

INFRASTRUCTURE - GSA RENT, OTHER RENT, AND WHITE OAK

| | FY 2018 | FY 2018 | FY 2019 | FY 2020 | |
|--|----------------|----------------|----------------|--------------------|---------------------------|
| | Enacted | Actuals | Annualized CR | President's Budget | +/- FY 2019 Annualized CR |
| FDA White Oak Consolidation Program..... | 50,559 | 49,453 | 50,772 | 58,926 | 8,154 |
| Budget Authority..... | 43,044 | 43,044 | 43,044 | 50,927 | 7,883 |
| Prescription Drug (PDUFA)..... | 3,597 | 3,597 | 3,810 | 3,848 | 38 |
| Tobacco Control Act..... | --- | --- | --- | --- | --- |
| Family Smoking Prevention and Tobacco Control Act..... | 3,918 | 2,812 | 3,918 | 4,151 | 233 |
| Other Rent and Rent Related Program..... | 121,919 | 121,530 | 123,881 | 146,251 | 22,370 |
| Budget Authority..... | 71,943 | 71,943 | 71,943 | 93,444 | 21,501 |
| User Fees..... | 49,976 | 49,587 | 51,938 | 52,807 | 869 |
| Prescription Drug (PDUFA)..... | 24,672 | 26,163 | 26,127 | 26,389 | 262 |
| Medical Device (MDUFA)..... | 5,187 | 8,672 | 5,239 | 5,291 | 52 |
| Generic Drug (GDUFA)..... | 12,946 | 9,426 | 13,075 | 13,206 | 131 |
| Biosimilars (BsUFA)..... | 805 | 766 | 1,070 | 1,081 | 11 |
| Animal Drug (ADUFA)..... | 720 | 720 | 790 | 797 | 7 |
| Animal Generic Drug (AGDUFA)..... | 273 | 261 | 264 | 266 | 2 |
| Tobacco Control Act..... | 4,898 | 3,579 | 4,898 | 5,283 | 385 |
| Food And Feed Recall..... | 43 | --- | 43 | 45 | 2 |
| Food Reinspection..... | 204 | --- | 204 | 212 | 8 |
| Voluntary Qualified Importer Program..... | 170 | --- | 170 | 177 | 7 |
| Third Party Auditor Program..... | 24 | --- | 24 | 25 | 1 |
| Outsourcing Facility..... | 34 | --- | 34 | 35 | 1 |
| GSA Rental Payments Program..... | 238,487 | 219,283 | 241,024 | 240,928 | -96 |
| Budget Authority..... | 170,208 | 170,208 | 170,208 | 171,570 | 1,362 |
| User Fees..... | 68,279 | 49,075 | 70,816 | 69,358 | -1,458 |
| Prescription Drug (PDUFA)..... | 33,373 | 20,205 | 35,341 | 35,695 | 354 |
| Medical Device (MDUFA)..... | 8,229 | 8,229 | 8,312 | 8,395 | 83 |
| Generic Drug (GDUFA)..... | 12,594 | 12,594 | 12,720 | 12,847 | 127 |
| Biosimilars (BsUFA)..... | 339 | 339 | 451 | 455 | 4 |
| Animal Drug (ADUFA)..... | 522 | 522 | 839 | 847 | 8 |
| Animal Generic Drug (AGDUFA)..... | 376 | 304 | 307 | 310 | 3 |
| Tobacco Control Act..... | 12,030 | 6,882 | 12,030 | 9,960 | -2,070 |
| Food And Feed Recall..... | 73 | --- | 73 | 76 | 3 |
| Food Reinspection..... | 348 | --- | 348 | 362 | 14 |
| Voluntary Qualified Importer Program..... | 290 | --- | 290 | 302 | 12 |
| Third Party Auditor Program..... | 47 | --- | 47 | 49 | 2 |
| Outsourcing Facility..... | 58 | --- | 58 | 60 | 2 |

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); the Drug Quality and Security Act (2013);

Allocation Methods: Direct Federal/Intramural

PROGRAM DESCRIPTION AND ACCOMPLISHMENTS

The Infrastructure Program directly supports FDA's priorities by providing secure, modern, and cost-effective office and laboratory space that empowers FDA's workforce to protect and promote the safety and health of families; to foster the competition and innovation that will improve healthcare, expand access to medical products, and advance public health goals; to empower consumers and patients to make better choices; and to strengthen science and efficient risk-based decision making. The Infrastructure Program consists of:

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

The Infrastructure Program supports FDA's offices and labs across the country and its headquarters White Oak Campus in Silver Spring, Maryland. The program provides the infrastructure and scientific facilities necessary for FDA's workforce to effectively protect and promote the safety and health of families. Therefore, the program directly affects the productivity and efficacy of the workforce, its ability to grow and strengthen, and its ability to empower consumers and patients to make informed health choices. Without adequate investment, FDA would be unable to respond to food safety, medical product, and public health emergencies, such as opioid addiction and abuse, tobacco use by American youth, and antimicrobial resistance. 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 that effectively support FDA's public health priorities, optimize the use of taxpayer

dollars, enhance workforce productivity, and ensure efficient operations. FDA promotes the efficient use of federal workspace and ensures that the appropriate information regarding the space required to support its escalating responsibilities is communicated to the Department for inclusion in the “Reduce the Footprint” Plan that HHS submits to the Office of Management and Budget.

Additionally, FDA’s energy saving projects decrease long-term energy usage and operating and maintenance costs, while increasing facility life spans and efficiency to support Executive Order 13834, Efficient Federal Operations.

Even though FDA replaced some of its geographically disparate facilities with new, state-of-the-art laboratories, office buildings, and support facilities as part of the White Oak Campus consolidation onto the Federal Research Center, FDA’s geographic consolidation of its headquarters facilities is still incomplete.

FDA is working with GSA to develop a housing strategy and migration plan for FDA headquarters programs and will consider using federal space on or near the Campus, including FDA-owned and GSA-owned locations, as well as leasing space close to Campus to continue FDA’s geographic consolidation. In addition, a new master plan has been developed for the Federal Research Center to finalize the housing strategy and ensure that environmental impacts have been considered. The new master plan was completed in November 2018 and was approved by the National Capital Planning Commission on December 6, 2018.

GSA Rental Payments

The GSA Rental Payments account includes rental payments for FDA’s GSA-managed office and laboratory facilities. These facilities enable FDA to protect consumers and patients by keeping contaminated, adulterated, counterfeit, and defective food and medical products from reaching the marketplace and by swiftly and effectively addressing food safety, medical product, and public health emergencies that arise. Without these strategically located facilities FDA staff could not conduct boots on the ground work including:

- Conducting inspections of approximately 40,000 regulated products and manufacturers annually
- Collecting and analyzing more than 45,000 samples of regulated products annually
- Recalling unsafe products, like the 9,199 recalls in FY 2017 alone
- Reviewing more than 40 million distinct product lines offered for entry into the U.S.
- Swiftly identifying the causes of foodborne illnesses that affect more than 48 million Americans each year, like the recent outbreaks caused by Duncan Hines cake mixes contaminated by Salmonella Agbeni and the multistate outbreak of E. coli O157:H7 infections linked to romaine lettuce from the Yuma growing region, to save lives
- Interdicting opioids at International Mail Facilities (IMFs) to combat the addiction crisis, which is the dominant public health problem in the U.S., killing an average of 115 Americans daily
- Keeping the U.S. drug supply safe; in FY 2017, 86 percent of packages that the FDA reviewed at IMFs contained illegal, illicit, unapproved, counterfeit and potentially dangerous drugs

- Reviewing medical products to improve health outcomes, such as the 200 devices FDA cleared, granted, or approved in the past few years that treat or manage pain and reduce the need to administer opioids
- Conducting criminal investigations, which resulted in 283 arrests, 226 convictions, \$205 million of assets forfeited and seized, and \$461 million in fines and restitution in FY 2017 alone.

FDA occupies almost 6.6 million rentable square feet of GSA-owned and GSA-leased office, laboratory, warehouse, and border/inspection-station space.

Approximately 70 percent of the GSA rent charges for GSA-owned or GSA-leased space are for headquarters facilities in the Maryland suburbs of Washington, D.C. FDA occupies GSA-owned or -leased space in approximately 265 buildings, including district offices, laboratories, resident posts, border stations, and field offices 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. 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.

