United States Government Accountability Office

Report to Congressional Requesters

May 2016

FOOD AND DRUG ADMINISTRATION

Comprehensive Strategic Planning Needed to Enhance Coordination between Medical Product Centers

GAO-16-500

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GAO Highlights

Highlights of GAO-16-500, a report to congressional requesters

Why GAO Did This Study

FDA—an agency within the Department of Health and Human Services (HHS)—has faced challenges in carrying out its responsibilities to ensure the safety and efficacy of medical products sold in the United States. In 2012, Congress required FDA to develop a SIMP for the three centers overseeing medical products that identifies initiatives for improving efficiency, initiatives for workforce development, and measures for assessing the progress of these initiatives. FDA issued the SIMP in July 2013.

GAO was asked to examine FDA's implementation of the SIMP. In this report, GAO (1) evaluates the extent to which the SIMP serves as a strategic planning document, (2) describes the types of plan initiatives, and (3) describes the mechanisms FDA has to evaluate the effectiveness of its plan initiatives. GAO analyzed FDA documents and spoke to FDA officials to assess the SIMP's development and use, along with the implementation status and evaluation mechanisms used for the SIMP's initiatives. GAO also assessed FDA's plan against leading practices for strategic planning. Finally, GAO analyzed FDA workforce data on hiring and attrition for fiscal years 2012 to 2015.

What GAO Recommends

GAO recommended that the Secretary of Health and Human Services direct FDA to engage in a strategic planning process to identify challenges that cut across the medical product centers, and document how it will achieve measurable goals and objectives in these areas. HHS agreed with the recommendation.

View GAO-16-500. For more information, contact Marcia Crosse at (202) 512-7114 or crossem@gao.gov.

What GAO Found

The Food and Drug Administration (FDA) developed a strategic integrated management plan (SIMP) for its three centers that oversee medical products (biologics, drugs, and medical devices); however, GAO found that the plan does not incorporate leading practices for strategic planning or document a comprehensive strategy for the centers. FDA officials explained that circumstances at the time of the SIMP's development, including leadership gaps, limited FDA's ability to structure the plan into an effective strategic planning document. While officials said they use a variety of other key documents for strategic planning—such as agency-level and initiative-specific plans—these other plans also do not describe a long-term strategy for addressing key issues that cut across medical product centers. For example, these other FDA documents do not describe the agency's plans for collaboration between the centers that could benefit certain initiatives, improve their decision-making, and improve the quality of evidence and clarity of guidance. FDA officials acknowledged the growing need for strategic planning across the medical product centers to improve center collaboration and address emerging issues. The absence of a comprehensive long-term plan for medical product oversight may hinder FDA's efforts to address emerging issues that require center collaboration, such as access to quality data. Fully documenting such a strategy, either in a separate plan or through existing documents, would help the agency identify measurable goals and objectives for the centers that align with its mission and help communicate its priorities to key stakeholders.

In the SIMP, FDA compiled mostly preexisting initiatives to improve the efficiency of each center's activities and develop its workforce. GAO found that for improving efficiency, FDA selected 30 initiatives that it grouped into three different themes—smarter regulation, process improvement, and business modernization. FDA had fully implemented a third of the initiatives prior to the SIMP's issuance in 2013; another half were implemented by March 2016. As of this date, the remaining initiatives had yet to be fully implemented. For workforce development, FDA included 19 recruitment, retention, and training initiatives, which generally reflected differences in center activities. FDA implemented 15 initiatives prior to the SIMP's issuance and 2 additional initiatives since then. Of the remaining initiatives, 1 was terminated and, as of March 2016, FDA was in the process of implementing the other initiative.

Although not generally reported in the SIMP, FDA officials identified mechanisms to assess the effectiveness of the majority of the initiatives included in the plan. Of the 30 efficiency initiatives, FDA officials identified 8 that have formal evaluations (such as third-party assessments) and 9 that are assessed informally (such as by gathering feedback). For the remaining 13, officials said they are either exploring effectiveness measures or have no plans to assess them because they consider it to be unnecessary or impractical. FDA identified mechanisms to assess 12 of the 19 workforce development initiatives, including through recruitment performance metrics and surveys of training participants. For 4 initiatives, the centers each use different approaches to assess training. For the remaining 3 initiatives, FDA either is developing a mechanism or described past assessment activities.

