



September 2020

FEDERAL PROPERTY

Formal Policies Could Enhance FDA's Property Management Efforts

Accessible Version

GAO Highlights

Highlights of [GAO-20-689](#), a report to congressional committees

Why GAO Did This Study

Three FDA regulatory centers have primary responsibility for ensuring human medical products' safety, security, and effectiveness. FDA uses personal property and real property (e.g., buildings) to help achieve this oversight mission.

Congress included a provision in statute for GAO to examine FDA's expenses related to property at the three centers and evaluate FDA's ability to further its mission through management of those assets. Among other things, this report: (1) identifies the funds FDA obligated for these centers, and (2) assesses FDA's use of quality information to manage the centers' personal property. GAO reviewed financial data and interviewed officials about FDA's obligations from fiscal years 2012 through 2019. In addition, GAO compared criteria related to using quality information to FDA's relevant policies and processes, and interviewed FDA and General Services Administration (GSA) officials about FDA's property management.

What GAO Recommends

GAO is making four recommendations to FDA and GSA, including that FDA establish and implement formal policies to use quality information to plan for, operate and maintain, and review performance of personal property used by the three centers. The agencies agreed with the recommendations.

View [GAO-20-689](#). For more information, contact David Trimble at (202) 512-2834 or TrimbleD@gao.gov or Kristen Kocielek at (202) 512-2989 or Kocielek@gao.gov.

September 2020

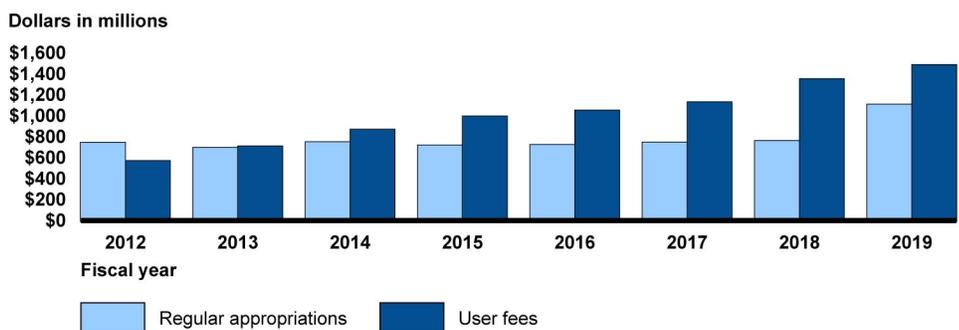
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Formal Policies Could Enhance FDA's Property Management Efforts

What GAO Found

From fiscal years 2012 through 2019, the Food and Drug Administration (FDA) obligated a combined total of \$14.7 billion to support operations at the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and the Center for Devices and Radiological Health. During this period, 56 percent of the three centers' total obligations came from user fees, which FDA negotiates with and collects from regulated industries (e.g., manufacturers). The other 44 percent of the centers' total obligations came from regular appropriations. On average, property-related expenses represented 12 percent of the centers' total annual obligations; approximately half of property-related expenses were for rent.

Obligations for Three of the Food and Drug Administration's Regulatory Centers by Budget Authority Type, Fiscal Years 2012 through 2019



Source: GAO analysis of FDA financial data on obligations. | GAO-20-689

In managing their personal property (e.g., scientific equipment, computers, and office furniture), these centers did not consistently use quality information related to three phases of asset management:

- (1) planning for property needs;
- (2) operating and maintaining property; and
- (3) reviewing property performance.

For example, officials at all three centers described informal, disparate processes for collecting and using information to identify and prioritize personal property needs. Furthermore, center staff conducted these activities differently, potentially resulting in inconsistent asset data. Using quality information—which involves consistently collecting, analyzing, and verifying the accuracy of data—can help agencies effectively manage assets such as personal property. It is a key characteristic integral to effective asset management, criteria GAO developed in prior work based on federal guidance and international standards. By establishing and implementing formal policies for using quality personal property information, FDA and the three centers can more effectively manage their personal property's useful life, plan for and respond to potential changes to the centers' funding and priorities, and maximize the value of the centers' personal property.

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Abbreviation

BSL	biosafety level
BsUFA	Biosimilar User Fee Act
CBER	Center for Biologics Evaluation and Research
CDER	Center for Drug Evaluation and Research
CDRH	Center for Devices and Radiological Health
FDA	Food and Drug Administration
FDARA	Food and Drug Administration Reauthorization Act
FDASIA	Food and Drug Administration Safety and Innovation Act
FTE	full-time equivalent
GDUFA	Generic Drug User Fee Amendments
GSA	General Services Administration
HHS	Department of Health and Human Services
ISO	International Organization for Standardization
MDUFA	Medical Device User Fee and Modernization Act
OFEMS	Office of Facilities, Engineering, and Mission Support Services
OMB	Office of Management and Budget
PDUFA	Prescription Drug User Fee Act

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September 23, 2020

The Honorable Lamar Alexander
Chairman
The Honorable Patty Murray
Ranking Member
Committee on Health, Education, Labor, and Pensions
United States Senate

The Honorable Anna G. Eshoo
Chairwoman
The Honorable Michael C. Burgess
Ranking Member
Subcommittee on Health
Committee on Energy and Commerce
House of Representatives

The Food and Drug Administration (FDA), within the Department of Health and Human Services (HHS), oversees the safety of drugs, biological products, and medical devices, among other things. Over the past couple of decades, rapid expansion of the industries that create these medical products has resulted in an increase in applications submitted to FDA for scientific review and approval.¹ As part of FDA's efforts to meet this demand and achieve its oversight mission, FDA plays a role in managing the GSA-held and leased office and laboratory space it uses as well as federally owned personal property such as computers, scientific equipment, and office furniture.² Effective management of real property can help ensure sound decision-making, as we reported in 2016 when we recommended that FDA document key information about its main campus to inform its planning efforts.³ We have also previously reported that effective management of personal property can provide

¹ FDA oversees medical products, in part, by reviewing and approving applications for such products before they may be marketed to consumers.

² 141 C.F.R. § 102-36.40.

³ FDA addressed our recommendations in 2018. See GAO, *FDA Facilities: Planning Efforts for White Oak Campus Should Further Incorporate Leading Practices to Address Ongoing Challenges*, [GAO-17-87](#) (Washington, D.C.: Dec. 7, 2016).

reasonable assurance of efficient operations and minimal resource waste.⁴

FDA is funded through budget authority, including regular appropriations and user fees that FDA negotiates with and collects from regulated industries (e.g., manufacturer associations and individual companies).⁵ FDA is currently subject to statutory limits on how it may obligate user fees.⁶ Beginning in October 2023, FDA will be subject to new limitations on its obligation of user fees for certain property and property-related expenditures.⁷ According to FDA officials, these limitations would alter how the centers obligate funds to equip and maintain facilities to support the function of FDA's integrated scientific teams and acquire, operate, and maintain property necessary to achieve its mission-related goals.⁸

The FDA Reauthorization Act of 2017 (FDARA) included a provision for GAO to examine property expenses FDA incurred from fiscal year 2012 through fiscal year 2019 at FDA's: (1) Center for Drug Evaluation and Research (CDER); (2) Center for Biologics Evaluation and Research (CBER); and (3) Center for Devices and Radiological Health (CDRH) and to evaluate FDA's ability to further its public health mission by managing property the centers use.⁹ These three centers are mainly located at FDA's White Oak Campus in Silver Spring, Maryland. The General Services Administration (GSA) has custody and control of the real

⁴ See GAO, *Federal Personal Property: Opportunities Exist to Improve Identification of Unneeded Property for Disposal*, [GAO-18-257](#), (Washington, D.C.: Feb. 16, 2018).

⁵ For purposes of our report, we use the term "regular appropriations" to refer to amounts derived from the General Fund of the Treasury and made available through annual appropriations. User fees are charges assessed to beneficiaries for goods or services provided by the federal government. FDA is authorized to collect user fees for reviewing certain applications and licenses, and to use the proceeds to cover the costs associated with these reviews, such as GSA rental payments and furniture, fixtures, and equipment. FDA's user fees are collected and available for obligation only to the extent and in the amount provided in advance in appropriation acts.

⁶ See appendix I for more information on the statutory authority for user fee programs and details on the ten user fee programs from which FDA's three human medical-product regulatory centers obligated funds.

⁷ FDA Reauthorization Act of 2017 (FDARA), Pub. L. No. 115-52, § 905(b), 131 Stat. 1005, 1089-90 (2017).

⁸ An obligation is a definite commitment that makes the government legally liable for the payment of goods and services ordered or received.

⁹ FDARA, Pub. L. No. 115-52, § 905, (a), 131 Stat. at 1088-89.

property on the campus and manages it.¹⁰ However, FDA is responsible for managing its personal property.

This report:

- identifies the funds FDA obligated for the three FDA centers primarily responsible for regulating human drugs, biological products, and medical devices, and
- assesses FDA's use of quality information in the management of personal property and real property used by these three centers.

To determine FDA's obligations for the three regulatory centers and to understand how FDA obtains, obligates, and disburses budgetary funds, we reviewed financial data on obligations from FDA's budget authority, including regular appropriations and user fees,¹¹ from fiscal years 2012 through 2019. This timeframe outlined in FDARA for GAO to conduct this work encompasses FDA's obligations of user fees made available by its 2012 user fee reauthorization and ends in fiscal year 2019, the most recent complete fiscal year. We also analyzed and summarized FDA's data to determine total obligations of regular appropriations and user fees for each year.¹² We categorized obligations based on the type of goods, services, or other items purchased. We selected and performed observations of two sample transactions that FDA processed through its financial system to obtain an understanding of FDA's obligation process. In addition, we interviewed knowledgeable agency officials and performed electronic and manual data testing for missing data, outliers, and obvious errors, and we followed-up with agency officials to clarify any identified discrepancies. From these interviews and data testing, we were able to determine the data to be reliable for the purposes of our audit. To develop an understanding of the context in which FDA obligates funds, we analyzed appropriations and full-time equivalent (FTE) information for

¹⁰ GSA serves as the federal government's landlord and has the authority to lease properties for use by other federal agencies.

¹¹ For the purposes of this report, our calculations related to regular appropriations included funds for Salaries and Expenses (S&E), emerging health threats, Ebola virus, Zika virus, and Opioids, International Mail Facilities, as well as additional funds for one-time activities directly related to improving the safety of the human drug supply.

¹² We reported the centers' obligations in nominal dollars, which are not adjusted for inflation.

fiscal years 2012 through 2019 in FDA budget justification materials.¹³ We also reviewed applicable laws for four of the ten user fee programs from which the three centers obligated the largest amount of funds from fiscal years 2012 through 2019.¹⁴

To assess FDA's use of quality information in the management of personal property and real property used by the three centers, we compared FDA's activities with six key characteristics of an effective asset management framework that we developed in our prior work.¹⁵ Of these, we selected the characteristic using quality information, in part, because it is a foundation upon which other key asset management characteristics build. Also, both the International Organization for Standardization (ISO) standards and the Office of Management and Budget's (OMB) *Circular A-11 Capital Programming Guide* discuss the critical role of quality information in decision-making and planning.¹⁶ We then compared FDA's use of information about property with applicable federal statutory and regulatory requirements, guidance, and leading practices. Specifically, we reviewed policies, processes, and planning documents related to FDA's property management. We also conducted a site visit to the White Oak campus to observe the facilities, scientific equipment, and other property the centers use. We interviewed and received written responses from officials from CDER, CBER, CDRH, FDA's Office of the Chief Scientist, and FDA's Office of Operations, including the Office of Facilities, Engineering, and Mission Support Services. To identify roles and responsibilities related to FDA's management of personal property and real property used by the three centers, we reviewed FDA documents and interviewed FDA and GSA

¹³ A full-time equivalent is a standard measure of labor that equates to 1 year of full-time work.

¹⁴ 21 U.S.C. §§ 379g, 379h, 379h-2 (PDUFA), 379i to 379j-1 (MDUFA), 379j-41 to 379j-43 (GDUFA), 379j-51 to 379j-53 (BsUFA). See appendix I for more information on the original authorizing legislation for the four largest user fee programs.

¹⁵ The International Organization for Standardization (ISO) is an international, independent, non-governmental organization with a membership of 163 national standards bodies, including the American National Standards Institute. ISO 55000 defines asset management as "the coordinated activity of an organization to realize value from assets." As we reported in 2018, asset management as a distinct concept developed in the 1980s, and since that time, organizations around the world have published a number of standards and leading practices. For more information, see GAO, *Federal Real Property Asset Management: Agencies Could Benefit from Additional Information on Leading Practices*, [GAO-19-57](#) (Washington D.C.: Nov. 5, 2018).

