

BUILDINGS AND FACILITIES

	FY 2004 Actual	FY 2005 Enacted	FY 2006 Estimate	Increase or Decrease
Program Level	\$22,504,000	\$0	\$7,000,000	+\$7,000,000
Budget Authority	\$22,504,000	\$0	\$7,000,000	+\$7,000,000

Historical Funding and FTE Levels

Fiscal Year	Program Level	Budget Authority	User Fees	Program Level FTE
2002 Actual ^{1/}	\$43,867,000	\$43,867,000	\$0	0
2003 Actual	\$17,043,000	\$17,043,000	\$0	0
2004 Actual	\$22,504,000	\$22,504,000	\$0	0
2005 Enacted	\$0	\$0	\$0	0
2006 Estimate	\$7,000,000	\$7,000,000	\$0	0

^{1/}Includes FDA's FY 2002 Appropriation and the Counterterrorism Supplemental.

STATEMENT OF BUDGET REQUEST

The Agency is requesting \$7,000,000 in program level resources for accomplishing its mission activities. This appropriation would provide funding for new construction and needed repairs and improvements which include Maryland site components which are now located in approximately 40 buildings in 16 separate locations; plus five regional offices, 19 field District complexes including 19 administrative and 13 specialized laboratory facilities nationwide; more than 120 field resident posts, eight field criminal investigation offices, two distinct program laboratory complexes outside the Washington D.C. Metro area; and the NCTR complex in Jefferson Arkansas. Overall, FDA maintains offices and staff in 49 states, and in the District of Columbia and Puerto Rico.

PROGRAM DESCRIPTION

The Building and Facilities appropriation provides funding for new construction and for needed repairs and improvements to existing facilities across the U.S.

STATEMENT OF BUDGET REQUEST

The Agency is requesting \$171,394,000 in program level resources for both government-owned and GSA-leased property, as needed for staff to accomplish FDA's 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 GSA space, while the Other Rent and Rent-Related account includes rent and rent-related charges that are not part of the GSA account.

- 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.

RATIONALE FOR BUDGET REQUEST

This request, for Budget Authority and User Fees, supports various activities that contribute to the accomplishment of program outputs and performance goals, and presents FDA's justification of base resources by strategic goals.

PROGRAM RESOURCE CHANGES

Program Account Restructuring

GSA Rent and Other Rent Activities Structure Change

To provide increased flexibility and accountability, eliminate the need for the many reprogramming requests to the Congress, place the accountability for rental costs within the operating program, and would better reflect the total cost of each program. This budget changes the way the GSA Rent and Other Rent-Related Activities budget lines are displayed by incorporating these resources into program level requests.

Office of Regulatory Affairs Estimate and Structure Change

This budget also establishes a single budget line item for the Office of Regulatory Affairs (ORA), to help it provide services more effectively, especially by providing much needed flexibility to respond shifting program priorities. This additional flexibility is essential to allow FDA to respond to emerging situations without being hindered in performing its mission critical activities. These activities have been removed from each program line and the Field estimates will be provided under the ORA to reflect the planned spending for each program area.

Budget Authority

GSA Rent + \$4,100,000

To help meet the rising costs of GSA rent, a total increase of \$4,100,000 is requested to help cover inflation on FDA's current GSA leased facilities.

User Fees

Prescription Drug User Fee Act III (PDUFA): + \$293,000

PDUFA authorized the FDA to collect fees from the pharmaceutical industry to augment appropriations spent on drug review. These fees expand the resources available for the process of reviewing human drug applications including reviewers, information management, space costs, acquisition of fixtures, furniture, equipment and other necessary materials so that safe and effective drug products reach the American public more quickly. The BT Act 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. These amendments are effective for five years and direct FDA to strengthen and improve the review and monitoring of drug safety; consider greater interaction with sponsors during the review of drugs and biologics intended to treat serious diseases and life-threatening diseases; and develop principles for improving first-cycle reviews. The increases will contribute to meeting these mandated directives.

Medical Device User Fee and Modernization Act (MDUFMA): + \$657,000

The FY 2006 request for the Devices and Radiological Health program meets the required trigger of \$220,961,000 in the Devices and Radiological Health Program, enabling FDA to collect the MDUFMA user fees that supplement the appropriated portion of the medical device review program. The Agency will be able to continue its efforts to improve the quality and timeliness of the medical review process and promote the delivery of new medical technologies to the American public. The MDUFMA User Fees it collects will allow FDA to continue to:

- Promote public health through major improvements in the review of expedited submissions for medical devices;
- Meet MDUFMA's performance goals and achieve the other improvements prescribed by MDUFMA;

- Provide information system improvements and modernization for the device tracking systems, Image system, other essential systems; and,
- Provide training and professional development for employees and contract with outside experts to ensure that the Agency keeps pace with technological change and medical advancements.

Animal Drug User Fee Act (ADUFA): + \$1,000,000

ADUFA enacted in November 2003, contained a required appropriations action enabling FDA's implementation of ADUFA. ADUFA helps the FDA, through a strengthened animal drug pre-market review program, to provide greater public health protection by ensuring that animal drug products that are approved to be safe and effective are readily available for both companion animals and animals intended for food consumption. Additional resources provided by ADUFA will also help FDA scientists keep pace with the rapid advances in science and medicine that drive the quality of health care for our animals. ADUFA, which requires new animal drug applicants, sponsors, and manufacturers to incur a fee to expedite their respective applications, will help provide a cost-efficient, high quality animal drug review process that is predictable and performance driven.

JUSTIFICATION OF BASE

GSA Rent

IMPROVING FDA'S BUSINESS PRACTICES

Through improving FDA's business practices, the Agency will ensure a world-class professional work force, effective and efficient operations and adequate resources to accomplish the mission. FDA will continue to:

- Occupy over 4.4 million net square feet of space, including parking, which is under the Salaries and Expenses appropriation. By FY 2006, FDA will occupy over 4.6 million square feet of GSA space, including parking; and,
- Incur GSA rent charges that are billed directly to FDA and indirectly through other agencies, and include the charges for all of GSA space, both government owned and GSA leased. About 47 percent of these 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 facility, 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 throughout the country.

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;
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