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Abbreviations

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
FDASIA	Food and Drug Administration Safety and Innovation Act of 2012
GDUFA	Generic Drug User Fee Amendments Act
GPRA	Government Performance and Results Act of 1993
HHS	Department of Health and Human Services
MDUFA	Medical Device User Fee and Modernization Act
PDUFA	Prescription Drug User Fee Act of 1992
SIMP	strategic integrated management plan

U.S. GOVERNMENT ACCOUNTABILITY OFFICE
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May 16, 2016

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

The Honorable Richard Burr
United States Senate

The Food and Drug Administration (FDA)—an agency within the Department of Health and Human Services (HHS)—is responsible for ensuring the safety and effectiveness of the millions of medical products sold in the United States that Americans use daily. FDA must ensure the safety and effectiveness of various types of medical products—drugs, biological products, and medical devices—and must do so throughout the products' lifecycle, including before and after they are brought to market.[1] However, FDA has faced challenges in carrying out the many responsibilities necessary for this oversight.

Our prior work and other studies have identified key management challenges FDA faces in order to successfully fulfill its mission. In 2009, we reported on FDA's challenges managing its growing medical product oversight responsibilities and recommended that the agency develop a more complete estimate of its resource needs.[2] In 2010, we identified significant management challenges at FDA and made recommendations

[1]Biological products are derived from living sources (such as humans, animals, and microorganisms), unlike drugs, which are chemically synthesized. Biologics include blood, vaccines, and allergenic products. 42 U.S.C. § 262(i).

Medical devices include instruments, apparatuses, machines, and implants that are intended for use to diagnose, cure, treat, or prevent disease, or to affect the structure or any function of the body. 21 U.S.C. § 321(h).

FDA considers oversight and research of animal drugs and feeds among its medical product responsibilities. We have excluded these efforts from the definition of medical products used in this report.

[2]FDA implemented our recommendation by launching a study to develop an evidence-based approach to resource estimation focused on medical products. GAO, *Food and Drug Administration: FDA Faces Challenges Meeting Its Growing Medical Product Responsibilities and Should Develop Complete Estimates of Its Resource Needs*, GAO-09-581 (Washington, D.C.: June 19, 2009).

to improve its strategic management and planning.[3] Among other challenges, our work, as well as the work of the Partnership for Public Service, identified challenges FDA experienced with recruiting, retaining, and developing its workforce, and coordinating internally.[4] In addition, HHS's Office of Inspector General found management challenges at FDA that weakened its ability to oversee regulated products, such as by preventing medication imports from foreign and unlicensed suppliers.[5]

The Food and Drug Administration Safety and Innovation Act (FDASIA), in addition to providing FDA with various responsibilities related to the oversight of medical products, required FDA to report on its implementation of management improvements for this oversight.[6] Specifically, FDASIA required FDA to develop and submit to Congress a strategic integrated management plan (SIMP) to identify (1) initiatives for improving efficiency, (2) initiatives for workforce development, and (3) measures for assessing the progress of these initiatives.[7] To satisfy this requirement, FDA issued the SIMP in July 2013.[8] In light of the documented management challenges within FDA and the importance of effective medical product oversight, you asked us to study FDA's implementation of the SIMP. In this report we

1. evaluate the extent to which FDA's SIMP serves as a strategic planning document for medical product oversight,

[3]Of the five recommendations we made, FDA implemented three related to updating planning documents and expanding training. Two recommendations relating to performance tracking are ongoing. GAO, *Food and Drug Administration: Opportunities Exist to Better Address Management Challenges*, GAO-10-279 (Washington, D.C.: Feb. 19, 2010).

[4]See Partnership for Public Service, *The State of the FDA Workforce* (Washington, D.C.: November 2012).

[5]See HHS Office of Inspector General, *FY 2014 Agency Financial Report: Fiscal Year 2014 Top Management and Performance Challenges Identified by the Office of Inspector General* (2014).

[6]Pub. L. No. 112-144, 126 Stat. 993 (2012).