¹⁶ OMB, *2019 Capital Programming Guide, Supplement V 3.0 OMB Circular A-11, Planning, Budgeting, and Acquisition of Capital Assets*. (Washington, D.C.: 2019).

officials. We also reviewed our prior work on personal property and real property management, as well as reports on federal user fees. More information on our scope and methodology can be found in appendix II.

We conducted this performance audit from June 2019 to September 2020 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

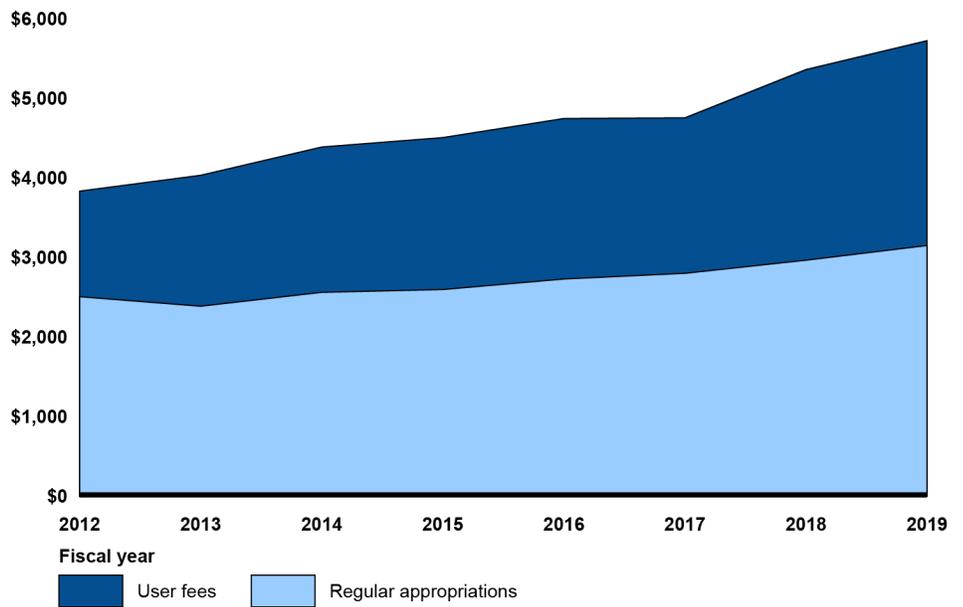
FDA's Budget Authority

From fiscal years 2012 through 2019, FDA's new annual budget authority—including both regular appropriations and user fees—increased by about 49 percent.¹⁷ However, user fee growth far outpaced the growth in regular appropriations (94 percent versus 26 percent). User fees provide a significant source of funding for FDA, as shown in figure 1. Generally, FDA's user fees are intended to supplement regular appropriations.

¹⁷ This annual budget authority excludes any carryover balances from prior fiscal years.

Figure 1: The Food and Drug Administration’s (FDA) Budget Authority by Type of Authority, Fiscal Years 2012 through 2019

Dollars in millions



Source: GAO analysis of FDA budget justification documents. | GAO-20-689

Note: These amounts have not been adjusted for inflation. The amounts used in this figure reflect what was provided in the final enacted appropriation.

FDA user fees are made available for obligation at the end of a multi-step process, which is authorized by federal statutes.

- Every 5 years, FDA negotiates performance goals, program enhancements, and user fee collection amounts with the regulated industries.¹⁸ FDA enters these negotiations with information from its annual user performance reports and other data (e.g., facilities usage and personnel costs).
- FDA then transmits a “commitment letter” to Congress for each user fee program in which FDA commits to performance goals and program enhancements. For example, FDA might agree to review and act on a certain number of drug applications within a certain timeframe, or increase the number of its FTEs by a certain amount. These “commitment letters” inform Congress’ reauthorization of the

¹⁸ In addition to negotiations with industry, FDA receives input from public stakeholders (e.g., academic experts and patient and consumer advocacy groups).

user fee programs, which in turn provide the statutory frameworks that govern the fees.

- Annual appropriations acts provide for the total amount of user fees FDA may collect and obligate for a fiscal year.
- Once FDA has collected the user fees, and Office of Management and Budget (OMB) has “apportioned” them, FDA may obligate user fees until it has expended those funds.¹⁹

Congress retains oversight over user fees. As such, information that provides visibility on how these funds are obligated are important for Congress to oversee agencies and programs. In addition, given the mix of public benefits and services to users inherent in regulatory programs, it is important for fee structures and costs to be transparent.

The purposes for which FDA can obligate user fees are set by statute. For example, for the four human medical-product user fee programs we reviewed,²⁰ FDA may obligate user fees for: (1) personnel and contractor costs; (2) information management and computer acquisition and maintenance; (3) leasing, maintenance, renovation, and repair of facilities, as well as acquisition, maintenance, and repair of fixtures, furniture, scientific equipment, and other necessary materials and supplies; and (4) collecting fees and administering user fee programs. In 2017, FDARA established new limitations. Effective October 1, 2023, FDA will no longer be authorized to obligate user fee funds from these four programs for maintenance, renovation, and repair of facilities, or for acquisition, maintenance, and repair of fixtures, furniture, and other necessary materials and supplies.²¹

Three FDA Regulatory Centers

FDA’s three medical-product regulatory centers have primary responsibility for ensuring the safety, effectiveness, and security of: drugs; biological products (i.e. cellular and gene therapy products, blood

¹⁹ An “apportionment” is the action by which OMB distributes amounts available for obligation in an appropriation or fund account. An apportionment divides amounts available for obligation, by specific time periods or activities, among other things, thereby limiting the amount of obligations that may be incurred.

²⁰ These user fee programs are commonly known as PDUFA, MDUFA, GDUFA, and BsUFA.

²¹ FDARA, Pub. L. No. 115-52, § 905(b), 131 Stat. at 1089-90.

and blood components, vaccines, and human tissues isolated from a variety of natural sources); and medical devices.

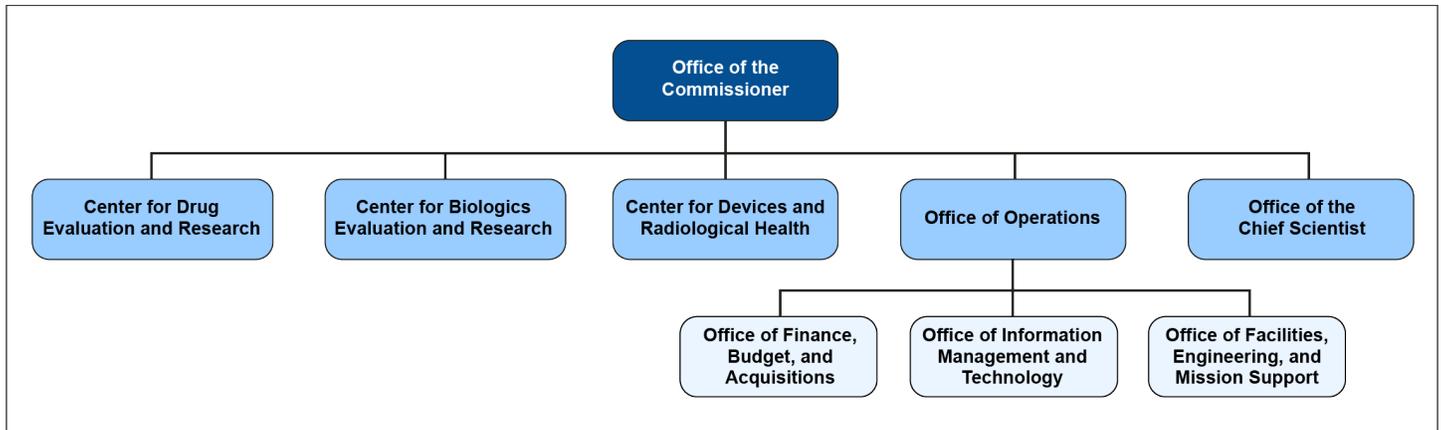
- CDER is responsible for overseeing over-the-counter and prescription drugs, and certain therapeutic biological products.
- CBER is responsible for overseeing original applications for biological products.
- CDRH is responsible for overseeing medical devices and for ensuring that radiation-emitting products, such as microwaves and x-ray machines, meet radiation safety standards.

Together, these three centers comprise a considerable amount of FDA's activities. Specifically, we found that these three centers received 44 percent of FDA appropriations in fiscal year 2019 and supported about 48 percent of FDA's total FTEs in fiscal year 2019, according to FDA's budget justification materials. In addition, as of 2019 these centers managed five laboratories, including 96 physical science suites, 56 biosafety level (BSL) 1 suites, 150 BSL-2 suites, and 10 BSL-3 suites, according to FDA documents.²²

Within FDA, a number of offices provide support for and oversee the three centers' activities, including property and property-related activities. (See fig. 2.) For example, within the Office of the Commissioner, the Office of Operations oversees core agency-wide functions and the Office of the Chief Scientist oversees cross-agency scientific coordination.

²² Laboratories that conduct research on pathogens fall into one of four biological safety levels. Each level of containment describes the laboratory practices, safety equipment, and facility safeguards for the level of risk associated with handling particular agents. According to FDA's documentation, a suite is a laboratory space or several connected spaces that are inspected together.

Figure 2: Organizational Structure of the Food and Drug Administration's (FDA) Oversight and Support for Property and Property-Related Activities at Three Regulatory Centers



Source: Food and Drug Administration. | GAO-20-689

FDA's agency-wide offices and its three regulatory centers share responsibility for overseeing and managing the personal property purchased and used by the three centers; such personal property includes information technology, furniture, office equipment and supplies, and more specialized items such as scientific equipment and laboratory supplies critical to the centers' missions. Regulatory centers share equipment from several laboratories. According to FDA officials, the Shared Resources Committee under the leadership of FDA's Chief Scientist, is responsible for cross-agency coordination of these resources.

FDA plays a limited role in managing the GSA-held and leased office and laboratory space used by the three centers. GSA has custody and control—and thus is the primary steward—of the federally owned real property used by the centers. In this landlord role, GSA acquires, operates, maintains, and disposes of real property.²³ FDA occupies and pays rent for GSA-held and leased space for the three centers at the federally owned White Oak campus and at other facilities in the national capital area, as well as for space at one facility in St. Louis, Missouri.

GSA and FDA have collaborated on a consolidation of FDA staff and contractors in the national capital area. As a result of this consolidation

²³ For leases that GSA procures for tenant agencies such as FDA, GSA serves as the lessee and pays rent to the building's owner, which serves as the lessor. The tenant agency pays monthly rent to GSA, which includes a fee for GSA's services, and uses the leased space subject to the terms of an occupancy agreement with GSA.

jointly funded by GSA and FDA, the three centers conduct nearly all their activities at the White Oak campus. According to FDA's 2018 master plan, the consolidation was intended to create a more efficient and cost-effective agency by increasing use of shared facilities and streamlining operations.²⁴

Leading Practices for Managing Personal and Real Property

Agencies manage assets, which include both personal property and real property,²⁵ to support their organizational strategic planning and sound decision-making with direction from federal laws, guidance, and leading practices. In our prior work, we defined an asset management framework as the processes, procedures, support systems, organizational roles and responsibilities, and policies used to enable asset management decisions.²⁶ Within that report, we illustrated four phases of this framework:

- 1) organizational strategic planning;
- 2) asset management strategy and planning, which includes property planning;
- 3) asset lifecycle delivery, which, in the context of this report, is the property lifecycle and includes operations and maintenance; and
- 4) review, which, for this report, is the review of property performance.

We also developed key characteristics integral to effective asset management. Applying these characteristics to the four phases of the

²⁴ GSA, *2018 Master Plan for the Consolidation of the U.S. FDA Headquarters at the Federal Research Center at White Oak Located in Silver Spring, Maryland* (Silver Spring, MD.: September 2018).

²⁵ The International Organization for Standardization (ISO) defines an asset as any item, thing, or entity that has potential or actual value to an organization. Physical assets usually refer to equipment, inventory, and properties owned by the organization and include real property and personal property.

²⁶ This framework was based on GAO analysis of leading practices. See [GAO-19-57](#). These leading practices included ISO 55000, an international consensus standard that applies to the broadest possible range of assets, organizations, and cultures.

asset management framework can help federal agencies optimize limited funding and make decisions to better target their policy goals and objectives. One key characteristic is using quality information—that is information that agencies have consistently collected, analyzed, and verified the accuracy of.²⁷ This step is necessary to support the organizational strategic planning phase. The critical role of using quality information is also addressed in leading practices established in the ISO 55000 standards and the OMB's Circular A-11 Capital Programming Guide. ISO 55000 standards are leading practices for implementing, maintaining, and improving an effective asset management framework and highlight the importance of quality information for organizational decision-making, including efforts to manage risk.²⁸ OMB's Circular A-11 Capital Programming Guide provides guidance to federal agencies on managing their capital assets.²⁹ Circular A-11 recommends—and in some cases requires—that agencies use information throughout the property's life. For example, the guidance states that quality information contains current, complete, accurate, verifiable, and relevant data that can help the agency to make informed decisions regarding the allocation of resources, among other uses. Further, the guide refers agencies to standards such as ISO 55000 if agencies deem them effective for managing their property.