In FY 2018, FDA:

- continued coordinating the design and construction for the relocation of two ORA laboratories to replace aging facilities and improve operations that protect the American food supply: one near Kansas City, Kansas, responsible for planning, processing, and analyzing food items, including infant and toddler foods; and one near San Francisco, California, responsible for sensory and microbiological analyses of foods, elemental analysis, food chemistry, and product sterility
- coordinated a prospectus lease acquisition for the relocation and replacement of an aging facility that will improve operations of the ORA laboratory near Atlanta, Georgia, that houses the Southeast Food and Feed Lab, with expertise in pesticide residues, chemotherapeutics, metals, entomology, nutrient analyses, colors, food additives, filth and decomposition, pathogens, molecular biology, and bacterial toxins; this location also houses the Southeast Tobacco Laboratory
- coordinated design and construction of two new leased office locations near the White Oak Campus to ensure housing for FDA's growing workforce resulting from its expanding mission and authorities, FDARA, and the 21st Century Cures Act
- coordinated leasing a training center and office space in an existing leased location in Rockville, Maryland, to support FDA's workforce in keeping with FDA's strategic priority to strengthen science and efficient risk-based decision making
- coordinated submitting a prospectus lease request for new office space near the White Oak Campus to house FDA's growing workforce resulting from its expanding mission and authorities, FDARA, and the 21st Century Cures Act
- relocated one ORA resident post and leased one new OCI field office to facilitate inspection and criminal investigation activities that protect public health
- vacated two office locations in Rockville, Maryland, as part of a headquarters lease consolidation, to minimize real estate costs and consolidate activities to promote operational excellence.

In FY 2019, FDA plans to:

- continue coordinating the construction for the relocation of two ORA laboratories to replace aging facilities and improve operations that protect the American food supply: one near Kansas City, Kansas, responsible for planning processing, and analyzing food items including infant and toddler foods; and one near San Francisco, California, responsible for sensory and microbiological analysis of foods, elemental analysis, food chemistry, and product sterility
- initiate design and construction activities to replace an aging facility and improve the operations of the ORA laboratory near Atlanta, Georgia, that houses the Southeast Food and Feed Lab, with expertise in pesticide residues, chemotherapeutics, metals, entomology, nutrient analyses, colors, food additives, filth and decomposition, pathogens, molecular biology, and bacterial toxins; this location also houses the Southeast Tobacco Laboratory
- occupy two new leased office locations near the White Oak Campus to ensure housing for FDA's growing workforce resulting from its expanding mission and authorities, FDARA, and the 21st Century Cures Act
- begin operations in a training center and office space in an existing leased location in Rockville, Maryland, to support FDA's workforce in keeping with FDA's strategic priority to strengthen science and efficient risk-based decision making
- gain Congressional approval for a prospectus lease for new office space near the White Oak Campus to ensure housing for FDA's growing workforce resulting from its expanding mission and authorities, FDARA, and the 21st Century Cures Act
- coordinate leasing a new under-prospectus office space near the White Oak Campus to ensure housing for FDA's growing workforce resulting from its expanding mission and authorities, FDARA, and the 21st Century Cures Act
- coordinate leasing four new locations for ORA resident posts and border stations to expand inspection operations that protect public health
- coordinate relocating seven ORA resident posts to facilitate inspection operations that protect public health
- coordinate increasing ORA's presence in nine IMFs to expand opioid interdiction efforts and combat the addiction crisis threatening American families
- expand CDER's laboratory in St. Louis, Missouri, that houses the Division of Pharmaceutical Analysis to increase its operations
- coordinate leasing a new CDER laboratory near the White Oak Campus to house a pilot plant for simulating the processing of drug substances and drug product manufacturing
- coordinate renovating existing buildings to provide additional storage and a security center on the White Oak Campus to support and protect FDA's expanding operations and growing workforce.

Other Rent and Rent-Related Activities

The Other Rent and Rent-Related Activities account includes 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:

- operation and maintenance contracts
- operation and maintenance repairs

- 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 that operate continuously and beyond the GSA standard 10-hour day
- other above-standard level services required to operate FDA facilities not provided by GSA in GSA-managed facilities.

This account ensures that FDA's offices and labs are functional and support the FDA workforce in meeting its public health mission by providing safe, efficient, reliable, and secure facilities. Without the services and repairs funded by this account, critical FDA operations, including research and regulatory work, would cease.

