

INFRASTRUCTURE

GSA RENT, OTHER RENT AND WHITE OAK CONSOLIDATION

Introduction

FDA's Infrastructure Program summarizes the budget program requirements that justify a \$266,536,000 request for FY 2008. The Infrastructure program narrative has three sections:

- summary of FDA's program resources, historical funding and FTE levels
- description of program functions of the Infrastructure Program
- description of the program resources changes, base resource activities, program accomplishments.

The Infrastructure Program funding table shows a three year span of program level resources, budget authority resources, and proposed user fees enacted in FY 2006, displayed in the FY 2007 President's Budget and FY 2007 Continuing Resolution and proposed in the FY 2008 budget request.

	FY 2006 Actuals	FY 2007 Continuing Resolution	FY 2007 President's Budget*	FY 2008 President's Budget	Increase or Decrease
Program Level	\$203,612,000	\$199,691,000	\$218,219,000	\$266,536,000	\$48,317,000
<i>GSA Rent</i>	<i>\$133,368,000</i>	<i>\$130,503,000</i>	<i>\$149,212,000</i>	<i>\$159,414,000</i>	<i>10,202,000</i>
<i>Other Rent</i>	<i>\$43,456,000</i>	<i>\$42,400,000</i>	<i>\$43,455,000</i>	<i>\$68,314,000</i>	<i>\$24,768,000</i>
<i>White Oak</i>	<i>\$26,788,000</i>	<i>\$26,788,000</i>	<i>\$25,552,000</i>	<i>\$38,808,000</i>	<i>13,256,000</i>
Budget Authority	\$173,558,000	\$173,558,000	\$187,823,000	\$229,509,000	\$41,686,000
<i>GSA Rent</i>	<i>\$116,403,000</i>	<i>\$116,403,000</i>	<i>\$126,871,000</i>	<i>\$131,533,000</i>	<i>\$4,662,000</i>
<i>Other Rent</i>	<i>\$35,400,000</i>	<i>\$35,400,000</i>	<i>\$35,400,000</i>	<i>\$59,168,000</i>	<i>\$23,768,000</i>
<i>White Oak</i>	<i>\$21,755,000</i>	<i>\$21,755,000</i>	<i>\$25,552,000</i>	<i>\$38,808,000</i>	<i>\$13,256,000</i>
User Fees	\$30,054,000	\$26,133,000	\$30,396,000	\$37,027,000	\$6,631,000
<i>GSA Rent</i>	<i>\$16,965,000</i>	<i>\$14,100,000</i>	<i>\$22,341,000</i>	<i>\$27,881,000</i>	<i>\$5,540,000</i>
<i>PDUFA</i>	<i>\$14,100,000</i>	<i>\$14,100,000</i>	<i>\$17,700,000</i>	<i>\$21,901,000</i>	<i>\$4,201,000</i>
<i>MDUFMA</i>	<i>\$2,237,000</i>	<i>\$0</i>	<i>\$3,270,000</i>	<i>\$3,552,000</i>	<i>\$282,000</i>
<i>ADUFA</i>	<i>\$628,000</i>	<i>\$0</i>	<i>\$1,371,000</i>	<i>\$1,441,000</i>	<i>\$70,000</i>
<i>Proposed Generic Drugs</i>	<i>--</i>	<i>--</i>	<i>--</i>	<i>\$987,000</i>	<i>\$987,000</i>
<i>Other Rent</i>	<i>\$8,056,000</i>	<i>\$7,000,000</i>	<i>\$8,055,000</i>	<i>\$9,146,000</i>	<i>\$1,091,000</i>
<i>PDUFA</i>	<i>\$7,000,000</i>	<i>\$7,000,000</i>	<i>\$7,000,000</i>	<i>\$8,000,000</i>	<i>\$1,000,000</i>
<i>MDUFMA</i>	<i>\$765,000</i>	<i>\$0</i>	<i>\$1,055,000</i>	<i>\$1,146,000</i>	<i>\$91,000</i>
<i>ADUFA</i>	<i>\$291,000</i>	<i>\$0</i>	<i>\$0</i>	<i>\$0</i>	<i>\$0</i>
<i>White Oak</i>	<i>\$5,033,000</i>	<i>\$5,033,000</i>	<i>\$0</i>	<i>\$0</i>	<i>\$0</i>
<i>PDUFA</i>	<i>\$5,033,000</i>	<i>\$5,033,000</i>	<i>\$0</i>	<i>\$0</i>	<i>\$0</i>