FDA Obligated Both Regular and User Fee Appropriations for the Three Centers'

²⁷ The other five key characteristics are establishing policies and plans, maximizing an asset portfolio's value, maintaining leadership support, promoting a collaborative organizational culture, and evaluating and improving asset management practices. See [GAO-19-57](#).

²⁸ ISO 55000 consists of three separate standards. Those standards are ISO 55000: 2014 Asset Management—Overview, Principles and Terminology; ISO 55001: Asset management—Management Systems—Requirements; ISO 55002: 2014 Asset Management—Management systems—Guidelines on the application of ISO 55001. For the purposes of our report, we refer to the three standards collectively as ISO 55000 standards.

²⁹ OMB, 2019 *Capital Programming Guide, Supplement V 3.0 OMB Circular A-11, Planning, Budgeting, and Acquisition of Capital Assets*. (Washington, D.C.: 2019)

Personnel, Property, and Other Mission-Related Needs

FDA Obligated Nearly \$14.7 Billion for Three Centers from Fiscal Years 2012 through 2019, with Over Half of These Obligations from User Fees

For fiscal years 2012 through 2019, the combined total funding that FDA obligated for CBER, CDER, and CDRH was \$14.65 billion. (See table 1.) During this period, FDA’s annual obligations for these three centers doubled, from \$1.3 billion in fiscal year 2012 to \$2.6 billion in fiscal year 2019, with an average increase of 10 percent each year. This increase is primarily attributed to the increase in obligations for CDER, which regulates over-the-counter and prescription drugs, including biological therapeutics and generic drugs. During this timeframe, CDER’s obligations increased by \$952 million, and in fiscal year 2019, CDER had approximately \$800 million more obligations than CBER and CDRH combined.

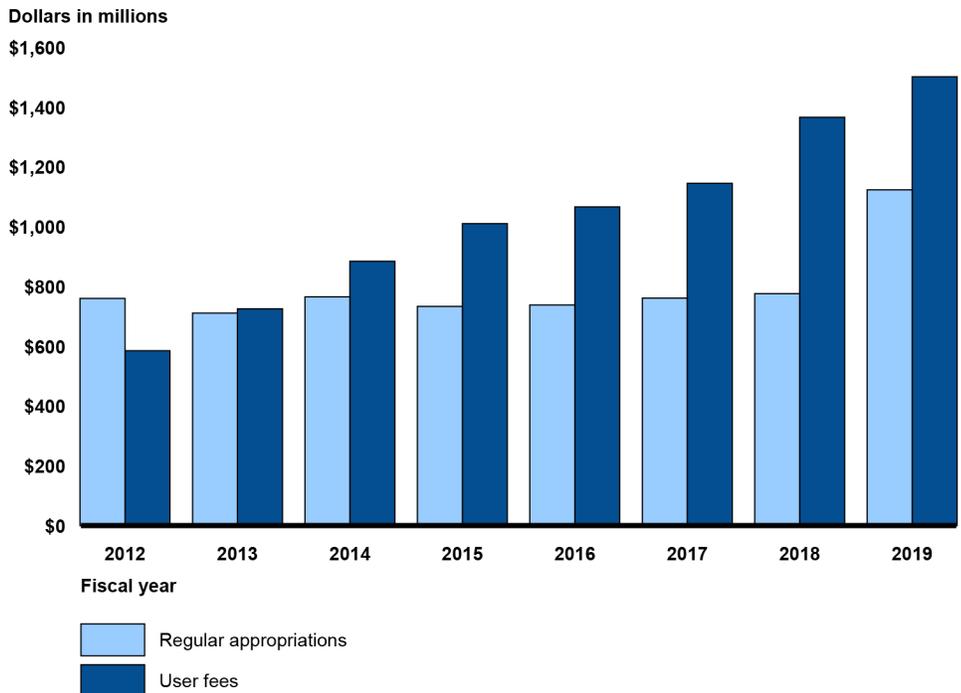
Table 1: Obligations for Three of the Food and Drug Administration’s (FDA) Regulatory Centers for Regular Appropriations and User Fees Combined, Fiscal Years 2012 through 2019

na	dollars in millions								
Regulatory center	2012	2013	2014	2015	2016	2017	2018	2019	Total
Center for Biologics Evaluation and Research	268	255	302	300	305	312	357	427	2,527
Center for Drug Evaluation and Research	765	870	1,009	1,102	1,149	1,241	1,409	1,717	9,263
Center for Devices and Radiological Health	311	311	338	340	349	353	376	480	2,858
Total	1,345	1,436	1,649	1,743	1,803	1,906	2,142	2,624	14,648

Source: GAO analysis of FDA financial data. | GAO-20-689

On average, for fiscal years 2012 through 2019, 56 percent of the three centers’ obligations were from user fees and 44 percent were from regular appropriations. During this timeframe, FDA’s obligations of both regular appropriations and user fees increased. Although in fiscal year 2012, the centers’ obligations from regular appropriations were greater than obligations from user fees, the opposite was the case for fiscal years 2013 through 2019. (See fig. 3.)

Figure 3: Obligations for Three of the Food and Drug Administration's (FDA) Centers by Budget Authority Type, Fiscal Years 2012 through 2019



Source: GAO analysis of FDA financial data on obligations. | GAO-20-689

Note: The figure includes obligations data from three FDA regulatory centers: Drug Evaluation and Research, Biologics Evaluation and Research, and Devices and Radiological Health.

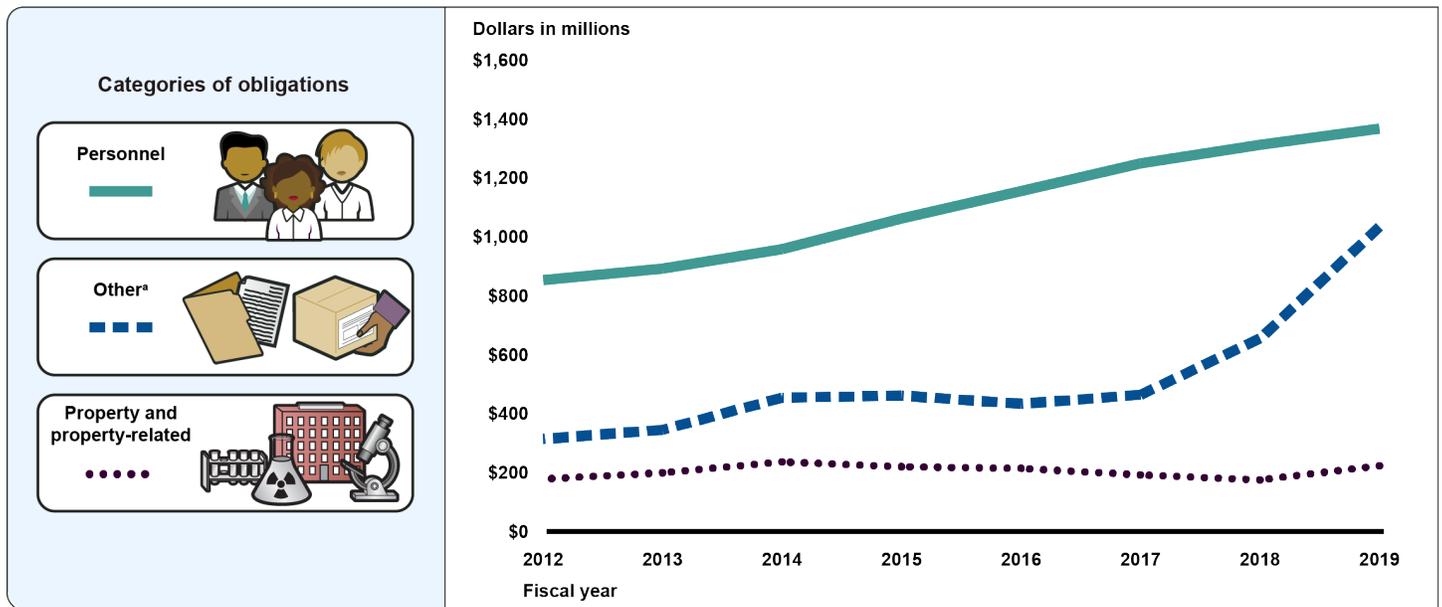
Personnel Represented about Two-Thirds of the Centers' Total Obligations, with Over Half of These Obligations from User Fees

For fiscal years 2012 through 2019, obligations for personnel averaged 61 percent of FDA's total annual obligations for the three centers. Property and property-related expenses represented 12 percent, and other expenses (e.g., research and development contracts) represented 27 percent of FDA's total annual obligations for the three centers during this period.³⁰ (See fig. 4.) Over half of the centers' obligations for personnel were from user fees with the balance coming from regular

³⁰ The other category includes obligations on advisory and assistance services, other goods and services from federal and non-federal sources, research and development contracts, grants and fixed charges, and shipping.

appropriations. Although property and property-related expenses represented only 12 percent of FDA’s total annual obligations for the three centers for fiscal years 2012 through 2019, new statutory limitations could alter how the centers obligate funds for these types of expenses.

Figure 4: Obligations for Three of the Food and Drug Administration’s (FDA) Centers by Category, Fiscal Years 2012 through 2019



Source: GAO analysis of FDA financial data on obligations. | GAO-20-689

Notes:

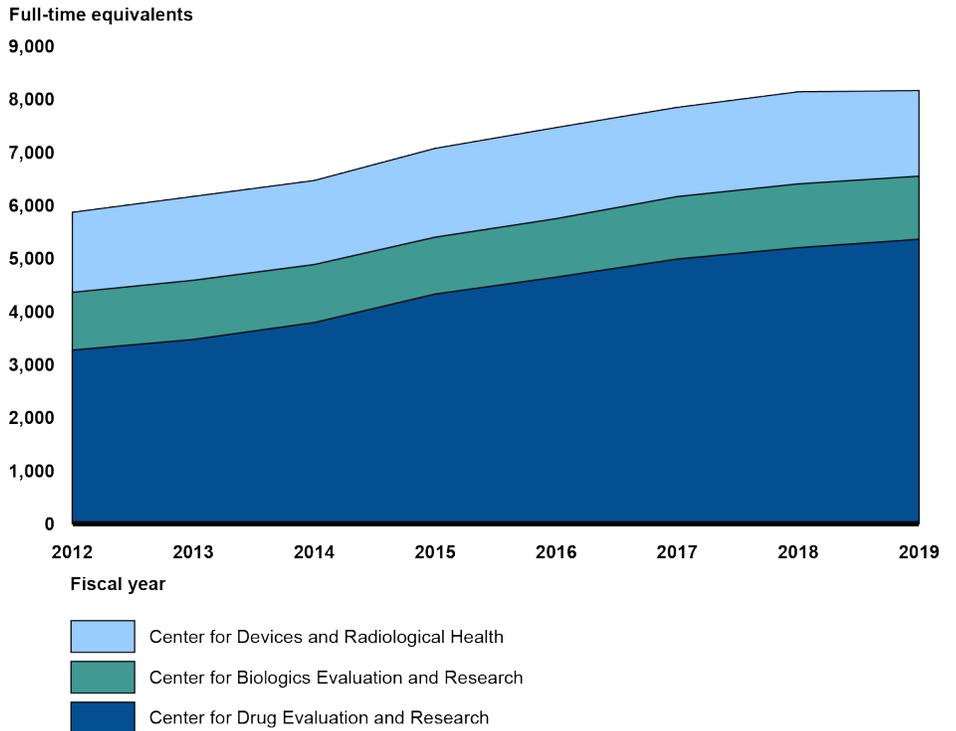
The figure includes obligations data from three FDA regulatory centers: Drug Evaluation and Research, Biologics Evaluation and Research, and Devices and Radiological Health.

The other category includes obligations on advisory and assistance services, other goods and services from federal and non-federal sources, research and development contracts, grants and fixed charges, and shipping.

