

INFRASTRUCTURE – GSA RENT, OTHER RENT, AND WHITE OAK

(Dollars in Thousands)	FY 2015 Final	FY 2015 Actuals	FY 2016 Enacted	FY 2017	
				President's Budget	+/- FY 2016
FDA White Oak Consolidation	47,116	46,687	52,346	47,461	-4,885
<i>Budget Authority</i>	<i>43,044</i>	<i>43,044</i>	<i>48,044</i>	<i>43,044</i>	<i>-5,000</i>
<i>Prescription Drug (PDUFA)</i>	<i>4,072</i>	<i>3,643</i>	<i>4,302</i>	<i>4,417</i>	<i>115</i>
Other Rent and Rent Related	116,406	115,424	119,560	123,928	4,368
<i>Budget Authority</i>	<i>72,943</i>	<i>72,943</i>	<i>73,484</i>	<i>71,943</i>	<i>-1,541</i>
<i>User Fees</i>	<i>43,463</i>	<i>42,481</i>	<i>46,076</i>	<i>51,985</i>	<i>5,909</i>
<i>Prescription Drug (PDUFA)</i>	<i>28,134</i>	<i>21,729</i>	<i>29,724</i>	<i>30,519</i>	<i>795</i>
<i>Medical Device (MDUFA)</i>	<i>4,027</i>	<i>4,354</i>	<i>4,558</i>	<i>4,425</i>	<i>-133</i>
<i>Generic Drug (GDUFA)</i>	<i>6,730</i>	<i>10,077</i>	<i>6,862</i>	<i>6,988</i>	<i>126</i>
<i>Biosimilars (BsUFA)</i>	<i>602</i>	<i>67</i>	<i>617</i>	<i>632</i>	<i>15</i>
<i>Animal Drug (ADUFA)</i>	<i>225</i>	<i>737</i>	<i>228</i>	<i>230</i>	<i>2</i>
<i>Animal Generic Drug (AGDUFA)</i>	<i>69</i>	<i>145</i>	<i>97</i>	<i>104</i>	<i>7</i>
<i>Family Smoking Prevention and Tobacco Control Act</i>	<i>3,233</i>	<i>5,372</i>	<i>3,502</i>	<i>6,250</i>	<i>2,748</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>---</i>	<i>---</i>	<i>45</i>	<i>45</i>	<i>---</i>
<i>Outsourcing Facility</i>	<i>26</i>	<i>---</i>	<i>26</i>	<i>26</i>	<i>---</i>
<i>Food Facility Registration and Inspection</i>	<i>---</i>	<i>---</i>	<i>---</i>	<i>843</i>	<i>843</i>
<i>Food Import</i>	<i>---</i>	<i>---</i>	<i>---</i>	<i>702</i>	<i>702</i>
<i>International Courier</i>	<i>---</i>	<i>---</i>	<i>---</i>	<i>192</i>	<i>192</i>
<i>Cosmetics</i>	<i>---</i>	<i>---</i>	<i>---</i>	<i>545</i>	<i>545</i>
<i>Food Contact Substance Notification</i>	<i>---</i>	<i>---</i>	<i>---</i>	<i>67</i>	<i>67</i>
GSA Rental Payments	228,428	219,966	239,105	240,205	1,100
<i>Budget Authority</i>	<i>168,882</i>	<i>168,882</i>	<i>176,683</i>	<i>170,208</i>	<i>-6,475</i>
<i>User Fees</i>	<i>59,546</i>	<i>51,084</i>	<i>62,422</i>	<i>69,997</i>	<i>7,575</i>
<i>Prescription Drug (PDUFA)</i>	<i>24,147</i>	<i>27,390</i>	<i>25,512</i>	<i>26,194</i>	<i>682</i>
<i>Medical Device (MDUFA)</i>	<i>7,058</i>	<i>1,280</i>	<i>7,978</i>	<i>7,743</i>	<i>-235</i>
<i>Generic Drug (GDUFA)</i>	<i>14,421</i>	<i>13,179</i>	<i>14,705</i>	<i>14,974</i>	<i>269</i>
<i>Biosimilars (BsUFA)</i>	<i>1,054</i>	<i>117</i>	<i>1,080</i>	<i>1,107</i>	<i>27</i>
<i>Animal Drug (ADUFA)</i>	<i>1,123</i>	<i>477</i>	<i>1,141</i>	<i>1,149</i>	<i>8</i>
<i>Animal Generic Drug (AGDUFA)</i>	<i>417</i>	<i>159</i>	<i>583</i>	<i>622</i>	<i>39</i>
<i>Family Smoking Prevention and Tobacco Control Act</i>	<i>10,572</i>	<i>8,482</i>	<i>10,592</i>	<i>13,280</i>	<i>2,688</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>---</i>	<i>---</i>	<i>77</i>	<i>77</i>	<i>---</i>
<i>Outsourcing Facility</i>	<i>43</i>	<i>---</i>	<i>43</i>	<i>43</i>	<i>---</i>
<i>Food Facility Registration and Inspection</i>	<i>---</i>	<i>---</i>	<i>---</i>	<i>1,495</i>	<i>1,495</i>
<i>Food Import</i>	<i>---</i>	<i>---</i>	<i>---</i>	<i>1,197</i>	<i>1,197</i>
<i>International Courier</i>	<i>---</i>	<i>---</i>	<i>---</i>	<i>332</i>	<i>332</i>
<i>Cosmetics</i>	<i>---</i>	<i>---</i>	<i>---</i>	<i>955</i>	<i>955</i>
<i>Food Contact Substance Notification</i>	<i>---</i>	<i>---</i>	<i>---</i>	<i>118</i>	<i>118</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 a fully integrated headquarters campus – 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 the appropriate information regarding space needs to support escalating priorities is communicated to the Department in the FDA Five-Year Timeline (FYTL) for inclusion in the “Reduce the Footprint” Plan that HHS submits to the Office of Management and Budget (OMB).