* Excludes \$8,188,000 in FY 2007 in PDUFA carryover fees to fund the White Oak Consolidation Project.

The historical funding and FTE levels tables show a five year history of program level funding, budget authority funding, and user fee funding.

Historical Funding and FTE Levels – GSA Rent

Fiscal Year	Program Level	Budget Authority	User Fees
2004 Actuals	\$121,680,000	\$114,354,000	\$7,326,000
2005 Actuals	\$127,617,000	\$113,479,000	\$14,138,000
2006 Actuals	\$133,368,000	\$116,403,000	\$16,965,000
2007 Continuing Resolution	\$130,503,000	\$116,403,000	\$14,100,000
2007 President's Budget	\$149,212,000	\$126,871,000	\$22,341,000
2008 President's Budget	\$159,414,000	\$131,533,000	\$27,881,000

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

Fiscal Year	Program Level	Budget Authority	User Fees
2004 Actuals	\$36,330,000	\$36,043,000	\$287,000
2005 Actuals	\$44,532,000	\$35,758,000	\$8,774,000
2006 Actuals	\$43,456,000	\$35,400,000	\$8,056,000
2007 Continuing Resolution	\$42,400,000	\$35,400,000	\$7,000,000
2007 President's Budget	\$43,455,000	\$35,400,000	\$8,055,000
2008 President's Budget	\$68,314,000	\$59,168,000	\$9,146,000

Historical Funding and FTE Levels – White Oak

Fiscal Year	Program Level	Budget Authority	User Fees
2004 Actuals	\$6,131,000	\$2,361,000	\$3,770,000
2005 Actuals	\$20,846,000	\$17,846,000	\$3,000,000
2006 Actuals	\$26,788,000	\$21,755,000	\$5,033,000
2007 Continuing Resolution	\$26,788,000	\$21,755,000	\$5,033,000
2007 President's Budget	\$25,552,000	\$25,552,000	\$0
2008 President's Budget	\$38,808,000	\$38,808,000	\$0

Statement of the Budget Request

FDA requests \$266,536,000 in program level resources for GSA Rent, Other Rent and Rent-Related Activities, and the headquarters' consolidation to the White Oak campus in FY 2008. This request provides rental payments to GSA for FDA's offices and laboratory facilities, guard services, security systems, and overtime-utility use. This request also provides funding for building preparation, fit-out, and relocation cost to newly constructed buildings for the FDA consolidation at White Oak, Maryland.

Program Description

FDA conducts its mission-critical work through its workforce, which occupies office and laboratory space that is rented from the General Services Administration (GSA). FDA also incurs charges related to guard service, security systems, and related rental costs that are not part of the GSA account. FDA currently occupies over 6.7 million square feet of GSA space, including parking. Approximately two-thirds of the GSA rent charges for government-owned or GSA-leased space are for facilities in the Washington, D.C. area. The largest amounts include charges for the Parklawn complex, Module II in Beltsville, CFSAN's College Park complex, and the newly occupied buildings at the White Oak, Maryland campus. In addition, FDA-occupied space comprises over 250 leases including District Offices, Regional Offices, laboratories, and resident posts across the nation and in Puerto Rico.

The Other Rent and Rent-Related account includes rent and rent-related charges that are not part of the GSA Rent account. These include Commercial Rent and Related Services and GSA Rent-Related Services. These funds are used for operating and maintaining FDA-owned, GSA-owned/FDA-managed, and FDA-leased properties located nationwide. Costs include commercial rent, utilities, operation and maintenance contracts, janitorial and grounds maintenance contracts, and security and guard services contracts.