The increase in obligations for personnel from fiscal years 2012 through 2019 was due in part, to FDA’s hiring of several thousand staff. According to FDA’s budget justification materials, the centers’ number of FTEs increased by 39 percent during this timeframe (see fig. 5). Those same documents show that, in fiscal year 2019, CDER supported 5,362 of the total 8,165 FTEs supported by the three centers. As we reported in 2016, increased user fees and the accompanying commitments to increase the

number of FTEs that FDA negotiated with industry have been key drivers of FDA's staffing growth in recent years.³¹

Figure 5: Full-time Equivalent Positions Supported by Three of the Food and Drug Administration's (FDA) Centers, Fiscal Years 2012 through 2019



Source: GAO analysis of FDA annual *Justification of Estimates for Appropriations Committees*. | GAO-20-689

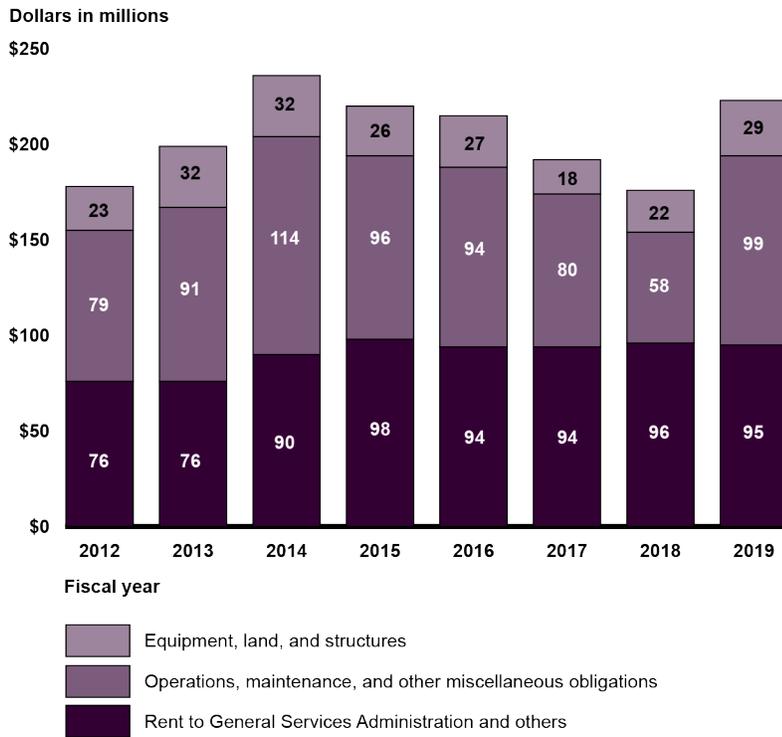
Rent Represented, on Average, Nearly Half of the Centers' Property Obligations, and Property Obligations Were Mainly from Regular Appropriations

For fiscal years 2012 through 2019, obligations for rent to GSA and others averaged 44 percent; operations, maintenance, and other

³¹ GAO, *FDA Facilities: Planning Efforts for White Oak Campus Should Further Incorporate Leading Practices to Address Ongoing Challenges*, [GAO-17-87](#) (Washington, D.C.: Dec. 7, 2016).

miscellaneous obligations averaged 43 percent;³² and equipment, land, and structures averaged 13 percent of FDA’s total property and property-related obligations for the three centers. During this timeframe, obligations for all three categories increased. (See fig. 6.)

Figure 6: Property and Property-Related Obligations for Three of the Food and Drug Administration’s (FDA) Centers, Fiscal Years 2012 through 2019



Source: GAO analysis of FDA financial data on obligations. | GAO-20-689

Notes:

The figure includes obligations data from three FDA regulatory centers: Drug Evaluation and Research; Biologics Evaluation and Research; and Devices and Radiological Health.

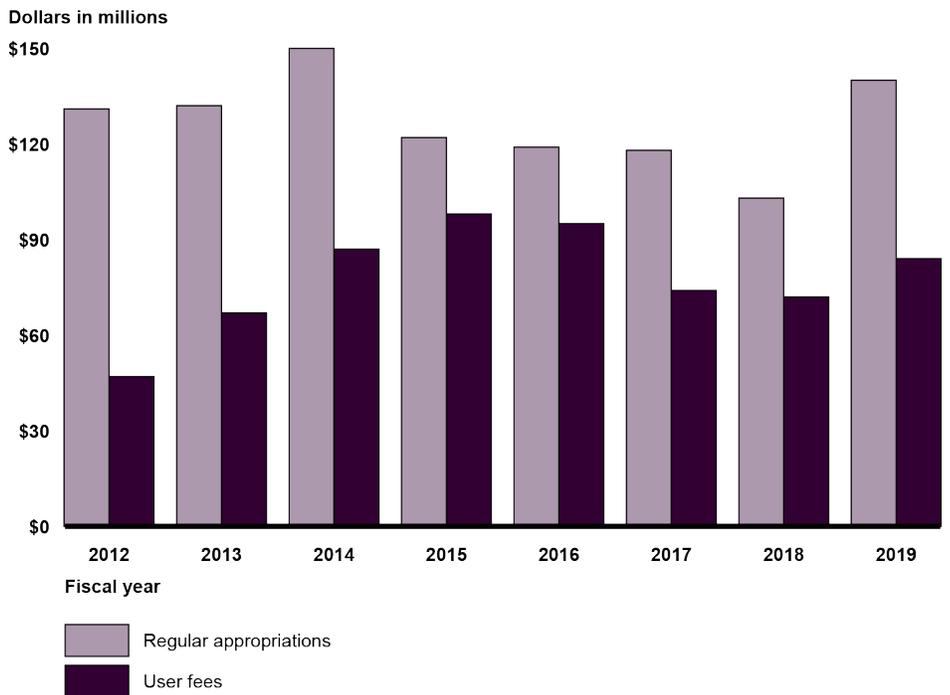
During this timeframe, on average 62 percent of these obligations were from regular appropriations and 38 percent were from user fees.

For fiscal years 2012 through 2019, the three FDA centers obligated more regular appropriations than user fees for property and property-related purposes. On average per fiscal year 2012 through 2019, 62 percent of the three centers’ property and property-related obligations were from

³² The operations, maintenance, and other miscellaneous obligations category includes operation and maintenance of facilities and equipment, communications, utilities, miscellaneous charges, and supplies and materials.

regular appropriations and 38 percent were from user fees. During this timeframe, property and property-related obligations of both regular appropriations and user fees fluctuated but increased from fiscal year 2012 to 2019. The proportion of obligations of each type of budget authority varied from year to year. (See fig. 7.) Taken together, rent to GSA and others, as well as operations, maintenance, and other miscellaneous obligations made up the majority of FDA's total annual property and property-related obligations for the three centers.

Figure 7: Property and Property-Related Obligations for Three of the Food and Drug Administration's (FDA) Regulatory Centers by Budget Authority Type, Fiscal Years 2012 through 2019



Source: GAO analysis of FDA financial data on obligations. | GAO-20-689

Note: The figure includes obligations data from three of the FDA's regulatory centers: Drug Evaluation and Research, Biologics Evaluation and Research, and Devices and Radiological Health.

Agencies Did Not Consistently Use Quality Information to Manage Real and Personal Property Used by Three FDA Centers

FDA Did Not Have Formal Policies for Centers That Address the Use of Quality Information to Manage Personal Property

FDA and the three regulatory centers we reviewed did not consistently use quality information about personal property to support sound decision-making across three phases of asset management, because they did not have formal policies to do so. As discussed above, using quality information—that is asset information that agencies consistently collect, analyze, and verify the accuracy of—to make decisions is a key characteristic integral to effective asset management. Agencies have flexibility in determining the type of information required to achieve their objectives, such as information on inventory, condition, maintenance, repair, and the extent to which the agency establishes and measures progress:³³

Centers Did Not Consistently Use Quality Information

We found the centers did not consistently use quality information when: (1) planning for personal property needs; (2) operating and maintaining personal property; and (3) reviewing personal property performance.

Planning for personal property needs. According to officials, researchers at the three centers identified their personal property needs based on their research objectives or individual projects, and then listed those needs in research proposals for center managers to review and prioritize. However, center staff conduct these activities differently within and among centers, potentially resulting in inconsistent asset information to identify the personal property needed to achieve their mission-related goals. For example, officials from CDER and CDRH stated that managers, such as laboratory directors, reviewed the age of equipment the centers already owned when identifying what needed to be

³³ See [GAO-19-57](#) for discussion of leading practices, ISO 55000, and key characteristics of an asset management framework.

replaced.³⁴ By contrast, a CBER official stated that one senior manager, in consultation with subject matter experts, reviewed equipment requests above \$150,000 to confirm that the center needed to purchase the equipment to achieve its research goals.

We also found that center managers did not consistently use quality information to prioritize personal property needs or link these decisions to the centers' mission-related goals. FDA and center officials stated that once researchers and managers identified personal property needs, center managers were to prioritize those needs. According to FDA officials, FDA's Office of Budget worked with center managers to develop annual budget priorities, which included personal property. However, based on interviews with center officials we found that they did not consistently set priorities for the centers' personal property or link property decisions to either FDA's or the centers' mission-related goals.³⁵ According to CBER officials, in 2019 the center initiated a new asset-planning system that linked its personal property priorities to the center's goals.³⁶ By contrast, CDER staff said they only occasionally linked personal property needs to the center's goals during budget reviews. CDRH officials said they link personal property needs to the center's goals and prioritized based on what the center could afford but did not provide documentation of these processes.

Operating and maintaining personal property. We found instances where FDA or center officials documented or described operations and maintenance information they collected about some types of personal property but did not use it to ensure existing equipment met agency needs. For example, according to center officials, FDA has established—and center staff follow—policies to support operating and maintaining some personal property, such as for the agency's information technology

³⁴ According to CDRH, its Office of Science and Engineering Laboratories created the Property Lifecycle Management Database to track the location of laboratory equipment, maintenance agreements, repairs and software used on equipment. CDRH and the other centers also used HHS's Personal Property Management Information System to track the inventory of their accountable personal property. Accountable property is a subset of personal property. FDA defines accountable property as personal property that has an acquisition cost of \$5,000 or more, or that is sensitive, particularly to theft or loss.

³⁵ The term mission-related goals refers to what FDA and the centers' mission-related planning documents call strategic goals, strategic priorities, or objectives.

³⁶ CBER's Biologics Planning, Execution, and Reporting System (BPERS) assists with budget execution, payroll planning, budget and acquisition planning, and reporting. According to center officials, BPERS went online in 2019.

hardware, including computers. We found other examples in which center staff tracked lab equipment use or tracked the costs to maintain and repair equipment in accordance with the manufacturer's recommendations.

Example of Laboratory Equipment Shared by Two Regulatory Centers

The Center for Biologics Evaluation and Research (CBER) and Center for Drug Evaluation and Research (CDER) share a high-field nuclear magnetic resonance spectrometer. This equipment allows researchers to analyze the molecular structure of complex biological products by observing and measuring the interaction of nuclear movement when researchers place a sample in a powerful magnetic field. According to CBER officials, the center tracked and reported on the spectrometer's operations and maintenance.



Source: Food and Drug Administration. | GAO-20-689

However, across and within the centers, staff did not consistently collect and use information about laboratory equipment and other property needed to achieve the centers' missions, and they differed in their use of the information they did collect. For example, CDRH staff tracked equipment maintenance agreements, repairs, and equipment software with their Property Lifecycle Management Database. CDRH officials said that they used this information to assess the equipment service contracts and maintenance costs and lab managers used the information to assess equipment performance but did not document the assessments. By contrast, CDER officials stated they did not use information regarding personal property operations and maintenance across CDER's offices. CDER officials stated that its Office of Pharmaceutical Quality, which oversees some labs on FDA's White Oak campus, has considered the age of equipment, use, and cost, among other factors, when determining whether to maintain, repair, or replace existing equipment, unlike other CDER offices. Moreover, CBER officials said that they generally did not collect maintenance data on personal property, although some purchase contracts for expensive equipment included maintenance agreements. For example, CBER officials provided a document for a spectrometer that the center operated and shared with CDER (see side bar). This document states the center is responsible for tracking and reporting operations and maintenance information for the spectrometer CBER shares with CDER to maximize the return on the agency's investment, which is in line with an effective asset management framework and OMB's operations and maintenance planning guidance.³⁷

Reviewing personal property performance. We found that the three centers did not use quality information about personal property for establishing and measuring progress toward a specific goal, to support

³⁷ OMB's *Capital Programming Guide* states that an operations and maintenance plan should include tracking of labor and material costs, training of staff for preventive maintenance, and budget expenditures for maintenance and repair.

decision-making regarding personal property performance.³⁸ For example, CDRH officials said laboratory staff were responsible for reviewing lab equipment performance and use, but did not provide details on how CDRH staff would use quality information about equipment performance to support decision-making. In addition, documentation CDRH officials provided did not include written guidance describing staff responsibilities, the information to be collected, or how the information would be used. In addition, in our review of CBER's documentation we found that the center's new asset-planning system did not record or track personal property performance measures. CDER officials from two offices that oversee laboratories described inconsistent approaches to collecting and using information about personal property performance and documented the reviews inconsistently. In one office, officials stated their performance reviews were informal, as they did not occur on a set schedule and staff did not document them. In another CDER office, officials stated they reviewed equipment to determine how often it was used and if it was fulfilling its purpose. However, they did not provide documentation to support this practice.

