and developing regulations, but also to obtaining the appropriate clearances in the Department and OMB, and explaining the public health impact of these regulations to the media, congress, industry and the public.

Legal Activities

- Provided leadership and direction in the effective use of enforcement actions:
  - In United States v. Lifescan, Lifescan Inc., a wholly-owned subsidiary of Johnson & Johnson, pled guilty in a federal court in California to misdemeanor criminal charges and was ordered to pay the government criminal and civil fines totaling $60 million. The criminal charges stemmed from defects in Lifescan's SureStep® blood glucose monitoring device, which the company knew about but failed to disclose to customers or to FDA in obtaining clearance to market the device; and,

  - In United States v. Undetermined quantities of articles of drug, street drug alternatives, a federal court in Maryland entered an order prohibiting Hit Products, Inc. and Organic Diversions, Inc. from introducing certain misbranded and unapproved new drugs into interstate commerce. The complaint alleged that the defendants' products are drugs because they are intended to be used as substitutes for illegal street drugs, such as marijuana, Ecstasy, hashish, and opium. As such, the products are intended to induce in the user psychological effects similar to those intended by the street drugs they mimic. This case was the Agency's first suit following issuance of a guidance document in April 2000

informing the public that any product promoted as an alternative to illegal street drugs would be regarded by FDA as a misbranded and unapproved new drug.

Provided leadership and direction in the successful defense of agency initiatives and decisions:

- In Nutritional Health Alliance v. FDA, a federal court in New York upheld FDA regulations that require unit-dose packaging for certain iron-containing drugs and dietary supplements; unit-dose packaging consists of separate, nonreusable containers for each tablet or capsule. The regulations were intended to prevent accidental iron overdosing among children; and,

- In aaiPHARMA, Inc. v. Thompson, a federal court in North Carolina denied a motion for a temporary restraining order that would have barred FDA from approving five abbreviated new drug applications for generic versions of fluoxetine hydrochloride (Prozac®).

Provided legal review and clearance of final and proposed regulations to achieve significant public health objectives:

- Amended a regulation to require licensed manufacturers of biological products to report errors and accidents in manufacturing that may affect the safety, purity, or potency of a product;

- Proposed to amend the food import regulations to require food products that, for safety reasons, are refused entry into the United States to be marked "United States Refused Entry." The proposed rule would also prohibit persons from refusing to affix this mark on refused food, from importing or offering to import a previously refused food, and from altering, removing, tampering with, or concealing a mark. The proposed rule is intended to protect the public health against unsafe imported food products and to facilitate the examination of imported products; and,

- Proposed to require the submission to the Agency of data and information regarding plant-derived bioengineered foods that would be consumed by humans or animals. FDA is proposing that this submission be made at least 120 days prior to the commercial distribution of such foods. FDA is taking this action to ensure that it has the appropriate amount of information about bioengineered foods to help to ensure that all market entry decisions by the industry are made consistently and in full compliance with the law.

International Activities

- Forged coherent, effective and strategic responses to the ever-increasing worldwide trade in products under FDA's responsibility, including:

Counter Terrorism

- Requested increased authority to strengthen FDA's oversight of food in the case of an emergency, allowing FDA to require information from food producers that will enable the Agency to rapidly address possible health hazards by quickly tracing the source and distribution of both domestic and imported food.

Food Safety

- Participated in planning for the Global Forum of Food Safety Regulators, a conference designed to enhance communication among food safety regulators worldwide. The intent is to increase the level of food safety, which will result in safer products being exported to the United States. FDA supported the United Nations World Health Organization (WHO) and the United Nations Food and Agricultural Organization (FAO) in the conference planning, provided one person to work with WHO on this project, and also provided planning process funding;

- Negotiated and completed the signing of a cooperative arrangement by U.S. and Mexican government officials that will improve the safety of food supplies in both countries, and in particular, food imports from Mexico. The arrangement, in conjunction with other cooperative measures, will help reduce the incidence of food-borne illnesses on both sides of the border;

- Provided support to, and participated in, the U.S. delegation to the XII Inter-American Meeting on Health and Agriculture, at the Ministerial Level, on Health and Agriculture (RIMSA). Provided guidance and direction to support the creation of the Pan American Commission for Food Safety (COPAIA), which was established by the Director of the Pan American Health Organization (PAHO); and,

- Completed the signing of an international agreement between the U.S. and Chile on molluscan shellfish.

