

INFRASTRUCTURE – GSA RENT, OTHER RENT, AND WHITE OAK

(Dollars in Thousands)	FY 2016 Final	FY 2016 Actuals	FY 2017 Annualized CR	FY 2018	
				President's Budget	President's Budget +/- FY 2017 CR
FDA White Oak Consolidation	52,346	48,944	51,765	56,882	5,117
<i>Budget Authority</i>	<i>48,044</i>	<i>48,044</i>	<i>47,953</i>	<i>12,561</i>	<i>-35,392</i>
<i>User Fees</i>	<i>4,302</i>	<i>900</i>	<i>3,812</i>	<i>44,321</i>	<i>40,509</i>
<i>Prescription Drug (PDUFA)</i>	<i>4,302</i>	<i>900</i>	<i>3,812</i>	<i>25,548</i>	<i>21,736</i>
<i>Medical Device (MDUFA)</i>				<i>8,072</i>	<i>8,072</i>
<i>Generic Drug (GDUFA)</i>				<i>5,571</i>	<i>5,571</i>
<i>Biosimilars (BsUFA)</i>				<i>662</i>	<i>662</i>
<i>Animal Drug (ADUFA)</i>				<i>80</i>	<i>80</i>
<i>Animal Generic Drug (AGDUFA)</i>				<i>17</i>	<i>17</i>
<i>Family Smoking Prevention and Tobacco Control Act...</i>				<i>4,371</i>	<i>4,371</i>
Other Rent and Rent Related	119,560	119,059	115,794	132,894	17,100
<i>Budget Authority</i>	<i>73,484</i>	<i>73,484</i>	<i>73,344</i>	<i>59,889</i>	<i>-13,455</i>
<i>User Fees</i>	<i>46,076</i>	<i>45,575</i>	<i>42,449</i>	<i>73,005</i>	<i>30,556</i>
<i>Prescription Drug (PDUFA)</i>	<i>29,724</i>	<i>26,302</i>	<i>26,340</i>	<i>34,848</i>	<i>8,508</i>
<i>Medical Device (MDUFA)</i>	<i>4,558</i>	<i>5,158</i>	<i>4,174</i>	<i>12,679</i>	<i>8,505</i>
<i>Generic Drug (GDUFA)</i>	<i>6,862</i>	<i>6,862</i>	<i>6,962</i>	<i>17,702</i>	<i>10,740</i>
<i>Biosimilars (BsUFA)</i>	<i>617</i>	<i>617</i>	<i>633</i>	<i>1,203</i>	<i>570</i>
<i>Animal Drug (ADUFA)</i>	<i>228</i>	<i>228</i>	<i>236</i>	<i>2,101</i>	<i>1,865</i>
<i>Animal Generic Drug (AGDUFA)</i>	<i>97</i>	<i>97</i>	<i>113</i>	<i>252</i>	<i>139</i>
<i>Family Smoking Prevention and Tobacco Control Act...</i>	<i>3,502</i>	<i>6,311</i>	<i>3,495</i>	<i>3,724</i>	<i>229</i>
<i>Food and Feed Recall</i>	<i>43</i>	<i>---</i>	<i>43</i>	<i>43</i>	<i>---</i>
<i>Food Reinspection</i>	<i>204</i>	<i>---</i>	<i>204</i>	<i>204</i>	<i>---</i>
<i>Voluntary Qualified Importer Program</i>	<i>170</i>	<i>---</i>	<i>170</i>	<i>170</i>	<i>---</i>
<i>Third Party Auditor Program</i>	<i>45</i>	<i>---</i>	<i>45</i>	<i>45</i>	<i>---</i>
<i>Outsourcing Facility</i>	<i>26</i>	<i>---</i>	<i>34</i>	<i>34</i>	<i>---</i>
GSA Rental Payments	224,105	220,122	235,570	249,783	14,213
<i>Budget Authority</i>	<i>161,683</i>	<i>161,683</i>	<i>176,347</i>	<i>128,490</i>	<i>-47,857</i>
<i>User Fees</i>	<i>62,422</i>	<i>58,439</i>	<i>59,223</i>	<i>121,293</i>	<i>62,070</i>
<i>Prescription Drug (PDUFA)</i>	<i>25,512</i>	<i>25,512</i>	<i>22,607</i>	<i>53,640</i>	<i>31,033</i>
<i>Medical Device (MDUFA)</i>	<i>7,978</i>	<i>7,978</i>	<i>7,306</i>	<i>25,591</i>	<i>18,285</i>
<i>Generic Drug (GDUFA)</i>	<i>14,705</i>	<i>14,705</i>	<i>14,920</i>	<i>20,213</i>	<i>5,293</i>
<i>Biosimilars (BsUFA)</i>	<i>1,080</i>	<i>---</i>	<i>1,107</i>	<i>3,076</i>	<i>1,969</i>
<i>Animal Drug (ADUFA)</i>	<i>1,141</i>	<i>1,141</i>	<i>1,184</i>	<i>3,156</i>	<i>1,972</i>
<i>Animal Generic Drug (AGDUFA)</i>	<i>583</i>	<i>583</i>	<i>681</i>	<i>1,327</i>	<i>646</i>
<i>Family Smoking Prevention and Tobacco Control Act...</i>	<i>10,592</i>	<i>8,520</i>	<i>10,572</i>	<i>13,444</i>	<i>2,872</i>
<i>Food and Feed Recall</i>	<i>73</i>	<i>---</i>	<i>73</i>	<i>73</i>	<i>---</i>
<i>Food Reinspection</i>	<i>348</i>	<i>---</i>	<i>348</i>	<i>348</i>	<i>---</i>
<i>Voluntary Qualified Importer Program</i>	<i>290</i>	<i>---</i>	<i>290</i>	<i>290</i>	<i>---</i>
<i>Third Party Auditor Program</i>	<i>77</i>	<i>---</i>	<i>77</i>	<i>77</i>	<i>---</i>
<i>Outsourcing Facility</i>	<i>43</i>	<i>---</i>	<i>58</i>	<i>58</i>	<i>---</i>