Centers Did Not Have Formal Policies for Consistently Managing Personal Property

The centers did not use quality information about personal property—a key characteristic integral to effective asset management because they did not have formal policies to do so. Neither FDA nor the centers had detailed formal policies requiring center staff to use quality information related to these three phases of asset management for all personal property critical to achieving the centers' missions. FDA has established high-level guidelines for collecting information on some types of laboratory equipment critical to scientific operations; this information includes three brief bullets on managing, maintaining and establishing qualifications for operating equipment.³⁹ However, when we asked center officials to describe and provide copies of policies related to asset

³⁸ "Performance" here refers to a range of information used in performance management, including: performance targets developed during planning and acquisition; usage rates; property cost from purchase through maintenance to disposal; and user satisfaction.

³⁹ Food and Drug Administration, *Guidelines for Establishing a Laboratory Quality Management System* (March 2019). These guidelines establish that proper equipment management is essential to preserve equipment performance, decrease repair costs, and increase equipment lifespan, among other benefits. FDA's Office of Laboratory Science and Safety developed these guidelines as required by FDA's Staff Manual Guide 2130.11, whose purpose is to produce quality scientific research; laboratory equipment management is secondary.

management, they neither mentioned nor provided a copy of these guidelines or described their implementation.

According to FDA officials, neither FDA nor the centers had developed or planned to develop additional policies or processes for consistently collecting, analyzing, and verifying the accuracy of information about personal property. One FDA official stated that FDA has the ability to produce standardized responses to data calls if HHS officials requested them. Nonetheless, the capacity to respond to data calls is not a substitute for having formal policies for collecting and using consistent information. As we previously reported, formal policies and plans that lay out how the agency conducts asset management activities, including the use of quality information, can help agencies ensure assets, such as personal property, support their missions and strategic objectives.⁴⁰ We have also made recommendations to OMB and GSA to provide agencies with guidance to improve personal property management, such as by using information on operating conditions to identify unneeded or idle property. These recommendations have not been implemented.⁴¹

In addition to not having formal policies, center officials did not consistently use quality information about personal property because they did not see the importance of this information to maximizing value from the centers' personal property and thereby reducing risks from potential changes in resources in the future. For example, center officials said they have had adequate funding to address their personal property needs, including purchasing and maintaining it. CDRH and CBER officials said that their primary concerns were growth in staffing and increased workload, not personal property. However, regardless of the level of funding, FDA and the centers have a responsibility to make good use of government resources. In addition, the potential for decreased funding flexibility for property expenditures in the future makes the need to develop an approach to consistently collect, analyze, and verify the

⁴⁰ In 2018, we reported that using quality information when making decisions about assets can help agencies ensure that they get the most value from their assets. See [GAO-19-57](#).

⁴¹ GAO, *Federal Personal Property: Opportunities Exist to Improve Identification of Unneeded Property for Disposal*, [GAO-18-257](#) (Washington, D.C.: Feb. 16, 2018). We recommended that OMB provide guidance to executive agencies on managing their property, emphasizing that agencies' policies or processes should reflect the requirement to continuously review and identify unneeded property. See also, *Federal Property: GSA Guidance Needed to Help Agencies Identify Unneeded Property in Warehouses*, [GAO-20-228](#) (Washington, D.C.: Dec. 20, 2019), in which we recommended that GSA establish and communicate guidance for agencies to assess utilization of and need for property.

accuracy of information related to these three phases of asset management more urgent.

Also, FDA and the centers' strategic-planning documents did not generally reflect how investment in personal property contributed to achieving the centers' strategic goals and objectives.⁴² For example, while FDA's and CBER's strategic-planning documents discuss the importance of some information technologies to achieving their mission-related goals, none of the plans we reviewed discussed how the use of other types of personal property contribute to achieving the centers' goals. Further, of the five strategic planning documents we reviewed, only CBER's plan addressed how the center was to manage risks associated with some of its personal property to prevent, for instance, laboratory accidents that effect researchers' well-being and safety.⁴³ However, none of the plans discussed collecting or using information on risks, such as personal property failure, even though this property, such as laboratory equipment, is essential to achieving the centers' mission. OMB's Circular A-11 states that an agency's strategic plan should include information, and other resources that are critical to mission delivery.⁴⁴

By not following leading practices for using quality information in decision-making, agencies may face some risks. For example:

- **Planning for personal property needs.** Without quality information, FDA leadership may not be able to: (1) provide transparency on its personal property needs (e.g., upgraded scientific equipment) during negotiations with regulated industries and public stakeholders regarding user fees to be charged to the regulated industries included in FDA's next reauthorization; (2) plan for potential changes in resource levels, such as when limitations go into effect on obligating user fees for personal property; or (3) effectively prioritize where to spend resources.⁴⁵ For example, FDA has invested in modernizing the process staff

⁴² See appendix II for a complete list of the strategic planning documents and plans we reviewed.

⁴³ In line with FDA's mission to protect public health, each of the documents we reviewed discussed the agency or center's efforts to manage or reduce risks to patient or public health.

⁴⁴ OMB, *2019 OMB Circular A-11, Preparation, Submission, and Execution of the Budget* (Washington, D.C.: June 2019).

⁴⁵ [GAO-19-57](#) and OMB, *Capital Planning Guide*.

use to report time spent on individual tasks. This modernization is intended to improve the accuracy of information on what tasks individual personnel perform.⁴⁶ This information could then be used to inform planning for personal property. For example, FDA could use information on tasks that personnel perform (e.g., scientific research, which requires specialized personal property) to identify personal property needs and plan for new staff hires.⁴⁷ However, according to officials, none of the three centers planned to use this information in planning for personal property needs.⁴⁸ We reported in 2018, that more centralized decision-making processes can provide improved standardization and clarity in the prioritization process, particularly for high value projects, and can help ensure that mission-critical projects receive funding.⁴⁹ Finally, without effective planning for personal property needs, FDA and the office responsible for fostering development and use of innovative technologies risk overlooking changes in the agency's needs and missing opportunities to use emerging technologies for more efficient review procedures or reduced staffing levels.⁵⁰

- **Operating and maintaining personal property.** Without quality information, centers may not properly manage their personal property's useful life, which can be shortened at potentially high cost and risk, thereby reducing the return on investment or jeopardizing achievement of mission-related goals. For example, a

⁴⁶According to FDA, staff time reporting could help ensure that FDA is optimizing its financial resources to deliver on its commitments to the public. Food and Drug Administration, *Resource Capacity Planning and Modernized Time Reporting Implementation Plan* (March 2018). FDARA directed FDA to contract for a report evaluating options and recommendations for a new methodology to assess resource and capacity needs in the review of human drug and biosimilar biological product applications, using personnel time reporting data. Pub. L. No. 115-52, §§ 102(c), 403(c), 131 Stat. at 1010, 1032 (codified at 21 U.S.C. §§ 379h(c)(2)(C)(i), 379j-52(c)(2)(B)(i)).

⁴⁷ As previously noted, FDA's 2017 user fee reauthorization includes additional limitations for which purposes FDA may obligate funds for certain property and property-related expenditures beginning in October 2023. See FDARA, Pub. L. No. 115-52, § 905(b), 131 Stat. at 1089-90.

⁴⁸ Food and Drug Administration, *Resource Capacity Planning and Modernized Time Reporting implementation Plan*, (March 2018).

⁴⁹ [GAO-19-57](#).

⁵⁰ FDA's Office of Regulatory Science and Innovations within the Office of the Chief Scientist is responsible for fostering the development and use of innovative technologies in the agency. OMB's Circular A-11 recommends that staffing requirements be based on assumptions that increases in productivity, including from investments in information technology, should result in lower personnel requirements.

document provided by CDER officials shows that the center underfunded maintenance and repairs of scientific equipment in previous years because center staff had incomplete information on repair costs. Further, according to FDA and center officials, FDA contract managers systematically tracked maintenance and repair information for some personal property through two maintenance contracts—one for laboratory equipment and one for above-standard equipment.⁵¹ FDA officials told us that not all laboratory equipment falls under these contracts, that center staff decide whether to use these contracts, and that FDA does not track maintenance and repair costs for this other equipment. However, neither FDA nor the centers have policies to guide decisions on the dollar value or type of equipment they do and do not track maintenance and repair costs for, other than for information technology.

- **Reviewing personal property performance.** Without quality information, FDA may not be able to ensure it is maximizing value from the centers' personal property in support of agency mission-related goals.⁵² Further, FDA risks poorly allocating resources and limiting its ability to compare actual and planned results in efforts to improve its planning process.⁵³

In addition, absent consistent quality information on its personal property, FDA may find it difficult to prioritize proposals for shared equipment. The centers also may have difficulty reporting to FDA-level offices on the following:

- (1) whether the White Oak consolidation led to greater efficiency and effectiveness through streamlined operations and the use of shared facilities as stated in FDA's master plan for consolidation at White Oak,⁵⁴ and

⁵¹ CBER is solely responsible for 82 percent of the 2,414 items under this maintenance contract used by the three centers we reviewed.

⁵² [GAO-19-57](#).

⁵³ OMB *Capital Programming Guide*.

⁵⁴ Food and Drug Administration, *2018 Master Plan for the Consolidation of the U.S. FDA Headquarters at the Federal Research Center at White Oak Located in Silver Spring, Maryland.*, (September 2018).

(2) accurate information on personal property to inform FDA's negotiations of user fee rates with regulated industries.

FDA and GSA Used Information to Manage Real Property Used by the Centers, but There Are Gaps in GSA's Assessments of Some Sensitive Facilities

FDA used quality information to manage real property at the three regulatory centers to support strategic planning and decision-making. For its part, GSA has assessed the condition of much, but not all, of the real property at these facilities. FDA and GSA both play a role in keeping the office spaces and laboratories that house the three centers in good working order so that they continue to support the centers' missions. As previously discussed, GSA has custody and control of and manages real property such as the office and laboratory space these centers use. FDA pays rent to GSA, and uses the space subject to the terms of occupancy agreements.

An Example of Tenant Improvements at a Food and Drug Administration (FDA) Laboratory

FDA is responsible for costs associated with tenant improvements above the standard ones the General Services Administration provides, such as this cold room unit, located in an FDA laboratory.



Source: Food and Drug Administration. | GAO-20-689

According to FDA officials, to achieve FDA's mission to protect public health, all GSA-held and leased space FDA occupies requires "tenant improvements"—modifications to the standard facilities and services that GSA provides. GSA includes a tenant improvement allowance as part of the rent FDA pays to GSA for occupying a facility. It is standard practice for tenant agencies to amortize the costs of tenant improvements over the lease term, an approach similarly used in the private sector, according to GSA officials. However, in some instances, FDA requires improvements above the standard that GSA provides that are not covered by this allowance, which GSA refers to as "above-standard." According to agreements with and guidance from GSA, FDA is financially responsible for these tenant improvements to GSA-held and leased space (e.g.

construction, operation, maintenance, and replacement of assets), as well as for additional needed services (e.g., utilities).⁵⁵

As discussed above, effective property management requires using quality information to support agencies' organizational strategic planning and sound decision-making. As with personal property, it is important that FDA use quality information to manage real property used by the centers,⁵⁶ including (1) planning for real property needs and (2) operating and maintaining real property.⁵⁷

Planning for real property needs. We found that FDA used quality information to identify and prioritize its real property needs based on the agency's strategic goals. Since fiscal year 2014, FDA has developed an annual 5-year strategic facilities plan to align its decisions and activities related to real property with the agency's strategic goals, and to identify and prioritize its real property needs.⁵⁸ FDA's Office of Facilities, Engineering, and Mission Support Services (OFEMS) has developed the annual plan through a systematic process. According to FDA officials, OFEMS coordinated with centers and the Office of Financial Budget and Acquisition to identify and prioritize real property needs according to available resources. OFEMS then summarized the most important information for each center for inclusion in the planning document.

In its *Five Year Strategic Facilities Plan for 2020-2024*, FDA identified addressing space constraints as a priority real property need for the three centers, given the potential for increases in FTEs after the next user-fee reauthorization in 2022. In 2016, FDA officials reported challenges in managing office space at the White Oak campus, due in part to staff growth, delayed construction of two planned office buildings, and OMB's space efficiency initiatives.⁵⁹ To accommodate more staff, FDA

⁵⁵ For costs in excess of the allowance, FDA may use agreements called "reimbursable work authorizations" to reimburse GSA for the provision of goods and services, indirect costs, and GSA fees associated with these "above standard" modifications.

⁵⁶ See [GAO-17-87](#).

⁵⁷ Once installed, the tenant improvements for which FDA is financially responsible function as part of the facility as a whole. Consequently, we determined that reviewing the performance of real property used by the centers fell solely under GSA's purview, and we did not include it in our assessment.

⁵⁸ The most recent version is FDA's *Five Year Strategic Facilities Plan for 2020-2024* (September 2019).