Drugs

- Processed 294 requests for export of unapproved drugs pursuant to 21CFR312.110. These approvals allow U.S. manufacturers to ship unapproved drugs and biological products for foreign clinical trials.

Agreements

- Engaged in implementation activities related to the Pharmaceutical GMP and Medical Devices Annexes to the U.S.-EU Mutual Recognition Agreement (MRA);

- Established an alert system for exchanging information about serious or life-threatening human/animal pharmaceutical product quality defects and recalls;

- Began assessment of the pharmaceutical GMP regulatory system of the United Kingdom to determine whether it is equivalent to the U.S. system; and,

- Completed the assessment process for three to four EU Conformity Assessment Bodies, which will then enable them to do independent work for FDA such as performing medical device product reviews and auditing/inspecting medical device manufacturing facilities.

Trade

- Provided advice and analysis to the Office of the U.S. Trade Representative, the Department of Commerce, and the USDA Foreign Agriculture Service on a broad range of trade negotiations and issues, pursuant to the Food and Drug Administration Modernization Act (FDAMA) to further U.S. trade objectives in ways that would not compromise FDA's health and consumer protection mandate; and,

- Continued efforts to eliminate potential barriers in the global marketing of products that are approved for use in the US. These efforts facilitate the Agency's efforts to promote mutual recognition and international harmonization aimed at approval systems as well as product surveillance.

Education and Outreach

- Established "FDA University", an Agency-wide learning venture designed to address the needs of an environment of rapidly expanding science and technology with increasing responsibilities and expectations, and continued resource constraints. The "FDA University" maximizes the use of existing Center/Office Staff Colleges and others with training responsibilities that are making significant contributions to workforce development while providing added focus on meeting common, Agency-wide needs. The "FDA University" includes classroom-based courses and workshops, incorporates new learning technologies and offers new opportunities for partnerships with academia and industry in an effort to leverage resources. "FDA University" could play a significant role in recruitment and retention; areas that are critical for FDA and many other federal agencies;

- Funded outreach programs for women about the value of our Mammography Quality Standards Act and the latest breast cancer diagnostic and treatment advances; and, continued partnering with the National Centers of Excellence in Women's Health (CoEs), and funded projects focusing on the pharmacokinetics and pharmacodynamics of antihypertensive medications used during pregnancy;

- Developed a new national public awareness campaign titled "Take Time To Care About Diabetes" to inform consumers that diabetes is a looming epidemic but that it is controllable using FDA-regulated products. It harnesses the resources of our partners (the National Association of Chain Drug Stores and the American Diabetes Association and dozens of others) to address this illness. The campaign:
  - uses thousands of community drug stores and groceries to print and distribute FDA materials;
  - provides information from FDA product centers using the food label, using devices to monitor blood glucose, and taking medications as prescribed;

    - uses the educational model that won the Year 2000 Health Care Quality Alliance's Pinnacle Award and Year 2001 National Association for Women's Health Award for Excellence; and,
    - works with other HHS agencies to coordinate all efforts.

- Initiated the Cancer Drug Development Patient Consultant Program to incorporate the perspective of patient advocates even earlier in the drug development process. The patient consultant provides advice to the FDA and to the drug sponsor on topics such as clinical trial design, endpoint determination, expanded access protocol development, and clinical trial patient recruitment strategies;

- Issued 82 press releases and talk papers. Those that addressed FY 2001 agency priorities included 27 on significant product approvals (12 drugs, 10 devices, five biologics), nine on postmarketing/medical error reduction actions, 10 related to food safety initiative, 11 related to the food safety initiative, 10 on product recalls and warnings, four on agency enforcement actions and three on cell and tissue issues. Facilitated the issuance of dozens of recall press releases issued by regulated industry; and,

- Created approximately 750 Web pages to help communicate with the public and industry about some of the Agency's most important initiatives including BSE, human protection, Lasik, food safety, product recalls, product approvals, regulatory guidance, and enforcement activities.