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

- Executive Order 13834, Efficient Federal Operations
- 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 their utility costs would be otherwise due to the energy saving features provided by the ESPC.

Benefits of the ESPC, in addition to annual energy cost savings, include improving Campus electrical power reliability, which safe-guards ongoing medical product research, and reducing recurring maintenance costs. In addition to monetary benefits to the taxpayer, the CUP provides electric power through efficient cogeneration and photovoltaic equipment, funded by the ESPC, to reduce the environmental impact (pollution) of the Campus compared to supporting the Campus by more traditional power sources.

When each ESPC phase begins to provide benefits to the Campus, including utilities to FDA-occupied buildings, FDA is required to pay its 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 \$2.4 million, utility cost savings of

approximately \$300 thousand annually, and a simple payback of approximately eight years. Construction is underway.

FDA awarded a second UESC contract with Southern California Edison Electric Power Company at Irvine with a capital investment of \$4.1 million, utility cost savings of approximately \$350 thousand annually, and a simple payback of approximately 12 years. Construction was completed. This project included the installation of solar panels, which will result in taxpayer energy cost savings and reduced environmental pollution compared to more traditional forms of electric power generation.

FDA implemented the design and construction of ECMs under a UESC for Dauphin Island, Alabama. It has a capital investment of \$458 thousand, utility cost savings of approximately \$36 thousand annually, and a simple payback of approximately 12.8 years. The contract was awarded, and construction has been completed.

FDA has completed an investment-grade audit for our facilities at the Muirkirk Road Campus to identify facilities projects. We awarded an approximately \$900 thousand contract to address urgent projects for replacement of air handling units supporting FDA laboratories. The remainder of the projects identified by the audit, totaling approximately \$5 million, are awaiting availability of funds. These projects will improve reliability of failing infrastructure systems and allow the Centers for Food Safety and Applied Nutrition (CFSAN) and Center for Veterinary Medicine (CVM) to continue their testing and oversight programs without disruption. These programs are responsible for promoting and protecting the public's health by ensuring that the nation's food supply is safe, sanitary, wholesome, and honestly labeled; cosmetic products are safe and properly labeled; and food and drugs for animals are safe.

CFSAN's Office of Applied Research Assessment (OARSA) is located at the Muirkirk Road Complex. A key part of OARSA's regulatory research focuses on developing and validating methods to detect foodborne hazards in the nation's food supply. This effort is continuous.

OARSA also is involved in conducting a multi-laboratory validation for detecting *Cyclospora* in water to be used during the potential outbreak season, or early spring. Multi-laboratory validation is a long (six-month) process involving OARSA labs, the FDA/ORA laboratories, as well as the CDC and USDA laboratories. This research would be negatively impacted if the OARSA laboratory was not operational. If shut down, OARSA would have to stop its part of the validation, the validation would be incomplete, and the process would have to be restarted. Restarting the process would require additional resources from three federal agencies. Ultimately, not having a validated detection method during the next outbreak season would delay response and negatively impact public health and food safety.

GSA is planning to perform audits in FDA-occupied leased facilities, such as the Jamaica 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 13834 Efficient Federal Operations. FDA's activities related to UESCs and renewable energy will mitigate the effect of FDA's operations on the environment.

White Oak

Congressional intent for geographically consolidating most 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 existing geographically disparate facilities with new, state-of-the-art laboratories, office buildings, and support facilities in one location. By consolidating much of its headquarters workforce, FDA increased opportunities for staff to collaborate face-to-face, while reducing overall facility operating costs. In-person collaboration fast-tracks advances and innovation in science, policy, and regulation that protect public health and accelerate access to lifesaving and life-improving products. Additionally, the consolidation centralized headquarters decision-making. During public health crises and emergencies, FDA's emergency operations center on Campus coordinates communications and actions across FDA programs, ORA, and federal, state, local, tribal territorial, and foreign regulatory public health counterparts.