⁵⁹ For more information about these initiatives, see [GAO-17-87](#).

implemented telework and alternative office strategies (i.e., desk sharing, office sharing, and hoteling). Even with plans to increase the concentration of staff assigned to the centers' existing office space and laboratories through 2024, FDA projected it would need privately owned, leased space in the national capital area to house an additional 1,400 staff. Continuing to use quality information to plan for and make sound decisions about the centers' space needs can help ensure that FDA effectively manages this challenge.

Operating and maintaining real property. We found that FDA and GSA use quality information about the operations and maintenance of facilities occupied by the centers. FDA and GSA officials said that GSA was responsible for most operations and maintenance at these facilities, including conducting condition assessments of real property.⁶⁰ FDA has played a supporting role in managing the facilities the centers use, such as by sharing with GSA occupancy and square footage information FDA calculated for its strategic facilities plan, according to FDA officials. In addition, FDA developed a list of all above-standard FDA mission-related equipment at the White Oak campus that FDA maintains and repairs by contracting with a private sector vendor.⁶¹

According to GSA officials, from September 2017 through May 2018 GSA formally assessed the condition of seven of the 13 White Oak facilities used by the centers. GSA engaged contractors to conduct these assessments through building-engineering reviews that identify immediate, intermediate, and long-term repair needs and improvements. GSA officials said that when funds for such reviews are not available, GSA instead relies on its management staff to collect information during their daily tours and inspections of the property and with operations and maintenance contractors.

GSA's formal and informal assessments informed its 5-year strategic asset investment-planning document, which GSA asset managers

⁶⁰ Among other things, an executive agency is required under 40 U.S.C. § 524(a)(11) to conduct an inventory of and assess real property under "control" of the executive agency. Here, GSA maintains custody and control over the real property that the centers use. Accordingly, GSA is responsible for conducting an inventory and assessing the condition of the White Oak facility.

⁶¹ According to FDA officials, some above-standard equipment is real property, but most is personal property that is real property related. For example, a temperature-controlled cold room unit used by CDRH is a tenant improvement to GSA's shell facility and considered real property, according to FDA officials.

formulate and update each year, according to GSA officials. The officials said that the planning document lists all the deficiencies and the timing for addressing the deficiencies within the next 5 years. GSA's asset team then consolidates, analyzes and prioritizes proposed repair and alteration projects for GSA regional and central Office approval, according to officials.

However, we found there are some gaps in the condition assessments GSA is using to make these determinations. GSA officials told us that their assessments did not include some areas—such as CBER's 10 BSL-3 laboratory suites.⁶² Moreover, we found that GSA's building-engineering reviews did not assess the condition of some tenant improvements—such as epoxy flooring and paint.

According to GSA officials, they can only conduct building-engineering reviews of areas FDA makes accessible. The officials stated that the team conducting the reviews was unable to access and observe numerous areas the centers use—including most laboratories—due to FDA restrictions. FDA restricts access to such facilities for safety and security concerns.⁶³ Additionally, FDA officials said these condition assessments were not necessary, as the centers have had minimal real-property repair needs in office buildings at the relatively new White Oak campus. However, when we raised the issue of GSA's lack of access, FDA officials contacted GSA. FDA officials reached out to GSA to offer to coordinate access for GSA teams to gain access to restricted areas to observe and conduct their reviews. Federal law requires, among other things, that agencies inventory and assess real property on an annual basis, including the age and condition of the property, the extent to which it is being utilized, and the estimated amount of capital expenditures projected to maintain and operate the property.⁶⁴ Furthermore, according to GSA guidance implementing these statutory requirements, there is

⁶² BSL-3 laboratories work with indigenous or exotic agents with known potential for airborne transmission or pathogens that may cause serious and potentially lethal infections.

⁶³ According to FDA's 2017 *Biosafety and Biosecurity Framework*, for some laboratories (e.g., BSL-3 laboratories), biometric access logs are maintained electronically and visitor logs are maintained manually. Additionally, the entrance and exit of all personnel including authorized personnel is recorded either electronically or manually.

⁶⁴ 40 U.S.C. § 524(a)(11). GSA requires certain elements to be reported only for federally owned property.

value in conducting condition assessments even of relatively new facilities.⁶⁵

Without complete condition assessments of real property used by the centers including tenant improvements, FDA and GSA officials may not have the information they need to determine the risk to mission priorities, estimate repair costs, and prioritize investments. If FDA budgets too few resources for repairing tenant improvements used by the centers, it may not be able to keep that property in a good state of repair to meet mission needs. If FDA budgets too many resources, it might not be able to allocate sufficient resources to higher-priority needs.

Conclusion

To achieve its mission, make sound decisions about the use of its funding, and meet its commitments to regulated industries, FDA has a responsibility to effectively manage its personal property and real property. Using quality information—that is asset information that the centers have consistently collected, analyzed, and verified the accuracy of—can help ensure that FDA and the centers make sound decisions and maximize the value of their property. It is especially important for FDA to use quality information to plan how it will manage its property in light of:

- increasing demand for its services,
- impending negotiations with regulated industries and public stakeholders,
- the start of the next user fee reauthorization cycle in 2022, and
- additional limitations on FDA’s obligation of funds for certain property and property-related purchases beginning in October 2023.

We found that FDA and three of its regulatory centers did not consistently use quality personal property information to support decision-making. We also found gaps in the information GSA collects for condition assessments of sensitive FDA-occupied facilities. FDA officials stated that they have reached out to GSA offering to coordinate access to these facilities. While this step is a good beginning, GSA has primary

⁶⁵ GSA Federal Real Property Council, *2020 Guidance for Real Property Inventory Reporting*, (Washington, D.C. June 10, 2020)

responsibility for these facilities and it is important that GSA take additional action to gain access and assess the condition. Without quality information about personal property and information from complete condition assessments for the real property it uses, FDA may not be able to plan for or respond to changes in its budget authority, strategic goals, or commitments to industry. Specifically, the centers may not be able (1) to provide transparency about how investment in property contributes to achievement of the centers' missions, (2) effectively manage their property's useful life, and (3) make the best use of funding without formal policies for using quality information to manage the centers' personal property. While the real property used by the centers is fairly new—particularly at the centers' primary location on the White Oak campus—complete condition assessments are important to determine the risk to mission priorities and prepare for inevitable repair and replacement costs.

Recommendations for Executive Action

We are making three recommendations to the Commissioner of FDA and one recommendation to the Administrator of GSA.

The Commissioner of FDA should establish and implement formal policies to use quality information (e.g., linking decisions to mission-related goals) in the three centers' planning for their personal property needs, consistent with key characteristics integral to asset management leading practices. (Recommendation 1)

The Commissioner of FDA should establish and implement formal policies to use quality information (e.g., tracking condition, and maintenance and repair costs) in the three centers' operations and maintenance of personal property, consistent with key characteristics integral to asset management leading practices. (Recommendation 2)

The Commissioner of FDA should establish and implement formal policies to use quality information (e.g., measuring and documenting performance) in the three centers' reviews of personal property performance, consistent with key characteristics integral to asset management leading practices. (Recommendation 3)

The Administrator of GSA should take steps to ensure that the condition of all White Oak facilities that FDA occupies are assessed, including limited access areas and tenant improvements that are above the standard services and facilities that GSA provides. (Recommendation 4)

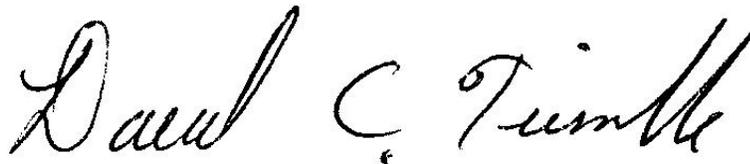
Agency Comments

We requested comments on a draft of this product from the Department of Health and Human Services (HHS) and the General Services Administration (GSA). Both agencies concurred with our recommendations. HHS and GSA provided comments, which are reproduced in full in appendices III and IV, respectively. HHS also provided technical comments, which we incorporated as appropriate.

HHS stated it plans to develop standard operating procedures related to personal property for FDA's medical-product regulatory centers to address three of our recommendations. GSA stated it will work more closely with FDA to survey and inspect all spaces at FDA's White Oak campus facilities to address the recommendation we made to GSA.

We are sending copies of this report to the appropriate congressional committees, the Secretary of the Department of Health and Human Services, the Administrator of the General Services Administration, and other interested parties. In addition, the report is available at no charge on the GAO website at <https://www.gao.gov>.

If you or your staff have any questions about this report please contact either David Trimble at (202) 512-2834 or Trimbled@gao.gov or Kristen Kociolek at (202) 512-2989 or Kociolekk@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix V.



David Trimble
Director, Physical Infrastructure



Letter

Kristen Kociolek
Director, Financial Management and Assurance

Appendix I: The Food and Drug Administration's (FDA) User Fee Programs for Human Medical Products

FDA's oversight of human medical products' safety is funded in part through user fees.¹ User fees are charges assessed to beneficiaries for goods or services provided by a public agency, such as FDA.² The FDA has statutory authority both to collect fees and to use or obligate the collections, to the extent and in the amount provided in advance in annual appropriations acts.

FDA obligates user fees at the end of a multi-step process that is authorized by federal statutes. Every 5 years, FDA negotiates performance goals, program enhancements, and user fees' collection amounts with regulated industries.³ FDA enters these negotiations with information from its annual user fee performance reports and other data (e.g., facilities usage and personnel costs.)The result is a letter for each user fee program transmitted to Congress. In these letters FDA commits to performance goals and program enhancements. For example, FDA might agree to review and act on a certain number of generic drug applications within a certain timeframe or to increase the number of its

¹ FDA is funded through budget authority provided in annual appropriations acts, including regular appropriations derived from the General Fund of the Treasury and user fees that FDA negotiates with and collects from regulated industries (e.g., drug, biological product, and medical device manufacturers).

² Agencies derive their authority to charge user fees either from the Independent Offices Appropriations Act of 1952 or from a specific statutory authority. Separate authority is needed for an agency, like the FDA, to retain and obligate collected fees. See GAO, *Federal User Fees: Key Considerations for Designing and Implementing Regulatory Fees*. [GAO-15-718](#), (Washington, D.C.: September 2015).

³ In addition to negotiations with industry, FDA receives input from public stakeholders (e.g. academic experts and patient and consumer advocacy groups) FDA has committed to performance goals such as timeframes within which FDA is to take action on submissions, hiring additional staff, and modifying processes and procedures to achieve better outcomes.

full-time equivalents by a certain amount.⁴ These “commitment letters” inform Congress’ reauthorization of the user fee programs. The reauthorizations in turn provide the statutory frameworks that govern the fees. Then, annual appropriations acts provide for the total amount of user fees FDA may collect and obligate for a fiscal year. Once FDA has collected the user fees, and the Office of Management and Budget has apportioned them, FDA may obligate them. User fees’ budget authority remains available until FDA has expended those funds.⁵

Since the first FDA user fee program in 1992, statutes have reauthorized and added to the number of user fee programs supporting regulation of human medical products. (See table 3.) The purpose of the human medical-product user fees is generally to supplement FDA’s regular appropriations so that FDA may process and make decisions on application reviews more quickly.⁶ FDA intends for quicker reviews to better ensure patients gain more timely access to high quality medical products. In 2012, the Food and Drug Administration Safety and Innovation Act (FDASIA) reauthorized human medical-product user fee programs for fiscal years 2013 through 2017.⁷ The FDA Reauthorization Act of 2017 (FDARA) reauthorized the same human medical-product user fee programs for 5 more years, for fiscal years 2018 through 2022.⁸ In late September 2020, FDA plans to begin congressionally mandated negotiations with regulated industries on user fee rates and FDA’s related program enhancements and performance goals—which may include

⁴ A full-time equivalent is a standard measure of labor that equates to 1 year of full-time work.

⁵ Unobligated balances of user fee collections available for obligation on a no-year authority basis may be carried forward from year to year.

⁶ One exception is user fees from tobacco regulation, from which the Center for Devices and Radiological Health (CDRH) obligated some funds. FDA’s tobacco user fees are only available for FDA’s tobacco regulation activities and only these user fees may be used for regulating tobacco. Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, § 101(b), 123 Stat. 1776, 1828-29 (2009) (codified at 21 U.S.C. § 387s(c)(2)(A)–(B)).

⁷ Pub. L. No. 112-144, 126 Stat. 993 (2012).

⁸ Pub. L. No. 115-52, 131 Stat. 1005 (2017).