The White Oak campus will replace existing disparate facilities with new, state-of-the-art laboratories, office buildings and support facilities. While the GSA appropriation will likely fund the design and construction of the new buildings at White Oak, FDA's appropriation will need to fund building fit-out and move costs. There are approximately 1,850 employees onsite at White Oak, and the last phase of the consolidation is currently scheduled for FY 2013. FDA initiated relocation activities in FY 2002 to the consolidated White Oak campus that, when completed, will accommodate more than 7,700 FDA employees and contractors.

Program Resource Changes

Budget Authority

GSA Rent: +\$4,662,000

The request funds the FY 2008 cost increases for GSA Rent. These mandatory costs have increased due to the White Oak campus consolidation and higher costs for services such as utilities and security.

Other Rent and Rent-Related: +\$23,768,000

The request funds an accumulated \$23,768,000 in increases in rent, security and utility costs, all of which are unavoidable items. The costs of Other Rent and Rent-Related Activities increased significantly in FY 2006 due to the new White Oak facility. The costs attributable to the White Oak campus increased because FDA is moving out of leased locations where costs, such as utilities and some security costs, are included in the GSA Rent bills. This funding will prevent FDA from charging unavoidable costs to FDA programs, allowing them instead to fund mission-related activities in food safety, medical product safety, and other high-priority public health activities.

White Oak Consolidation: +\$13,256,000

With the approval of the White Oak Master Plan in 2002, FDA began its relocation to a new campus. When completed, FDA will consolidate more than 7,700 employees located in 20 different locations across the D.C. metropolitan region into new, state-of-the-art facilities. This consolidation will eliminate the fragmentation that limits FDA's performance. This consolidation will yield cost savings and improved efficiencies, and permit FDA to fully leverage a modern work environment to meet the public health challenges of the 21st century. Including amounts budgeted for FY 2007, the total FDA and GSA White Oak investment to date exceeds \$700 million. FDA's base funding and the \$13,256,000 requested increase would allow FDA to prepare the CDRH Office Building for occupancy.

User Fees

Current Law User Fees

Prescription Drug User Fee Act: +\$5,201,000

In FY 2007, PDUFA collections included a one time increase of \$31,600,000 for the final year adjustment under the PDUFA III statute. In allocating this one time increase among the programs, FDA included estimates for the Rent Program based on FY 2006 actuals. For FY 2008, the Rent Program estimates include increases for inflation. Because FDA has not completed the public comment period regarding FDA's proposed recommendations for PDUFA reauthorization, the FY 2008 PDUFA estimate is based on straight reauthorization of PDUFA III with no programmatic enhancements or adjustments.

In the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Congress renewed FDA's authority to collect PDUFA user fees. This authority is effective for five years and directs FDA to strengthen and improve the process for the review of human drugs and to improve risk management for drugs approved under PDUFA. The authority to collect fees under PDUFA expires on September 30, 2007.

Proposals to reauthorize PDUFA are currently under discussion. The PDUFA user fee is expected to bring in \$339,195,000 in collections for FY 2008, with the Rent Program increase being \$5,201,000 for a total of \$29,901,000. These FY 2008 amounts assume that the current authorities in effect for PDUFA III continue in FY 2008. FDA may need to amend its budget request when Congress reauthorizes PDUFA IV and establishes new performance goals and fee levels.

PDUFA user fees help the Rent Program provide office space, utilities, and guard services to employees and contractors who support the user fee process.

Medical Devices User Fee and Modernization Act: +\$373,000

Enacted in 2002, MDUFMA improves the quality and timeliness of the medical device review. It authorizes FDA to collect user fees to supplement appropriations for the medical device review program. FDA collects fees from device manufacturers that submit premarket applications and premarket notifications. The authority to collect fees under MDUFMA expires on September 30, 2007.