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Rent Activities

	FY 2001 Actual Obligations	FY 2002 Current Estimate	FY 2003 +/-FY 2002 Current Estimate	FY 2003 Baseline Estimate
Total Program Level **BA** **User Fees**	**$124,033,000** **$118,173,000** **$5,860,000**	**$147,864,000** **$141,624,000** **$6,240,000**	**($5,670,000)** **($6,570,000)** **+ $900**	**$142,194,000** **$135,054,000** **$7,140,000**
GSA Rent **BA** Admin Consolidation	**$87,276,000**	**$98,876,000**	**($320,000)** ($320,000)	**$98,556,000** ($320,000)
PDUFA II	**$5,860,000**	**$6,240,000**	**($6,240,000)**	**0**
PDUFA III	**0**	**0**	**+ $7,140,000**	**$7,140,000**
Other Rent and Rent-Related Activities **BA** *Counter Terrorism*	**$30,897,000**	**$42,748,000** 12,950,000	**($6,250,000)** ($6,250,000)	**$36,498,000** $6,700,000

Note: FY's 2001/2002 do not reflect comparable adjustments of $286,000 and $305,000, respectively, for the FY 2003 Administrative Consolidation of public and legislative affairs to DHHS.

Historical Funding

GSA Rent

Fiscal Year	Program Level	Budget Authority	User Fee
1999 Actuals	$88,294,000	$82,866,000	$5,428,000
2000 Actuals	$93,340,000	$87,697,000	$5,643,000
2001 Actuals	$93,136,000	$87,276,000	$5,860,000
2002 Current Estimate *1/*	$105,116,000	$98,876,000	$6,240,000
2003 Estimate	$105,696,000	$98,556,000	$7,140,000

1/Includes FDA's FY 2002 Appropriation and the Counter Terrorism Supplemental.

Other Rent and Rent-Related Activities

Fiscal Year	Program Level	Budget Authority	User Fee
1999 Actuals	$25,854,000	$25,854,000	$0
2000 Actuals	$32,452,000	$32,452,000	$0
2001 Actuals	$30,897,000	$30,897,000	$0
2002 Current Estimate *2/*	$42,748,000	$42,748,000	$0
2003 Estimate	$36,498,000	$36,498,000	$0

2/Includes FDA's FY 2002 Appropriation and the Counter Terrorism Supplemental.

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, and costs associated with moving staff and equipment during the consolidation of FDA laboratory facilities.

PROGRAM RESOURCE CHANGES

GSA Rent

- **Transfer of Legislation and Public Affairs: - $320,000**

During FY 2003, legislative and public affairs will be consolidated at the Department level. FDA's portion of this transfer will be 80 FTE and $7,317,000. To ensure an orderly, logical, and rational transition. The GSA rent portion of this consolidation is $320,000.

Other Rent and Rent-Related Activities

Counter Terrorism

The FY 2003 request builds upon funding FDA received from the FY 2002 appropriation plus the FY 2002 emergency supplemental. As a result, while FDA has received increased funding to support counter terrorism, some of the programs are showing either no funding increase, or a slight decrease. The FY 2003 request annualizes those dollars received as one-time money in the supplemental -- a significant increase to the Agency of $152,276,000 in total. The funding changes shown below are the differences once these annualized dollars are removed.

For rent, in FY 2003, FDA will continue to utilize $6,700,000 of the $12,950,000 provided in the supplemental to maintain the physical security efforts begun in FY 2002.

FDA received $12,950,000 to increase physical security and provide for increased guard services, improved security systems and physical barriers at the entrances to buildings and parking lots.

Counter Terrorism - Physical Security: - $6,250,000 ($6,700,000 annualized from Counter Terrorism Supplemental)

- Continue monitoring security standards at all facilities, plan for improved security measures and procedures, and effectively coordinate with all FDA components;

- Consider options for maintaining the continuity of critical mission activities in the event of a catastrophic event. These options include remote site back-up computing capabilities and off-site work locations for the most critical staff of the Agency; and,

- Conduct periodic environmental sampling of Headquarters mailrooms that receive mail directly from the Postal Service, safety supplies, sampling for laboratory and analytical costs, as well as for the mail screening operations. Certify bio-safety Level 3 Laboratories used for bioterrorism and decontamination and recertification of biological safety cabinets.