Appendix I: The Food and Drug Administration's (FDA) User Fee Programs for Human Medical Products

additional staff hiring—in preparation for the next 5-year reauthorization cycle.⁹

Table 2: Human Medical-Product User Fee Programs from which Three Food and Drug Administration (FDA) Regulatory Centers Obligated Funds in Fiscal Years 2012 through 2019

User fee program	Description	Original authorizing legislation
Prescription Drug User Fee Act (PDUFA)	Under this program, FDA is authorized to assess and collect fees on certain human drug applications to support the human drug application review processes.	Prescription Drug User Fee Act of 1992, Pub. L. No. 102-571, 106 Stat. 4491, 4491-4500
Medical Device User Fee Amendments (MDUFA)	Under this program, FDA is authorized to assess and collect user fees for certain medical device applications and submissions and other specified annual fees, which provide additional funds to FDA for the medical device application review process. Medical devices range from tools (e.g. bandages and surgical clamps) to complicated devices (e.g. pacemakers). Generally, medical devices include items used for the diagnosis, cure, mitigation, treatment, or prevention of a disease. See 21 U.S.C. § 321(h).	Medical Device User Fee and Modernization Act of 2002, Pub. L. No. 107-250, 116 Stat. 1588, 1589-1602
Generic Drug User Fee Amendments (GDUFA)	Under this program, FDA is authorized to assess and collect user fees associated with human generic drug products, including on certain types of applications and facilities, among other specified activities. These funds are available to support FDA's human generic drug activities, including the review of generic drug submissions and inspection of facilities.	Generic Drug User Fee Amendments of 2012, Pub. L. No. 112-144, 126 Stat. 1008, 1008-26
Biosimilar User Fee Act (BsUFA)	Under this program, FDA is authorized to assess and collect user fees for biosimilar biological products in connection with product development, review of certain applications for approval, and product approvals. These funds may defray the costs of the process for the review of biosimilar biological product applications. Biosimilar biological products are biological products, such as insulin, that are similar to other products FDA has already approved.	Biosimilar User Fee Act of 2012, Pub. L. No. 112-144, 126 Stat. 1026, 1026-39
Export Certification (EREA)	Under this program, FDA is authorized to assess and collect user fees in providing a certification that a food, drug, animal drug, or device being exported meets applicable requirements. These certificates may provide foreign entities with assurance that FDA-regulated products exported to their countries may be marketed in the United States or that they meet specific U.S. regulations.	FDA Export Reform and Enhancement Act of 1996, Pub. L. No. 104-134, 110 Stat. 1321-313, 1321-314
Outsourcing Facility (DQSA)	Under this program, FDA is authorized to assess and collect fees in connection with the establishment and inspection of outsourcing facilities; these fees are available for the costs of oversight of these facilities. Established by the same authorizing law in 2013, outsourcing facilities may compound sterile drugs without patient-specific prescriptions. Such facilities register with and are subject to inspection by FDA.	Drug Quality and Security Act, Pub. L. No. 113-54, 127 Stat. 587, 593-97 (2013)

⁹ FDA's user fee reauthorizations establish the fee requirements and the process by which FDA establishes the annual fee rates. The reauthorizations require FDA to provide annual reports on its progress in meeting negotiated performance goals for the 5-year period. See, e.g., FDARA, Pub. L. No. 115-52, § 904, 131 Stat. at 1082-88.

Appendix I: The Food and Drug Administration's (FDA) User Fee Programs for Human Medical Products

User fee program	Description	Original authorizing legislation
Mammography Quality Standards (MQSA)	Under this program, FDA is authorized to assess and collect fees from mammography facilities to cover the costs of inspections.	Mammography Quality Standards Act of 1992, Pub. L. No. 102-539, 106 Stat. 3547, 3561
Priority Review Voucher (Rare Pediatric Diseases)	Under this program, FDA is authorized to collect fees from a drug sponsor that uses a rare pediatric disease priority review voucher when the sponsor uses the voucher for review of a human drug application. These vouchers are awarded to sponsors of approved rare pediatric disease product applications that meet all the requirements of this program. The sponsor may be subject to other applicable user fees.	Food and Drug Administration Safety and Innovation Act, Pub. L. No. 112-144, 126 Stat. 993, 1094-98 (2012)
Priority Review Voucher (Tropical Diseases)	Under this program, FDA is authorized to collect fees from a drug sponsor that uses a tropical disease priority review voucher when the sponsor uses a voucher for review of a human drug application. These vouchers are awarded to sponsors of approved tropical disease product applications—such as for the treatment or prevention of Zika or malaria—that meet all the requirements of this program. The sponsor may be subject to other applicable user fees.	Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823, 972-74
Family Smoking Prevention and Tobacco Control	Under this program, FDA is authorized to assess and collect user fees from individual domestic manufacturers and importers of tobacco products based on their respective market share in each tobacco product class. These funds are available for the costs of FDA's tobacco regulation activities.	Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776, 1826-30 (2009)

Source: GAO analysis of FDA documents and legal statutes. | GAO-20-689

Note: FDA's medical-product regulatory centers include the: Center for Drug Evaluation and Research (CDER); Center for Biologics Evaluation and Research (CBER); and Center for Devices and Radiological Health (CDRH).

Congress retains oversight over user fees. Accordingly, information that provides visibility on how these funds are obligated is important for Congress to oversee agencies and programs. In addition, given the mix of public benefits and services to users inherent in regulatory programs, it is important for fee structures and costs to be transparent.

The purposes for which FDA may obligate user fees are set by statute. For example, pursuant to PDUFA, MDUFA, GDUFA, and BsUFA,¹⁰ FDA may obligate its funding for: (1) personnel and contractor costs; (2) information management and computer acquisition and maintenance; (3) leasing, maintenance, renovation, and repair of facilities, as well as acquisition, maintenance, and repair of fixtures, furniture, scientific equipment, and other necessary materials and supplies; and (4) collecting fees and administering user fee programs. In 2017, FDARA established new limitations. Effective October 1, 2023, FDA will no longer be authorized to obligate user fee funds from these four programs for maintenance, renovation, and repair of facilities, or for acquisition,

¹⁰ These are the four of the ten user fee programs from which the three centers obligated the largest amount of funds from fiscal years 2012 through 2019.

**Appendix I: The Food and Drug
Administration's (FDA) User Fee Programs for
Human Medical Products**

maintenance, and repair of fixtures, furniture, and other necessary materials and supplies.¹¹

¹¹ FDARA, Pub. L. No. 115-52, § 905(b), 131 Stat. at 1089-90.

Appendix II: Objectives, Scope, and Methodology

This report: (1) identifies the funds Food and Drug Administration (FDA) obligated for the three FDA centers primarily responsible for regulating human drugs, biological products, and medical devices,¹ and (2) assesses FDA's use of quality information in the management of personal property and real property used by these three centers, which are the Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER), and Center for Devices and Radiological Health (CDRH).

To determine FDA's obligations for the three regulatory centers and to understand how FDA obtains, obligates, and disburses budgetary funds, including user fees, we obtained and reviewed financial data on obligations from FDA's budget authority, including regular appropriations and user fees, from fiscal years 2012 through 2019.² For purposes of our report, we use the term "regular appropriations" to refer to amounts derived from the General Fund of the Treasury and made available through annual appropriations. Also, our calculations related to regular appropriations included funds for Salaries and Expenses (S&E), emerging health threats, Ebola virus, Zika virus, and Opioids, International Mail Facilities, as well as additional funds for one-time activities directly related to improving the safety of the human drug supply. The timeframe outlined in FDARA for GAO to conduct this work encompasses FDA's obligations of user fees made available for obligation by its 2012 user fee reauthorization and ends in fiscal year 2019, the end of the most recent complete fiscal year.³

¹ An obligation is a definite commitment that makes the government legally liable for the payment of goods and services ordered or received.

² User fees are charges assessed to beneficiaries for goods or services provided by the federal government. FDA is authorized to collect user fees for reviewing certain applications and licenses and use the proceeds to cover the costs associated with these applications, such as lease payments and furniture, fixtures and equipment. FDA's user fees are collected and available for obligation only to the extent and in the amount provided in advance in appropriation acts.

³ For the most recent statute reauthorizing PDUFA, MDUFA, GDUFA, and BsUFA, see FDARA, Pub. L. No. 115-52, 131 Stat. at 1005.

We also analyzed and summarized FDA's data to determine total obligations of regular appropriations and user fees for each year. We reported the centers' obligations in nominal dollars, which are not adjusted for inflation. In addition, we categorized the data by obligations for personnel, property and property-related, and "other" expenses. Further, we categorized property and property-related obligations by rent to the General Services Administration (GSA) and others; equipment, land, and structures; and operations, maintenance, and other miscellaneous obligations. This analysis provided a comprehensive overview of how FDA obligated its budgetary funds based on the type of goods, services, or other items purchased. We selected and performed observations of two sample transactions that FDA processed through its financial system to obtain an understanding of FDA's obligation process. In addition, we interviewed knowledgeable agency officials and performed electronic and manual data testing for missing data, outliers, and obvious errors, and we followed-up with agency officials to clarify any identified discrepancies. From these interviews and data testing, we were able to determine the data to be reliable for the purposes of our audit.

To develop an understanding of the context in which FDA obligates funds for property, we analyzed appropriations and full-time equivalent (FTE) information for fiscal years 2012 through 2019 in FDA's budget justification materials.⁴ Furthermore, we reviewed our prior work on federal user fees. We also reviewed applicable laws for four of the ten user fee programs from which the three centers obligated the largest amount of funds from fiscal years 2012 through 2019.⁵ The programs for these four user fees pertain to prescription drugs, generic drugs, biological products, and medical devices for humans.

To assess FDA's use of quality information in the management of personal property and real property used by the three centers, we compared FDA's activities with six key characteristics integral to effective asset management that we developed in our prior work.⁶ In that prior work we illustrated four phases of an asset management framework: (1)

⁴ A full-time equivalent is a standard measure of labor that equates to 1 year of full-time work.

⁵ 21 U.S.C. §§ 379g, 379h, 379h-2 (PDUFA), 379i to 379j-1 (MDUFA), 379j-41 to 379j-43 (GDUFA), 379j-51 to 379j-53 (BsUFA). See appendix I for more information on the original authorizing legislation for the four largest user fee programs.

⁶ An asset management framework is the processes, procedures, support systems, organizational roles and responsibilities, and policies used to enable management decisions.

organizational strategic planning; (2) asset management strategy and planning, which includes property planning; (3) property lifecycle delivery, which, in the context of this report, is the property lifecycle and includes operations and maintenance; and (4) review, which, for this report, is the review of property performance. We then reviewed policies, processes, and planning documents related to FDA's property management.⁷ We also conducted a site visit to the White Oak campus to observe the facilities, scientific equipment, and other property the centers use. To identify roles and responsibilities related to FDA's management of personal property and real property used by the three centers, we reviewed FDA documents and interviewed FDA and GSA officials. We interviewed or received written responses from officials from CDER, CBER, CDRH, FDA's Office of the Chief Scientist, and FDA's Office of Operations, including the Office of Facilities, Engineering, and Mission Support Services.

We reviewed FDA's collection and use of property management information with the following requirements, guidance, and leading practices:

- **Applicable federal requirements.** Some statutes and regulations direct how and when agencies should collect and use information to support decision-making. In particular, agencies are required to annually assess the condition of real property.⁸
- **Office of Management and Budget (OMB) guidance.**⁹ OMB's *Capital Programming Guide* provides guidance to federal agencies on managing capital assets.

⁷ We reviewed the following, which we collectively refer to as strategic planning documents or plans: Food and Drug Administration (FDA), *2018 Master Plan for the Consolidation of the U.S. FDA Headquarters at the Federal Research Center at White Oak Located in Silver Spring, Maryland*. (Silver Spring, MD: September 2018); FDA, *2018 Strategic Policy Roadmap* (January 2018); Center for Biologics Evaluation and Research, *CBER Interim Strategic Plan Fiscal Years 2017-2019* (Silver Spring, MD); Center for Drug Evaluation and Research, *FDA Center for Drug Evaluation and Research (CDER) Strategic Plan 2013-2017*; and Center for Devices and Radiological Health, *2018-2020 Strategic Priorities* (January 2018).

⁸ 40 U.S.C. § 524.

⁹ Office of Management and Budget (OMB), *2019 Capital Programming Guide, Supplement V 3.0 OMB Circular A-11, Planning, Budgeting, and Acquisition of Capital Assets*. (Washington, D.C.: 2019).

- **International Organization for Standardization (ISO) “ISO 55000” standards.**¹⁰ These international consensus standards describe leading practices for implementing, maintaining, and improving an effective asset management framework, including highlighting the importance of quality information for organizational decision-making.
- **Other GAO-developed leading practices.** Using quality data is one of six key characteristics integral to effective asset management that supports agency missions and strategic objectives, which we developed in our prior work.¹¹

We reviewed FDA practices that related to several of the six key characteristics integral to effective asset management. We focused on assessing whether FDA's practices used quality data for the following reasons: (1) FDA will require quality data on its property to address future limitations on how it can spend user fees it collects and to effectively negotiate with regulated industries, as discussed above; (2) effective organizational strategic planning requires management to define the quality data needed to make informed decisions at all levels of an organization; and (3) using quality data is a foundation from which other key characteristics build. Specifically, establishing formal policies and plans, maximizing an asset portfolio's value, and evaluating and improving asset management practices each rely on using quality data. Further, both ISO standards and OMB guidance discuss the importance of information in decision-making and planning. As illustrated in our prior work, using quality information in the property planning, property lifecycle

¹⁰ The ISO is an international, independent, non-governmental organization with a membership of 163 national standards bodies, including the American National Standards Institute. Originally published in 2014 and updated in 2018, the International Organization for Standardization (ISO) 55000 consists of three separate standards. Those standards are *ISO 55000: 2014 Asset Management – Overview, Principles and Terminology*; *ISO 55001: Asset management – Management Systems – Requirements*; and *ISO 55002: 2014 Asset Management - Management systems – Guidelines on the application of ISO 55001*.