Proposals to reauthorize MDUFMA are currently under discussion. The MDUFMA user fee is expected to bring in \$47,500,000 in collections, with the Rent Program increase being \$373,000, for a total of \$4,698,000. These FY 2008 amounts assume that the current authorities in effect for MDUFMA continue in FY 2008. FDA may need to amend its budget request when Congress reauthorizes MDUFMA and establishes new performance goals and fee levels.

MDUFMA user fees help the Rent Program provide office space, utilities and guard services to employees and contractors who support the user fee process.

Animal Drug User Fee Act: + \$70,000

Enacted in November 2003, 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 receive FDA approval are safe and effective, and are readily available for both companion animals and animals intended for food consumption. ADUFA will help provide a cost-efficient, high quality animal drug review process that is predictable and performance driven. The GSA Rent portion of the ADUFA increase is \$70,000, for a total of \$1,441,000.

ADUFA user fees help Rent Activities to provide office space, utilities and guard services to employees and contractors who support the user fee process.

Proposed User Fees

Generic Drugs: +\$987,000

Applications to market generic drugs, Abbreviated New Drug Applications (ANDAs), are critical to lowering federal spending on pharmaceuticals. Since 2002, the number of ANDAs has more than doubled.

This proposal is to modify the Food, Drug, and Cosmetic Act to establish user fees for each new application and annually for approved generic products. The additional resources generated by the proposed generic drug user fees would allow FDA to reduce the time to conduct reviews of ANDAs and respond to the growing number of generic drug applications. The GSA Rent and Rent-Related amounts associated with this user fee is \$987,000.

Justification of Base

GSA Rent

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. The Agency currently occupies 6.7 million square feet of GSA space, including parking. Approximately two-thirds of the GSA rent charges for government-owned or GSA-leased space are for facilities in the Washington, D.C. area. The largest amounts include charges for the Parklawn complex, Module II in Beltsville, CFSAN's College Park complex, and the newly occupied buildings at the White Oak, Maryland campus. In addition, FDA-occupied space comprises approximately 250 leased offices, including District Offices, Regional Offices, laboratories, and resident posts that are strategically placed across the nation and in Puerto Rico.

Other Rent and Rent-Related Activities

Other Rent and Rent-Related activities are conducted in two areas:

- *Commercial Rent and Related Services:* These are 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:* These are recurring reimbursable services provided by GSA that are over and above the standard ten hour period that GSA covers in its rent charges. Services include security systems, guard services, and HVAC (Heating, Ventilating, and Air Conditioning Control) beyond the standard level funded by GSA. Additionally, recurring services and one-time repairs to operate and maintain buildings delegated to FDA by GSA for management of day-to-day operations are included. These services include utilities and all recurring services for building operation, such as janitorial, guard, grounds maintenance, and operation and maintenance of HVAC systems.

White Oak Consolidation Project

The White Oak Consolidation Program continues its coordinated efforts to execute the 2006 Updated Master Plan design and provide a new state of the art campus for the FDA at White Oak. The campus will replace existing fragmented facilities with new, state-of-the art laboratories, office buildings and support facilities. To date, there are 1,850 employees onsite at White Oak, and the final phase of the consolidation is currently scheduled for FY 2013.

Base funds will provide funding for the installation of information technology equipment and cabling at the CSU II, CDRH and OC/ORR office buildings, and provide security for the North and Southwest parking structures. However, if FDA cannot relocate the CDRH, OC and ORR employees to White Oak, the agency will be faced with additional GSA rental costs that exceed \$13 million between FY 2008 and FY 2009.