Other Resource Changes

FDA received $4,000,000 in FY 2002 for the Center for Drug Evaluation and Research (CDER) move into the White Oak facility. These funds were for a one-time need; however, FDA will need these funds in FY 2003 and will:

- Use $2,000,000 in FY 2003 for recurring facility-related costs for the new CFSAN building in College Park, Maryland. CFSAN is planning to relocate to College Park by February 2002. Some costs for College Park will be offset by the reduction of costs at FB-8; however, FB-8 was a delegated facility that was substantially supported by funds from GSA. FDA will be responsible for all utilities and operation and maintenance services at College Park; and,

- Use $2,000,000 in FY 2003 for facility-related costs of the Los Angeles laboratory not related to GSA. FDA requests funds for one-time costs to equip and occupy the Los Angeles laboratory portion of the facility. These funds will support telecommunications equipment and necessary connections and moving costs to relocate the functions to a new state-of-the-art facility, scheduled to open in 2004.

Proposed Law User Fees

Prescription Drug User Fee Act III (PDUFA) III: + $7,140,000

The FDA Modernization Act of 1997 reauthorized the collection of user fees to enhance the review process of new human drugs and biological products and established fees for applications, establishments, and approved products. PDUFA expires at the end of 2002. FDA is working on a proposal to reauthorize PDUFA and make enhancements to it. FDA strongly believes in the success of PDUFA and that it serves as a model for reinventing government with Congress, the Agency, the industry, and consumer groups all working together providing necessary resources, setting performance goals, and

establishing accountability. GSA Rent will receive $7,140,000 of the FY 2003 budget request of $272,038,000 in new user fees to reauthorize (PDUFA).

JUSTIFICATION OF BASE

GSA Rent

Counter Terrorism

- Incur costs for additional space to support more than 800 new field and headquarters counter terrorism staff;

- Plan to occupy over 4.1 million net square feet of space, including parking, which is under the Agency's Salaries and Expenses appropriation. By FY 2003, FDA will occupy over 4.5 million net square feet of GSA space, including parking; and,

- Receive GSA rent charges that are billed directly to the Agency and indirectly 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

- Commercial Rent and Related Services. Consists of recurring activities that FDA pays directly to non-Federal sources under the delegation of direct lease and service authority. Services include rental of space, and all recurring services for building operations;

- GSA Rent-Related Services. Includes 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 heating, ventilation, and air conditioning (HVAC) beyond the standard level funded by GSA; and,

- GSA Building Delegation Services account. Provide 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.

SELECTED FY 2001 ACCOMPLISHMENTS

Other Rent and Rent-related

College Park Move. The construction of CFSAN's College Park facility was completed in October 2001.

Counter Terrorism

FDA Safety and Security Staff evaluated FDA's facilities nationwide to improve employee security and its response to emergencies due to the recent counter terrorist event and issues concerning anthrax exposure. The following precautions were implemented:

- Temporarily closed the mailroom at the Parklawn facility and rerouted mail through an off-site screening facility to reduce the risks involved with screening;
- Increased the number of guards at many facilities across the nation and will continue to add more guards as necessary;
- Installed additional disabled parking space markers for those buildings where changes in entry have negatively affected disabled employees;
- Increased screening procedures at all facilities for visitors and employees;
- Limited the number of access doors to each facility so that all visitors and employees are required to go through proper screening procedures;
- Conducted surveys of FDA facilities to enhance security measures where necessary; and,
- Met with GSA to discuss security concerns at our multi-tenant facilities.

