

RENT ACTIVITIES

	FY 2004 Actual	FY 2005 Enacted ^{1/}	FY 2006 Estimate	Increase or Decrease
Program Level	\$158,010,00	\$165,344,000	\$171,394,000	+\$6,050,000
Budget Authority	\$150,397,000	\$149,237,000	\$153,337,000	+ \$4,100,000
GSA Rent and Other Rent Related Activities:				
<i>Foods Program</i>	\$23,168,000	\$23,187,000	\$23,615,000	+ \$428,000
<i>Human Drugs Program</i>	\$18,544,000	\$20,059,000	\$20,518,000	+ \$459,000
<i>Biologics Program</i>	\$7,272,000	\$5,979,000	\$6,039,000	+ \$60,000
<i>Animal Drugs & Feeds Program</i>	\$12,043,000	\$12,259,000	\$12,477,000	+ \$218,000
<i>Devices and Rad. Health Program</i>	\$16,315,000	\$17,702,000	\$18,012,000	+ \$310,000
<i>National Center for Toxicological Research</i>	\$217,000	\$229,000	\$229,000	\$0
<i>Office of Regulatory Affairs Program</i>	\$64,416,000	\$62,526,000	\$65,001,000	+ \$2,475,000
<i>Other Activities Program</i>	\$8,422,000	\$7,296,000	\$7,446,000	+ \$150,000
User Fees	\$7,613,000	\$16,107,000	\$18,057,000	\$1,950,000
GSA Rent and Other Rent Related Activities:				
<i>PDUFA</i>	\$6,146,000	\$12,407,000	\$12,700,000	+ \$293,000
<i>MDUFMA</i>	\$1,367,000	\$3,329,000	\$3,986,000	+ \$657,000
<i>ADUFA</i>	\$100,000	\$371,000	\$1,371,000	+ \$1,000,000

Includes structure changes to FDA's budget, which displays GSA and Other Rent and Rent Related Activities in the Program line, and the Office of Regulatory Affairs as its own program. ORA estimates are for information purposes only and are not included in the Center program level total.

^{1/}*Contains budget authority rescission of 0.8 percent.*

Historical Funding and FTE Levels

Fiscal Year	Program Level	Budget Authority	User Fees	Program Level FTE
2002 Actual ^{1/}	\$99,916,000	\$98,876,000	\$1,040,000	0
2003 Actual	\$150,511,000	\$141,292,000	\$9,219,000	0
2004 Actual	\$158,010,000	\$150,397,000	\$7,613,000	0
2005 Enacted	\$165,344,000	\$149,237,000	\$16,107,000	0
2006 Estimate	\$171,394,000	\$153,337,000	\$18,057,000	0

Does not contain GSA Rent or Other Rent and Rent Related Activities.

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

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 the field program 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 Office of Regulatory Affairs to reflect the planned spending for each program area.

FDA White Oak Consolidation Structure Change

To provide increased flexibility and to better reflect the total cost of the White Oak Consolidation effort, this budget changes the way the budget line is displayed by adding an individual line to display the consolidation project.

Budget Authority

Buildings and Facilities: +\$7,000,000

Managing a nationwide inventory of leased and owned real property assets that include a substantial amount of lab facilities requires regular repair, improvement and maintenance activities on a preventative and, on an emergency basis. Modifying these spaces to accommodate programs and maintain the buildings as they age allows FDA employees to perform their duties in a safe, healthful and productive work place.

Without funding in FY 2006, FDA will delay completion of projects, which will cause additional operating costs to support personnel and equipment in different buildings and postponing planned inter-center research projects. FDA could be in a position of having to shut-down laboratories and buildings due to safety issues, with field operations bearing the brunt of any such closures. Restoration is especially important, and not receiving the requested resources could lead to rising costs due to the continued delays in maintenance and deterioration of the FDA facilities.

JUSTIFICATION OF BASE

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.

STATUS OF MAJOR PROJECTS

White Oak

The White Oak Consolidation Program continues its coordinated efforts to execute the 2000 Master Plan design to provide a new state of the art facility for the FDA at White Oak.

On December 11, 2003, a dedication ceremony was held for the Life Sciences Laboratory, a state of the art chemistry, bioscience and animal research facility. As the first new building to open on the site, the laboratory provides approximately 124,000 gross square feet, for 120 employees from the Center for Drug Evaluation and Research (CDER) and the Center for Devices and Radiological Health (CDRH).

Construction for the CDER Office Building I began on November 15, 2002, and has progressed on schedule for occupancy in spring 2005. This building provides 560,000 gross square feet of modern office space to accommodate the Office of New Drugs, comprised of approximately 1,700 scientists and support staff. The facility also includes a 60,000 square foot, efficient document storage center, mail room and support space.

Construction of the Central Shared Use Building began in October 2004. When complete this facility will provide employees and visitors with a cafeteria, conference and training center, credit union, fitness center, health unit, central library and R&W store, along with housing the Agency security command center, central data center and NTEU offices. The first phase of this building, including the cafeteria, fitness center and security command center, is scheduled for completion in spring 2006.

The CDRH Engineering/Physics Laboratory construction contract was awarded in January 2005 with construction completion expected in February 2007. This building will provide approximately 128,000 square feet of high tech laboratories engaged in evaluating electromagnetic and medical devices, radiological instruments and consumer appliances generating radiological signals. The facility consists of numerous vibration isolation slabs, electromagnet shielding, an anechoic chamber and laser devices especially dedicated to the program science. This facility is scheduled for occupancy in 2006.

With design to be complete in spring 2005, the approximately 291,000 gross square foot, CDER Office Building II will accommodate the Center Director's office and the balance

of the CDER scientific and support staffs. This is a uniquely designed office building in that the entire building will be equipped with an under-floor ventilation system. This design change provides for more offices benefiting from indirect outside daylight, taller windows, more efficient distribution of air and electrical wiring along with IT/Telecom and security wiring.

Finally, the first phase of the site's parking garages is at the 75% design level with the start of construction planned for 2005. This concrete parking structure will contribute approximately 800 spaces to the overall parking for the campus.

Arkansas Regional Laboratory (ARL)

As a part of FDA's plan to restructure its eighteen field laboratories, ARL is one of five multi-disciplined laboratories and will provide laboratory support for a seventeen statewide area and for the U.S.-Mexican border stretching from Otay Mesa, California to Brownsville, Texas. The ARL provides analytical support in chemistry and microbiology. The ARL scientists are testing products regulated by the FDA to ensure compliance with the FFDCRA, which will include products produced in the U.S. and imported.

Winchester Engineering and Analytical Center:

The Winchester Engineering and Analytical Center (WEAC) located in Winchester, MA, serves as a national resource for evaluation of radiological and other medical devices. WEAC is the only FDA facility that provides specialized engineering and analytical services and radionuclide analysis. This laboratory was constructed in 1952, is in poor condition, and cannot be adequately renovated to meet modern laboratory standards.

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 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.

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