FDA also promotes maximum utilization of Federal workspace. FDA’s energy saving projects decrease 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 is replacing and centralizing existing geographically disparate facilities with new, state-of-the art laboratories, office buildings, and support facilities as part of the White Oak Campus consolidation.

GSA Rental Payments

The GSA Rental Payments account includes FDA rental payments to cover FDA's office and laboratory facilities. FDA occupies six million square feet of GSA owned or GSA leased office, laboratory, and warehouse space. More than two-thirds 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 290 buildings, including district offices, regional offices, laboratories, resident posts, and border stations across the nation and in Puerto Rico.

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

During FY 2015, FDA:

- relocated from two headquarters office buildings to collocate in one leased location in Rockville, Maryland – released one of the two vacated office buildings to GSA
- completed decommissioning and released a CBER lab at headquarters
- vacated two ORA resident posts
- vacated the Kansas City Lab Annex
- relocated one OCI field office
- relocated five ORA resident posts.

In FY 2016, FDA plans to:

- release the second vacated office building from which staff were collocated in one leased location in Rockville, Maryland
- relocate two ORA resident posts
- lease new space for headquarters.

FDA strives to be cost effective and energy efficient when it acquires the necessary space to meet the 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 13514, Federal Leadership in Environmental, Energy, and Economic Performance
- HHS' Efficient Energy Management Assessments
- the Energy Policy Act of 2005
- HHS Sustainable and High Performance Buildings Policy
- HHS Sustainable Buildings Plan
- the 2006 Federal Leadership in High Performance and Sustainable Buildings Memorandum of Understanding.

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 FDA would have paid for utilities if the energy saving features provided by the ESPC were not implemented. 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 third Utility Energy Service Contract (UESC) with Washington Gas at the Muirkirk Road Campus with a capital investment of \$958,863 with utility cost savings of approximately \$143,706 annually in water, sewer, electricity, and fuel costs at a simple pay back of 6.7 years. This project was substantially completed as of March 2015. FDA is currently in the procurement stage of a fourth UESC with Washington Gas at the Muirkirk Road Campus with a capital investment of \$2,481,327 and utility cost savings of approximately \$313,700 annually at a simple payback of 7.91 years.

The UESC for its 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 substantially complete, energy conservation measures are operational, and savings are underway.