Authorizing Legislation: The Federal Food Drug and Cosmetic Act (21 U.S.C. 321-399); Radiation Control for Health and Safety Act (21 U.S.C. 360hh-360ss); The Federal Import Milk Act (21 U.S.C. 142-149); Public Health Service Act (42 U.S.C. 201, et seq.); Foods Additives Amendments of 1958; Color Additives Amendments of 1960; Animal Drug Amendments (21 U.S.C. 360b); Controlled Substances Act (21 U.S.C. 801-830); The Fair Packaging and Labeling Act (15 U.S.C. 1451-1461); Safe Drinking Water Act (21 U.S.C. 349); Saccharin Study and Labeling Act; Federal Anti-Tampering Act (18 U.S.C. 1365); Medical Device Amendments of 1976; Infant Formula Act of 1980; Drug Enforcement, Education, and Control Act of 1986; Generic Animal Drug and Patent Term Restoration Act; Prescription Drug Marketing Act of 1987; Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. 201); Nutrition Labeling and Education Act of 1990; Prescription Drug Amendments of 1992; Safe Medical Device Amendments of 1992; Dietary Supplement Health and Education Act of 1994; Animal Medicinal Drug Use Clarification Act of 1994; Animal Drug Availability Act of 1996; Food Quality Protection Act of 1996; Federal Tea Tasters Repeal Act (42 U.S.C. 41); Safe Drinking Water Act Amendments of 1996 (21 U.S.C. 349); Food and Drug Administration Modernization Act of 1997; Antimicrobial Regulation Technical Corrections Act of 1998; Medical Device User Fee and Modernization Act of 2002; Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Animal Drug User Fee Act of