Figure 25 State-of-the-Art Laboratories at White Oak



Figure 26 State-of-the-Art Laboratories at White Oak



Figure 27 Anecoic Chambers Laboratory



Figure 28 Nuclear Magnetic Resonance Laboratory Supporting CBER and CDER



Figure 29 Flow Cytometry Core Facility: Highly Specialized and Expensive Equipment for Vaccine and Cell Therapy Studies



Figure 30 State-of-the-Art White Oak Infrastructure: Advanced Air Terminal Units Supporting Laboratories

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 Campus above-standard infrastructure, building fit-out, specialized equipment, move costs, and operations and logistics.

White Oak funding supports Campus operations and requirements including:

- space alteration activities to meet the needs of rapidly changing laboratory research and medical product review programs
- above-standard Campus and building infrastructure design and construction required by laboratory functions, without which Campus operations would be limited and/or disrupted
- FDA information technology and security infrastructure, equipment, cabling and audiovisual, without which Campus activities would come to a halt
- commissioning and certification of the specialized laboratories required for scientific evaluation and research necessary for medical product approvals and regulations
- support services, including conference center management, labor and loading dock services, and operations and maintenance services, including maintenance of vital specialized laboratory equipment, without which the Campus could not reliably function
- transportation services, including parking management and a campus shuttle and circulator bus program critical to support the growing Campus staff and operations
- a centralized safety program to support expanded lab operations and Campus occupancy and protect the health and well-being of the federal workforce.

FDA initiated relocation activities to White Oak in FY 2002. The total number of employees currently assigned to the White Oak Campus is almost 11,000 as a result of completing the occupancy of the Biodefense Laboratory Complex (two office and two lab buildings) in FY 2014 and instituting alternative office strategies, including increased telework.

In FY 2016, FDA provided funding to GSA to develop an FDA Headquarters housing strategy and migration plan to complete FDA's headquarters geographic consolidation, as well as to develop a new master plan for the Federal Research Center. This planning began in earnest in FY 2017, continued through FY 2018, and is anticipated to be completed in FY 2019.

In FY 2019, in addition to funding Campus operations, FDA will initiate above-GSA-standard repair and improvement projects required to support FDA's specialized functions in support of program requirements.

FUNDING HISTORY – GSA RENTAL PAYMENTS

| Fiscal Year | Program Level | Budget Authority | User Fees |
|----------------------------|----------------------|-------------------------|------------------|
| FY 2016 Actual | \$220,122,000 | \$161,683,000 | \$58,439,000 |
| FY 2017 Actual | \$220,653,000 | \$170,208,000 | \$50,445,000 |
| FY 2018 Actual | \$219,283,000 | \$170,208,000 | \$49,075,000 |
| FY 2019 Annualized CR | \$241,024,000 | \$170,208,000 | \$70,816,000 |
| FY 2020 President's Budget | \$240,928,000 | \$171,570,000 | \$69,358,000 |

FUNDING HISTORY - OTHER RENT AND RENT-RELATED ACTIVITIES

| Fiscal Year | Program Level | Budget Authority | User Fees |
|----------------------------|----------------------|-------------------------|------------------|
| FY 2016 Actual | \$119,059,000 | \$73,484,000 | \$45,575,000 |
| FY 2017 Actual | \$116,653,000 | \$71,943,000 | \$44,710,000 |
| FY 2018 Actual | \$121,530,000 | \$71,943,000 | \$49,587,000 |
| FY 2019 Annualized CR | \$123,881,000 | \$71,943,000 | \$51,938,000 |
| FY 2020 President's Budget | \$146,251,000 | \$93,444,000 | \$52,807,000 |

FUNDING HISTORY - WHITE OAK

| Fiscal Year | Program Level | Budget Authority | User Fees |
|----------------------------|----------------------|-------------------------|------------------|
| FY 2016 Actual | \$48,944,000 | \$48,044,000 | \$900,000 |
| FY 2017 Actual | \$46,856,000 | \$43,044,000 | \$3,812,000 |
| FY 2018 Actual | \$49,453,000 | \$43,044,000 | \$6,409,000 |
| FY 2019 Annualized CR | \$50,772,000 | \$43,044,000 | \$7,728,000 |
| FY 2020 President's Budget | \$58,926,000 | \$50,927,000 | \$7,999,000 |

BUDGET REQUEST

The FY 2020 Total Budget Request is \$446,105,000, of which \$315,941,000 is budget authority and \$130,164,000 is user fees. This level provides a net increase of \$30,428,000 compared to the amount in the FY 2019 Annualized Continuing Resolution. Budget authority increases by \$30,746,000 and user fees decrease by -\$318,000.