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Buildings and Facilities

	FY 2001 Actual Obligations	FY 2002 Current Estimate	FY 2003 +/-FY 2002 Current Estimate	FY 2003 Baseline Estimate
Total Program Level	**$33,207,000**	**$34,281,000**	**($26,281,000)**	**$8,000,000**
Current Law BA B&F Consolidation	-	-	($26,281,000)	$8,000,000

Historical Funding

Fiscal Year	Program Level	Budget Authority	User Fee
1999 Actuals	$16,178,000	$16,178,000	$0
2000 Actuals	$10,553,000	$10,553,000	$0
2001 Actuals	$33,207,000	$33,207,000	$0
2002 Current Estimate *1/*	$34,281,000	$34,281,000	$0
2003 Estimate	$8,000,000	$8,000,000	$0

1/ Includes FDA's FY 2002 Appropriation and the Counter Terrorism Supplemental.

MISSION

FDA Buildings and Facilities appropriation provides funding for needed repairs and improvements to existing owned or leased facilities all across the United States.

PROGRAM RESOURCE CHANGES

Management Efficiencies: -$26,281,000

FDA's FY 2003 budget reflects a reduction in construction funding. The $3,000,000 needed for the completion of the final phase of the Arkansas Regional Laboratory will be delayed. The decrease amount also reflects a reduction for the Los Angeles laboratory that was fully funded in FYs 2001 and 2002. The laboratory reduction is $22,639,000. These reductions are necessary to allow FDA to devote resources to its highest priority – counter-terrorism. Any remaining FDA projects, not covered by the $8,000,000 left for FDA to individually manage its repairs and improvements needs, will be delayed to future years.

JUSTIFICATION OF BASE

Repairs and Improvements

Base resources of $8,000,000 cover the costs of repairs and improvements to FDA facilities, owned and leased. Included are Maryland site components which are now located in some 40 buildings in 18 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 and complexes outside the Washington D.C. 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.

For comparison purposes, industry components regulated by FDA spend between nine percent and 12 percent of the value of their physical plants on maintenance, alteration, and repair, while FDA's spends about two percent on laboratories and laboratory support facilities for the same purpose. This makes it more difficult for FDA scientists to keep pace with the technological advances that fuel incoming premarket applications. Planned repairs and improvement projects for FY 2003 are as follows:

1.	ORA, Nationwide - Miscellaneous Repair and Improvement	$925,000
2.	ORA, Seattle, WA - Upgrade Casework	185,000
3.	NCTR, Jefferson, AR - Upgrade fire alarm systems bldgs 14, 62, 12	370,000
4.	NCTR, Jefferson, AR - Partial renovation of HVAC at 14c	833,000
5.	NCTR, Jefferson, AR - General maintenance and repair roof of building 5D & 6Y	815,000
6.	NCTR, Jefferson, AR - Completion and renovation of building 51	231,000
7.	NCTR, Jefferson, AR - Design of Environmental Mgt. System control system	292,000
8.	NCTR, Jefferson, AR - Partial renovation of building 62	787,000
9.	CFSAN, Dauphin Island, AL - HVAC renovation	833,000
10.	CFSAN, Laurel, MD - Purchase Glasswasher	278,000
11.	CDER, White Oak, MD - Anticipated program changes for new laboratory	278,000
12.	CBER, Bethesda, MD - Convert offices to 4 laboratories in Building 29	370,000
13.	CBER, - Renovations in Buildings 29 and 29A	218,000
14.	CDRH, Rockville, MD - Retrofit of existing laboratory	1,400,000
15.	CVM, Laurel, MD - MOD II, Epoxy floors for animal holding space	185,000
	TOTAL	**$8,000,000**

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:

- The $3,000,000 received in FY 2002 will be used to continue purchase of major mechanical and electrical equipment for Building 50 office space renovation and start the fit out of the interior. Building 50 will be about 55 percent complete at the end of FY 2002;

- The FYs 1999, 2000, and 2001 appropriations included $3,000,000 each to begin and continue construction of Phase III.

Los Angeles Laboratory

A contract for this project was negotiated, and construction begun on Phase I for site work, construction of the building's structure, and exterior walls. The Los Angeles Laboratory project is on schedule with a completion date of June 8, 2003, and the scheduled move-in is to begin in August, 2003. The contract for Phase II construction was awarded on November 29, 2001.

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