2003 (21 U.S.C. 379j-11 - 379j-12); Project Bioshield Act of 2004 (21 U.S.C.360bbb-3); Minor Use and Minor Species Animal Health Act of 2004; Food Allergy Labeling and Consumer Protection Act of 2004 Medical Device User Fee Stabilization Act of 2005; Sanitary Food Transportation Act of 2005 Dietary Supplement and Nonprescription Drug and Consumer Protection Act (21 U.S.C. 379aa-1); Food and Drug Administration Amendments Act of 2007; The Family Smoking Prevention and Tobacco Control Act of 2009 (P.L. 111-31); Protecting Patients and Affordable Care Act of 2010; The Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333); FDA Food Safety Modernization Act, Public Law 111-353 (January 4, 2011); The Food and Drug Administration Safety and Innovation Act (P.L. 112-144); and the Drug Quality and Security Act (2013)

Allocation Methods: Direct Federal/Intramural

PROGRAM DESCRIPTION AND ACCOMPLISHMENTS

The Infrastructure Program supports FDA’s mission of protecting the public health by providing secure and cost-effective office and laboratory space to perform mission-critical work. The Infrastructure Program consists of:

- General Services Administration (GSA) Rental Payments
- Other Rent and Rent Related Activities
- White Oak.

The Infrastructure Program ensures that FDA’s offices and labs across the country and its fully integrated headquarters Campus in White Oak, Maryland, are functioning to enable FDA to carry out its mission and respond to food safety and medical product emergencies. Investing in FDA’s facility priorities provides the infrastructure and scientific capabilities necessary to ensure FDA can achieve the regulatory responsibilities, strategic priorities, and program initiatives outlined in this document. Programmatic funds may also support improvements critical to FDA’s mission.

As FDA strategically manages its infrastructure, it focuses on creating high-quality work environments, optimizing the use of taxpayer dollars, enhancing productivity, and ensuring efficient operations to protect the public’s health. For example, FDA ensures that the appropriate information regarding the space required to support its escalating responsibilities is communicated to the Department in the FDA Five-Year Timeline for inclusion in the “Reduce the Footprint” Plan that HHS submits to the Office of Management and Budget.

FDA also promotes maximum utilization of Federal workspace. FDA’s energy saving projects decreased long-term energy usage and operating and maintenance costs while increasing facility life span and efficiency to support Executive Order 13514 – Federal Leadership in Environmental, Energy, and Economic Performance.

As another example, FDA replaced and centralized existing geographically disparate facilities with new, state-of-the-art laboratories, office buildings, and support facilities as part of the White Oak Campus consolidation. FDA is working with GSA to develop a housing strategy and migration plan for FDA headquarters functions and will consider using Federal space near the Campus, to complete FDA’s geographic consolidation, including FDA-owned and GSA-owned locations, as well as leasing space in close proximity to the Campus. In addition, a new master plan will be developed for the Federal Research Center and necessary updates will be made to the Muirkirk Road Complex master plan in order to finalize the housing strategy and ensure that environmental impacts have been considered.

GSA Rental Payments

The GSA Rental Payments account includes rental payments for FDA's GSA-managed office and laboratory facilities. FDA occupies almost seven million rentable square feet of GSA-owned and GSA-leased office, laboratory, and warehouse space. More than 60 percent of the GSA rent charges for GSA-owned or GSA-leased space are for facilities in the Washington, D.C. area. FDA occupies GSA space in approximately 270 buildings, including district offices, regional offices, laboratories, resident posts, and border stations across the nation and in Puerto Rico and the Virgin Islands.

The GSA Rental Payments account ensures that the FDA workforce has the space necessary to carry out FDA's public health mission.

During FY 2016, FDA:

- vacated one office building in Rockville, MD, as part of a headquarters lease consolidation
- completed decommissioning and released space for a relocated CDER lab in St. Louis, MO
- vacated two ORA resident posts
- relocated one ORA resident post.