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

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 unifying 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 replaces and centralizes 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
- internal communications and information technology – infrastructure, equipment, cabling and audiovisual
- security – infrastructure and equipment
- surplus of furniture and equipment
- decommissioning of FDA vacated laboratories final commissioning and certification of the specialized laboratories
- critical support and maintenance of vital specialized laboratory equipment
- start up and operation of a critical Safety Program to support the new labs Complex
- security features to expand the CUP.

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.

In FY 2015, FDA initiated 25 projects in support of commissioning the White Oak laboratories, including the Biosafety Level 3 (BSL3) laboratories and vivarium facilities allowing their certification for use. FDA also initiated two studies for Building 25 and Building 45 in preparation of GSA funding to complete construction of these remaining buildings identified in the 2009 White Oak Master Plan.

In FY 2016, FDA will initiate a study for housing an additional 3,800 headquarters staff. This increase is due to new and expanded authorities and public health responsibilities beyond what was planned for in the 2009 Master Plan.

FUNDING HISTORY – GSA RENTAL PAYMENTS

Fiscal Year	Program Level	Budget Authority	User Fees
FY 2013 Actual	\$190,151,000	\$149,970,000	\$40,181,000
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 Enacted	\$239,105,000	\$176,683,000	\$62,422,000
FY 2017 President's Budget	\$240,205,000	\$170,208,000	\$69,997,000

FUNDING HISTORY - OTHER RENT AND RENT-RELATED ACTIVITIES

Fiscal Year	Program Level	Budget Authority	User Fees
FY 2013 Actual	\$88,129,000	\$64,058,000	\$24,071,000
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 Enacted	\$119,560,000	\$73,484,000	\$46,076,000
FY 2017 President's Budget	\$123,928,000	\$71,943,000	\$51,985,000

FUNDING HISTORY - WHITE OAK

Fiscal Year	Program Level	Budget Authority	User Fees
FY 2013 Actual	\$57,159,000	\$53,684,000	\$3,475,000
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 Enacted	\$52,346,000	\$48,044,000	\$4,302,000
FY 2017 President's Budget	\$47,461,000	\$43,044,000	\$4,417,000

BUDGET REQUEST

The FY 2017 Budget Request is \$411,594,000, of which \$285,195,000 is budget authority and \$126,399,000 is user fees. The budget authority decreases by \$13,016,000 compared to the FY 2016 Enacted level and user fees increase by \$13,599,000.

The Infrastructure Program ensures that FDA's offices and labs across the country – and a 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
- the FDA Strategic Goal to Strengthen Organizational Excellence and the FDA Strategic Priority of Stewardship
- enhanced productivity and capabilities needed for the agency to achieve its expanding public health mission.

GSA Rental Payments

The FY 2017 Budget request for GSA Rental Payments is \$240,205,000, of which \$170,208,000 is budget authority and \$69,997,000 is user fees. The budget authority decreases by \$6,475,000 compared to the FY 2016 Enacted level and user fees increase by \$7,575,000.

The rental properties that provide office and laboratory space for FDA employees are essential facilities. The FY 2017 Budget Request for GSA Rental Payments covers the cost of rental payments to GSA for FDA's six million square feet of GSA-rented office and laboratory space.

Other Rent and Rent-Related

The FY 2017 Budget request for Other Rent and Rent-Related is \$123,928,000, of which \$71,943,000 is budget authority and \$51,985,000 is user fees. The budget authority decreases by \$1,541,000 compared to the FY 2016 Enacted level and user fees increase by \$5,909,000.

The FY 2017 Budget will allow FDA to operate, maintain, and secure its facilities in an appropriate and sustainable manner to support 16,000 staff members.

White Oak

The FY 2017 Budget request for White Oak consolidation and operations activities is \$47,461,000, of which \$43,044,000 is budget authority and \$4,417,000 is user fees. The budget authority decreases by \$5,000,000 compared to the FY 2016 Enacted level and user fees increase by \$115,000.

The FY 2017 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. The FY 2017 Budget request will fund support services, transportation services, labor, and loading dock services, and a centralized safety program.

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