The request will cover rent increases the agency anticipates in FY 2020 that are related to market changes, including new Occupancy Agreements replacing those expiring in FY 2019 and FY 2020 for approximately 64 GSA Occupancy Agreements that will cause rental rates to reset to market rates. In addition, FDA will also occupy expansion space in one existing and two new GSA-leased buildings, which will house user-fee growth. The increase in OR&RR is needed to meet cost escalations associated with operations and maintenance contracts, utilities, security, 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 because several of the buildings on Campus are 10 or more years old. Accordingly, the FY 2020 Budget request includes funding to address ongoing, above GSA-standard repairs and improvements and meet program needs, including campus utility infrastructure capacity and reliability improvements, and security infrastructure and the campus safety program.

The Infrastructure Program supports FDA's offices and labs across the country and its headquarters White Oak Campus in Silver Spring, Maryland. The program provides the infrastructure and scientific facilities necessary for FDA's workforce to effectively protect and

promote the safety and health of families. Therefore, the program directly affects the productivity and efficacy of the workforce, its ability to grow and strengthen, and its ability to empower consumers and patients to make informed health choices. Without adequate investment, FDA would be unable to respond to food safety, medical product, and public health emergencies, such as opioid addiction and abuse, tobacco use by American youth, and antimicrobial resistance.

GSA Rental Payments

The FY 2020 Budget request for GSA Rental Payments is \$240,928,000, of which \$171,570,000 is budget authority and \$69,358,000 is user fees. The budget authority increases by \$1,362,000 compared to the amount requested in the FY 2019 Annualized Continuing Resolution, and user fees decrease by -\$1,458,000. The GSA-managed properties that provide office and laboratory space for FDA employees are essential facilities. The GSA-managed properties that provide office and laboratory space for FDA employees are essential facilities. The FY 2020 Budget Request for GSA Rental Payments covers the cost of rental payments to GSA for FDA's almost 6.6 million square feet of GSA-managed space. Increased funding will also address the following critical needs:

- Increased rent and utility costs due to the renewal of a large number of leases expiring in FY 2019 and FY 2020, due to current higher market rates for rent and utilities at leased locations
- Planned lease costs for increasing facilities needs in the National Capital Region and FDA field locations
- Continued rent for existing labs in San Francisco and Kansas City while decommissioning is completed
- Real estate taxes increases.

Other Rent and Rent-Related

The FY 2020 Budget request for Other Rent and Rent Related is \$146,251,000, of which \$93,444,000 is budget authority and \$52,807,000 is user fees. The budget authority increases by \$21,501,000 compared to the amount requested in the FY 2019 Annualized Continuing Resolution and user fees increase by \$869,000. The FY 2020 Budget will allow FDA to operate, maintain, and secure its facilities in an appropriate and sustainable manner to support more than 17,000 staff members. It will also provide adequate funding to address increased utility and maintenance costs associated with FDA's aging owned buildings.

White Oak

The FY 2020 Budget request for White Oak is \$58,926,000, of which \$50,927,000 is budget authority and \$7,999,000 is user fees. The budget authority increases by \$7,883,000 compared to the amount requested in the FY 2019 Annualized Continuing Resolution and user fees increase by \$271,000. The FY 2020 Budget provides the necessary resources for increased above GSA-standard repairs and improvements, as well as mission support services on a daily basis for the almost 11,000 employees assigned to the White Oak Campus. The FY 2020 Budget request will fund capacity and reliability improvements for the White Oak Campus utility infrastructure, support services, transportation services, labor, and loading dock services, and a centralized safety program.

Reliability of the utility infrastructure at White Oak is critical to Campus operations, especially laboratory operations. For example, utility outages adversely impact CBER laboratory activities supporting U.S. readiness for seasonal and pandemic influenza. CBER's laboratories play several critical roles in the development and manufacture of influenza vaccines, from participating in global surveillance for circulating influenza strains and developing candidate vaccine strains to deriving and distributing critical reagents for manufacturers to use in their assessment of influenza vaccine quality. If utility outages disrupt any one of these activities, it could delay vaccine availability to the public, thus negatively impacting public health and increasing flu-related deaths.