In FY 2017, FDA plans to:

- receive Congressional approval for the relocation of the ORA laboratory in Atlanta, GA
- coordinate design and construction for the relocation of ORA laboratories near Kansas City, KS and San Francisco, CA
- relocate three ORA resident posts and two OCI field locations
- vacate one office building in Rockville, MD as part of a headquarters lease consolidation
- lease office space close to White Oak Campus for office headquarters functions that cannot be accommodated on Campus until additional Federal construction is funded.

FDA strives to be cost effective and energy efficient when it acquires the space required to meet its mission in accordance with nationally recognized standards.

Other Rent and Rent Related Activities

The Other Rent and Rent Related Activities account includes commercial rent and rent related charges that are not part of the GSA Rental account. These funds cover costs for operating and maintaining FDA and GSA facilities located nationwide. Costs include:

- commercial rent
- operation and maintenance contracts
- janitorial and grounds maintenance contracts
- above standard security and guard services contracts
- standard utilities in FDA owned facilities
- essential overtime utilities in laboratories and data centers
- other above-standard level services not provided by GSA in GSA-managed facilities.

This account ensures that FDA's offices and labs are functional and supports the FDA workforce in meeting its public health mission by providing safe, efficient, and secure facilities.

Additionally, FDA is implementing energy efficiencies that will result in significant savings in the Other Rent and Rent Related Activities account. These projects support:

- Executive Order 13693, Planning for Federal Sustainability in the Next Decade
- HHS' Efficient Energy Management Assessments
- Energy Policy Act of 2005
- HHS Sustainable and High Performance Buildings Policy
- HHS Sustainable Buildings Plan
- 2006 Federal Leadership in High Performance and Sustainable Buildings Memorandum of Understanding
- Energy Independence and Security Act of 2007.

For the White Oak Campus, GSA entered into Energy Savings Performance Contracts (ESPCs) with Honeywell Corporation to build a Central Utility Plant (CUP), provide utilities, and perform operations and maintenance activities in a phased approach consistent with the construction and occupancy of the Campus. FDA entered into a memorandum of understanding with GSA and committed to a long-term occupancy of the Campus, including an agreement to pay a share of the costs associated with the ESPCs. Under this agreement, FDA's share of these costs is less than they would be otherwise due to the energy saving features provided by the ESPC.

When each ESPC phase begins to provide benefits to the Campus, including utilities to FDA-occupied buildings, FDA is required to pay the agreed-upon share. The most recent example is GSA's "ESPC III," which covers the expansion of the CUP. The CUP expansion provides the utilities needed to occupy and operate the new Life Sciences – Biodefense Laboratory Complex (LSBC).

FDA awarded a fourth Utility Energy Service Contract (UESC) with Washington Gas at the Muirkirk Road Campus with a capital investment of \$2,921,064 and utility cost savings of approximately \$313,700 annually at a simple payback of 9.31 years. Construction is underway.

The UESC for the FDA owned site in Irvine, California, with Southern California Edison Electric Power Company, with a capital investment of \$2,570,000 and cost savings of about \$254,741 per year with a simple payback of 10.1 years is complete, energy conservation measures are operational, and savings are underway.

FDA awarded a second UESC contract with California Southern Edison Electric Power Company at Irvine with a capital investment of \$5,287,314, utility cost savings of approximately \$351,150 annually, and a simple payback of 15 years. Construction is underway.

FDA has also begun an investment grade audit for our facilities at the Muirkirk Road Campus and in Dauphin Island, Alabama. We anticipate these studies will result in implementation of energy efficiency projects.

GSA is performing audits in FDA-occupied leased facilities, such as the Queens, New York lab. UESCs in GSA-leased buildings will provide energy savings if implemented.

Awarding additional UESCs and procuring renewable energy will contribute to HHS sustainability goals established in the HHS Strategic Sustainability Plan developed in accordance with Executive Order 13514, Federal Leadership in Environmental, Energy, and Economic Performance. FDA's activities related to UESCs and renewable energy will help reduce greenhouse gas emissions.