Selected FY 2006 Accomplishments

GSA Rent Activities

FDA is continually striving to improve its business practices. This will help ensure a world class professional workforce, effective and efficient operations and adequate resources to accomplish the mission. In the course of the day-to-day activities conducted in the performance of GSA Rent-related responsibilities, there were accomplishments worth noting. The list below is representational and not comprehensive:

- negotiated with GSA to delay rent start for the White Oak Central Shared Use Building 1 until October 1, 2006. This saved FDA approximately \$300,000 in FY 2006
- consolidated ORA field activities in Northern Virginia from two locations to one, saving FDA \$43,000 annually in rent costs
- terminated leases on schedule at 1451 Rockville Pike and 9201 Corporate as employees were relocated to White Oak, with minimal double-rent payments incurred (leases totaled \$5.8 million annually in rent)
- worked with ORA to close ten field locations and terminated those leases. This saved FDA over \$293,000 annually in rent costs
- relocated activities from the Park Building to space vacated in the Parklawn Building to permit GSA to terminate the Park Building lease
- in addition to vacating 49,000 RSF in the Park Building, FDA relinquished 69,800 RSF in the Parklawn Building, thus saving just under \$1 million in annual rent costs
- relocated one ORA District Office and three ORA Resident Posts due to lease expirations; in addition, FDA negotiated with GSA and the lessor to reduce the size of one Resident Post, resulting in an annual rent savings of \$100,000
- negotiated with GSA for a rent credit for space rendered unusable due to flooding at the Wiley Building. Through the end of FY06, \$345,346 has been credited to FDA
- acquired temporary expansion space at 7519 Standish Place and completed build out of CVM document control unit and CDER office space and conference facility

- acquired two locations for new OCI field offices: in Philadelphia and in Providence
- acquired additional temporary emergency replacement space in Mandeville, and Metairie, LA, and in Nashville to accommodate ORA District Office staff evacuated from New Orleans following Hurricane Katrina
- worked with ORA, GSA, and the lessor to relocate undamaged equipment and furnishing to the replacement space and to dispose of unusable equipment and furnishings
- recouped \$2.9 million in FY06 by catching GSA and DHS errors, over-billings, and double-billings in their monthly rent bills
- completed decommissioning and terminated licenses at 12709 Twinbrook Parkway in order to terminate the lease upon its expiration on December 31, 2005.

Rent and Rent-Related Activities

In the course of the day-to-day activities conducted in the performance of Rent-Related responsibilities, there were accomplishments worth noting. The list below is representational and not comprehensive:

- instituted an Energy Saving Program in FDA, communicating to managers new ways of saving costs in gas, electric, and water consumption (included conducting the first FDA Earth Day program, focusing on environmental and energy savings in FDA-owned and GSA-owned/FDA-operated facilities)
- Assumed responsibility for three new buildings at the White Oak Campus (Building 21, Building 22 and the Central Shared Used (CSU) Building).

White Oak Consolidation Project

In the course of the day-to-day activities conducted in the performance of White Oak Consolidation Project-related responsibilities, there were accomplishments worth noting. The list below is representational and not comprehensive.

The LABQUEST coalition was established to support community planning and redevelopment of the White Oak site after the BRAC Commission announced the closure of the Federal Research Center (FRC) at White Oak in 1994:

- attending monthly meetings that bring together the local community, members of the Maryland Delegations, local business representatives, NTEU representatives, and FDA and GSA employees

- discussing the relocation of the FDA to the FRC; the necessary transportation; housing; and, amenities to accommodate FDA's employees, scientists, vendors and visitors to the area.

The White Oak Consolidation Program continues its coordinated efforts to execute the 2006 Updated Master Plan design to provide a new state of the art facility for the FDA at White Oak.

- completed construction of the North Garage
- completed the Central Shared Use Facility; this facility contains a cafeteria, conference and training center, credit union, fitness center, health unit, central biosciences library, Agency security command center, central data center and NTEU offices
- commenced construction of the CDER Office II Building in February 2006; provides approximately 298,000 gross square feet of office space and is scheduled for occupancy in Spring 2008, and will accommodate the Center Director's office and the balance of the CDER scientific and support staffs
- commenced construction of the CDRH Office Building on November 1, 2006; provides approximately 394,000 gross square feet of office space and is scheduled for occupancy in Spring 2009.