¹¹ In 2018, we established six key characteristics of an asset management framework. The other key characteristics are establishing formal policies and plans, maximizing an asset portfolio's value, maintaining leadership support, promoting a collaborative organizational culture, and evaluating and improving asset management practices. See GAO, *Federal Real Property Asset Management: Agencies Could Benefit from Additional Information on Leading Practices*, [GAO-19-57](#) (Washington D.C.: Nov. 5, 2018).

delivery, and review of property performance phases is necessary to support the organizational strategic-planning phase.¹²

We conducted this performance audit from June 2019 to September 2020 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

¹² See [GAO-19-57](#).

Appendix III: Comments from the Department of Health & Human Services

Appendix III: Comments from the Department
of Health & Human Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

September 4, 2020

David Trimble
Physical Infrastructure
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Kristen Kociolek
Financial Management and Assurance
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Mr. Trimble and Ms. Kociolek,

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, "*Federal Property: Formal Policies Could Enhance FDA's Property Management Efforts*" (GAO-20-689).

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

Sarah C. Arbes -S
Digitally signed by
Sarah C. Arbes -S
Date: 2020.09.04
10:11:49 -04'00'

Sarah Arbes
Assistant Secretary for Legislation

Attachment

**Appendix III: Comments from the Department
of Health & Human Services**

**GENERAL COMMENTS FROM THE DEPARTMENT OF HEALTH & HUMAN SERVICES
ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED —
FEDERAL PROPERTY: FORMAL POLICIES COULD ENHANCE FDA'S PROPERTY
MANAGEMENT EFFORTS (GAO-20-689)**

The U.S. Department of Health and Human Services appreciates the opportunity to review and comment on this report. FDA faces ongoing challenges of maintaining its facilities and personal property that enables scientists and regulators to meet the industry standards of the 21st Century. Effective personal property maintenance protects capital investment and supports work performance. To that end, the FDA plans to develop standard operating procedures for its medical product centers related to personal property maintenance that supports the agency's mission-related goals. Such standards would prove optimal if they were broadly adopted across all agency centers.

Recommendation 1: The Commissioner of FDA should establish and implement formal policies to use quality information (e.g., linking decisions to mission-related goals) in the three centers planning for their personal property needs, consistent with key characteristics integral to asset management leading practices.

HHS Response: HHS concurs with this recommendation. FDA will report on the progress of this development in its statement of action.

Recommendation 2: The Commissioner of FDA should establish and implement formal policies to use quality information (e.g., tracking age, condition, and maintenance and repair costs) in the three centers' operations and maintenance of personal property, consistent with key characteristics integral to asset management leading practices.

HHS Response: HHS concurs with this recommendation. FDA will report on the progress of this development in its statement of action.

Recommendation 3: The Commissioner of FDA should establish and implement formal policies to use quality information (e.g., measuring and documenting performance) in the three centers' reviews of personal property performance, consistent with key characteristics integral to asset management leading practices.

HHS Response: HHS concurs with this recommendation. FDA will report on the progress of this development in its statement of action.

Appendix IV: Comments from the General Services Administration

Appendix IV: Comments from the General Services Administration

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The Administrator

August 31, 2020

The Honorable Gene L. Dodaro
Comptroller General of the United States
U.S. Government Accountability Office
Washington, DC 20548

Dear Mr. Dodaro:

The U.S. General Services Administration (GSA) appreciates the opportunity to review and comment on the draft report, *FEDERAL PROPERTY: Formal Policies Could Enhance FDA's Property Management Efforts* (GAO-20-689).

The U.S. Government Accountability Office (GAO) recommends that the GSA Administrator take steps to ensure that the condition of all of the facilities occupied by the U.S. Food and Drug Administration (FDA) at the White Oak campus in Silver Spring, Maryland, are assessed, including limited access areas and tenant improvements that are above the standard services and facilities that GSA provides.

GSA agrees with the draft report's findings, as well as the recommendation addressed to GSA, and therefore will take appropriate action to conduct building surveys and inspections at FDA's White Oak campus facilities. GSA commits to working more closely with FDA to ensure that all spaces are addressed in the surveys and inspections. FDA has committed to working with GSA in regard to providing access to all surveyors and inspectors moving forward. GSA is confident that this action will satisfactorily remedy the concern raised by GAO.

If you have any questions or concerns, please contact me at (202) 969-7277 or Jeffrey A. Post, Associate Administrator, Office of Congressional and Intergovernmental Affairs, at (202) 501-0563.

Sincerely,

Handwritten signature of Emily W. Murphy in blue ink.

Emily W. Murphy
Administrator

cc: Mr. David Trimble, Director, Physical Infrastructure, GAO
Ms. Kristen Kociolek, Director, Financial Management and Assurance, GAO

1800 F Street, NW
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Appendix V: GAO Contacts and Staff Acknowledgements

GAO Contacts

David Trimble, (202) 512-2834, or Trimbled@gao.gov.

Kristen Kociolek, (202) 512-2989, or Kociolekk@gao.gov.

Staff Acknowledgments

In addition to the contacts named above, Lori Rectanus (Director), Amelia Shachoy (Assistant Director); Jonathan Meyer (Assistant Director); Jaclyn Mullen (Analyst-in-Charge); Oluwaseun Ajayi; Matthew Bond; Diana Lee; Jon Melhus; Christie Pugnetti; Malika Rice; Kevin Scott; Janet Temko-Blinder; Laurel Voloder; and Elizabeth Wood, made key contributions to this report.

Appendix VI: Accessible Data

Data Tables

Accessible Data for Obligations for Three of the Food and Drug Administration's Regulatory Centers by Budget Authority Type, Fiscal Years 2012 through 2019

Fiscal year	Regular appropriations	User fee
2012	760	585
2013	711	725
2014	765	884
2015	733	1010
2016	738	1066
2017	761	1145
2018	776	1366
2019	1123	1501

Appendix VI: Accessible Data

Accessible Data for Figure 1: The Food and Drug Administration's (FDA) Budget Authority by Type of Authority, Fiscal Years 2012 through 2019

Fiscal year	Regular appropriations	User fees
2012	2505.81	1326.4
2013	2386.02	1645.34
2014	2560.69	1825.97
2015	2595.82	1909.35
2016	2728.1	2017.19
2017	2799.67	1954.22
2018	2964.37	2396.27
2019	3148.97	2574.46

Appendix VI: Accessible Data

Accessible Data for Figure 3: Obligations for Three of the Food and Drug Administration's (FDA) Centers by Budget Authority Type, Fiscal Years 2012 through 2019

Fiscal year	Regular appropriations	User fee
2012	760	585
2013	711	725
2014	765	884
2015	733	1010
2016	738	1066
2017	761	1145
2018	776	1366
2019	1123	1501

Appendix VI: Accessible Data

Accessible Data for Figure 4: Obligations for Three of the Food and Drug Administration's (FDA) Centers by Category, Fiscal Years 2012 through 2019

Fiscal year	Personnel	Other^a	Property and property-related
2012	853	314	178
2013	892	345	199
2014	958	454	236
2015	1062	461	220
2016	1155	433	214
2017	1249	464	192
2018	1312	655	175
2019	1367	1034	223

Appendix VI: Accessible Data

Accessible Data for Figure 5: Full-time Equivalent Positions Supported by Three of the Food and Drug Administration's (FDA) Centers, Fiscal Years 2012 through 2019

Fiscal year	Center for Drug Evaluation and Research	Center for Biologics Evaluation and Research	Center for Devices and Radiological Health
2012	3272	1089	1510
2013	3473	1115	1582
2014	3792	1093	1585
2015	4329	1072	1675
2016	4648	1102	1718
2017	4989	1177	1682
2018	5203	1202	1737
2019	5362	1189	1614

Appendix VI: Accessible Data

Accessible Data for Figure 6: Property and Property-Related Obligations for Three of the Food and Drug Administration's (FDA) Centers, Fiscal Years 2012 through 2019

Fiscal year	Rent to General Services Administration and others	Operations, maintenance, and other miscellaneous obligations	Equipment, land, and structures
2012	76	79	23
2013	76	91	32
2014	90	114	32
2015	98	96	26
2016	94	94	27
2017	94	80	18
2018	96	58	22
2019	95	99	29

Accessible Data for Figure 7: Property and Property-Related Obligations for Three of the Food and Drug Administration's (FDA) Regulatory Centers by Budget Authority Type, Fiscal Years 2012 through 2019

Fiscal year	Regular appropriations	User fees
2012	131	47
2013	132	67
2014	150	87
2015	122	98
2016	119	95
2017	118	74
2018	103	72
2019	140	84

Agency Comment Letters

Accessible Text for Appendix III Comments from the Department of Health & Human Services

Page 1

September 4, 2020

David Trimble

Physical Infrastructure

U.S. Government Accountability Office

441 G Street NW

Washington, DC 20548

Kristen Kociolek

Financial Management and Assurance

U.S. Government Accountability Office

441 G Street NW

Washington, DC 20548

Dear Mr. Trimble and Ms. Kociolek,

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, "Federal Property: Formal Policies Could Enhance FDA's Property Management Efforts" (GAO-20-689).

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

Sarah Arbes

Assistant Secretary for Legislation

Attachment

Page 2

The U.S. Department of Health and Human Services appreciates the opportunity to review and comment on this report. FDA faces ongoing challenges of maintaining its facilities and personal property that enables scientists and regulators to meet the industry standards of the 21st Century. Effective personal property maintenance protects capital investment and supports work performance. To that end, the FDA plans to develop standard operating procedures for its medical product centers related to personal property maintenance that supports the agency's mission-related goals. Such standards would prove optimal if they were broadly adopted across all agency centers.

Recommendation 1: The Commissioner of FDA should establish and implement formal policies to use quality information (e.g., linking decisions to mission-related goals) in the three centers planning for their personal property needs, consistent with key characteristics integral to asset management leading practices.

HHS Response: HHS concurs with this recommendation. FDA will report on the progress of this development in its statement of action.

Recommendation 2: The Commissioner of FDA should establish and implement formal policies to use quality information (e.g., tracking age, condition, and maintenance and repair costs) in the three centers' operations and maintenance of personal property, consistent with key characteristics integral to asset management leading practices.

HHS Response: HHS concurs with this recommendation. FDA will report on the progress of this development in its statement of action.

Recommendation 3: The Commissioner of FDA should establish and implement formal policies to use quality information (e.g., measuring and documenting performance) in the three centers' reviews of personal property performance, consistent with key characteristics integral to asset management leading practices.

HHS Response: HHS concurs with this recommendation. FDA will report on the progress of this development in its statement of action.

Accessible Text for Appendix IV Comments from the General Services Administration

August 31, 2020

The Honorable Gene L. Dodaro

Comptroller General of the United States

U.S. Government Accountability Office

Washington, DC 20548

Dear Mr. Dodaro:

The U.S. General Services Administration (GSA) appreciates the opportunity to review and comment on the draft report, **FEDERAL PROPERTY: Formal Policies Could Enhance FDA's Property Management Efforts** (GAO-20-689).

The U.S. Government Accountability Office (GAO) recommends that the GSA Administrator take steps to ensure that the condition of all of the facilities occupied by the U.S. Food and Drug Administration (FDA) at the White Oak campus in Silver Spring, Maryland, are assessed, including

limited access areas and tenant improvements that are above the standard services and facilities that GSA provides.

GSA agrees with the draft report's findings, as well as the recommendation addressed to GSA, and therefore will take appropriate action to conduct building surveys and inspections at FDA's White Oak campus facilities. GSA commits to working more closely with FDA to ensure that all spaces are addressed in the surveys and inspections. FDA has committed to working with GSA in regard to providing access to all surveyors and inspectors moving forward. GSA is confident that this action will satisfactorily remedy the concern raised by GAO.

If you have any questions or concerns, please contact me at (202) 969-7277 or Jeffrey A. Post, Associate Administrator, Office of Congressional and Intergovernmental Affairs, at (202) 501-0563.

Sincerely,

Emily W. Murphy

Administrator

cc: Mr. David Trimble, Director, Physical Infrastructure, GAO

Ms. Kristen Kocielek, Director, Financial Management and Assurance,
GAO

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