White Oak

Congress' intent for geographically consolidating the majority of FDA Headquarters on the White Oak Campus was to speed operational excellence and ensure a scientifically stronger FDA. Toward that goal, the White Oak Campus replaced and centralized existing geographically disparate facilities with new, state-of-the-art laboratories, office buildings, and support facilities into one location. While the GSA appropriation funds the design and construction of the new buildings at White Oak, FDA's budget authority and various user fees fund building infrastructure, fit-out, specialized equipment, move costs, and operations and logistics at the Campus.

White Oak funding supports campus operations and requirements including:

- relocation activities, including surplus of furniture and equipment, and decommissioning of FDA vacated laboratories
- FDA information technology and security infrastructure, equipment, cabling and audiovisual
- commissioning and certification of the specialized laboratories
- support services, including conference center management and labor and loading dock services, and operations and maintenance services, including maintenance of vital specialized laboratory equipment
- transportation services, including parking management and a campus shuttle and circulator bus program
- a centralized safety program to support expanded lab operations and Campus occupancy.

FDA initiated relocation activities to White Oak in FY 2002. The total number of employees currently assigned to the White Oak Campus is approximately 9,000 as a result of completing the occupancy of the Biodefense Laboratory Complex (two office and two lab buildings) in FY 2014.

FDA provided funding to GSA to develop an FDA Headquarters housing strategy and migration plan as well as develop a new master plan for the Federal Research Center. This planning will include possible options to house staff at FDA's other two Headquarters consolidated locations – the Muirkirk Road Complex in Laurel, Maryland and FDA's College Park, Maryland facilities. FDA also completed new projects in support of commissioning and certification of the laboratories and other critical facilities on Campus, which are considered above standard by GSA guidelines.

In FY 2017, in addition to funding Campus operations, FDA will initiate above GSA standard repair and improvement projects in support of our program requirements.

FUNDING HISTORY – GSA RENTAL PAYMENTS

Fiscal Year	Program Level	Budget Authority	User Fees
FY 2014 Actual	\$209,372,000	\$162,076,000	\$47,296,000
FY 2015 Actual	\$219,966,000	\$168,882,000	\$51,084,000
FY 2016 Actuals	\$220,122,000	\$161,683,000	\$58,439,000
FY 2017 Annualized CR	\$235,570,000	\$176,347,000	\$59,223,000
FY 2018 President's Budget	\$249,783,000	\$128,490,000	\$121,293,000

FUNDING HISTORY - OTHER RENT AND RENT RELATED ACTIVITIES

Fiscal Year	Program Level	Budget Authority	User Fees
FY 2014 Actual	\$109,416,000	\$74,674,000	\$34,742,000
FY 2015 Actual	\$115,424,000	\$72,943,000	\$42,481,000
FY 2016 Actuals	\$119,059,000	\$73,484,000	\$45,575,000
FY 2017 Annualized CR	\$115,794,000	\$73,344,000	\$42,450,000
FY 2018 President's Budget	\$132,894,000	\$59,889,000	\$73,005,000

FUNDING HISTORY - WHITE OAK

Fiscal Year	Program Level	Budget Authority	User Fees
FY 2014 Actual	\$61,603,000	\$58,044,000	\$3,559,000
FY 2015 Actual	\$46,687,000	\$43,044,000	\$3,643,000
FY 2016 Actuals	\$48,944,000	\$48,044,000	\$900,000
FY 2017 Annualized CR	\$51,765,000	\$47,953,000	\$3,812,000
FY 2018 President's Budget	\$56,882,000	\$12,561,000	\$44,321,000

BUDGET REQUEST

The FY 2018 Total Budget with Adjustments is \$439,559,000, of which \$200,940,000 is budget authority and \$238,619,000 is user fees. This level provides a net increase of 36,431,000.

Budget authority decreases by \$96,704,000 compared to the FY 2017 Annualized CR level and user fees increase by \$133,135,000. The request will cover rent increases the agency anticipates in FY 2018 that are related to market changes, including new Occupancy Agreements replacing those expiring for 37 buildings that will cause rental rates to reset to market rates. In addition, FDA will also occupy expansion space in an existing GSA-leased building and two new GSA-leased buildings in FY 2018 to address user fee growth. The increase in OR&RR is needed to meet cost escalations associated with operations and maintenance contracts, utilities and Energy Savings Performance Contract payments for its owned and leased buildings nationwide. In addition, the OR&RR increase is also needed to address more demands for repairs and non-

standard maintenance requests as FDA's owned buildings continue to age and equipment and systems failures occur. Operating costs at the White Oak Campus continue to increase with inflation, and due to the fact that several of the buildings on Campus are 10 or more years old. Additional funding is needed to address ongoing above GSA standard repairs and improvements and meet program needs.

The Infrastructure Program ensures that FDA's offices and labs across the country and its fully integrated headquarters Campus are optimally functioning to enable FDA to carry out its mission and respond to food safety and medical product emergencies. Further, it supports:

- FDA's mission of protecting the public health by providing secure and cost-effective office and laboratory space to perform mission-critical work
- FDA's Strategic Goal to Strengthen Organizational Excellence and the FDA Strategic Priority of Stewardship
- enhanced productivity and capabilities needed to achieve FDA's expanding public health mission.

Proposed Appropriations Language Changes to Rent Cost

The FY 2018 President's Budget proposes striking the "not to exceed" (NTE) language from FDA's appropriation language for rent costs. A large majority of FDA's owned buildings, including laboratories, were transferred to FDA from other federal agencies and these buildings as well as the associated site infrastructure were constructed between 30 to 60 years ago. Many of the buildings, including critical research and regulatory laboratories, are aged and the building systems, finishes, and layouts are past their useful life, creating unsafe and unhealthy work environments, which in turn compromises FDA's ability to meet scientific needs. Historically funding for necessary major improvements for site infrastructure and building systems and equipment has been very limited and below the amount needed to even sustain the current poor condition. Accordingly, operations and maintenance costs are continuing to increase as more equipment and systems fail and more maintenance is needed to keep buildings operational. Major equipment failures could occur and the current "not to exceed" restriction severely limits FDA's ability to address these needs as well as other increased maintenance costs to ensure FDA's mission critical facilities remain operational. Without this flexibility, equipment and system failures will likely result in closing these critical buildings, which will have an immediate and significant impact on the FDA mission and the public health.

GSA Rental Payments

The FY 2018 Budget request for GSA Rental Payments is \$249,783,000, of which \$128,490,000 is budget authority and \$121,293,000 is user fees. The budget authority decreases by \$47,857,000 compared to the FY 2017 Continuing Resolution level and user fees increase by \$62,070,000.

The GSA-managed properties that provide office and laboratory space for FDA employees are essential facilities. The FY 2018 Budget Request for GSA Rental Payments covers the cost of rental payments to GSA for FDA's almost seven million square feet of GSA-managed office and laboratory space.

Other Rent and Rent Related

The FY 2018 Budget request for Other Rent and Rent Related is \$132,894,000, of which \$59,889,000 is budget authority and \$73,005,000 is user fees. The budget authority decreases by

\$13,455,000 compared to the FY 2017 Continuing Resolution level and user fees increase by \$30,556,000.

The FY 2018 Budget will allow FDA to operate, maintain, and secure its facilities in an appropriate and sustainable manner to support over 16,000 staff members.

White Oak

The FY 2018 Budget request for White Oak consolidation and operations activities is \$56,882,000, of which \$12,561,000 is budget authority and \$44,321,000 is user fees. The budget authority decreases by \$35,392,000 compared to the FY 2017 Continuing Resolution level and user fees increase by \$40,509,000.

The FY 2018 Budget provides the necessary resources for ongoing above GSA standard repairs and improvements, and mission support services for the almost 9,000 employees occupying the White Oak Campus on a daily basis. The FY 2018 Budget request will fund support services, transportation services, labor, and loading dock services, and a centralized safety program.