[7]Pub. L. No. 112-144, § 1131, 126 Stat. 1119.

[8]See U.S. Department of Health and Human Services, Food and Drug Administration, *Report to Congress: Strategic Integrated Management Plan for the Center for Drug Evaluation and Research (CDER), the Center for Biologics Evaluation and Research (CBER), and the Center for Devices and Radiological Health (CDRH), Food and Drug Administration Safety and Innovation Act of 2012 Section 1131* (July 2013).

2. describe the types of initiatives that FDA chose to include in the SIMP, and
3. describe the mechanisms FDA has to evaluate the effectiveness of the efficiency and workforce initiatives described in the SIMP.

To evaluate the extent to which FDA's SIMP serves as a strategic planning document for medical product oversight, we examined the plan for strategic planning activities, and spoke to officials from FDA's three medical product centers, which are responsible for overseeing medical products, and the agency's planning offices to understand how FDA developed the SIMP. We also spoke with officials from five industry groups that together represent each of the three medical product areas to obtain their views on the SIMP. We reviewed relevant criteria from GAO's body of work on effectively managing performance under the Government Performance and Results Act of 1993 (GPRA), as enhanced by the GPRA Modernization Act of 2010.[9] Among other things, GPRA requires that federal agencies develop long-term strategic plans containing nine key elements, such as agency-wide goals and strategies for achieving those goals. We have previously reported that these elements serve as the foundation for effective strategic planning, and therefore can serve as leading practices at lower levels within federal agencies.[10] As such, we assessed the SIMP against the seven relevant strategic planning

[9]See GAO, *Managing For Results: GPRA Modernization Act Implementation Provides Important Opportunities to Address Government Challenges*, GAO-11-617T (Washington, D.C.: May 10, 2011); *Executive Guide: Effectively Implementing the Government Performance and Results Act*, GAO/GGD-96-118 (Washington, D.C.: June 1, 1996); *Managing For Results: Executive Branch Should More Fully Implement the GPRA Modernization Act to Address Pressing Governance Challenges*, GAO-13-518 (Washington, D.C.: June 26, 2013).

[10]For example, see GAO, *Foreign Aid Reform: Comprehensive Strategy, Interagency Coordination, and Operational Improvements Would Bolster Current Efforts*, GAO-09-192 (Washington, D.C.: April 17, 2009).

elements identified in GPRA to determine whether the plan contained these key elements.[11]

To describe the types of initiatives FDA chose to include in the SIMP, we reviewed the plan and identified the initiatives FDA selected for improving efficiency and developing its workforce at the medical product centers. We also reviewed separate FDA medical product guidance and workforce planning documents related to the initiatives to further describe each initiative's purpose. We spoke with officials from each medical product center, as well as FDA human resources officials to learn more about the initiatives and determine each initiative's implementation status. We then compared the characteristics of these initiatives and their implementation status across centers to describe key differences.

To describe the mechanisms FDA has to evaluate the effectiveness of the efficiency and workforce initiatives described in the SIMP, we reviewed the plan and identified measures of effectiveness. We also analyzed related FDA guidance documenting performance results to compare differences in monitoring activities across medical product centers. We interviewed officials from each medical product center, as well as the agency's human resources office to assess if the agency had additional mechanisms in place to measure the effectiveness of the initiatives in the SIMP. We did not assess each mechanism to determine if the approach was effective or appropriate for monitoring and evaluation. Finally, we analyzed workforce data for fiscal years 2012 through 2015—from the year FDASIA was enacted to the most recently available year—to assess hiring and attrition trends for FDA and each of the medical product centers. We interviewed officials on their use of the agency's hiring and personnel databases, and on potential issues associated with the

[11]The seven relevant strategic planning requirements in GPRA are: (1) a mission statement; (2) a description of how the agency's goals and objectives incorporate input from congressional consultations; (3) general (also known as strategic or long-term) goals and objectives; (4) a description of the strategies and resources required to achieve the agency's goals and objectives; (5) program evaluations used to establish or review the agency's general goals and objectives; (6) a description of how the agency's performance goals and priority goals relate to the general goals and objectives; and (7) an identification of key factors external to the agency and beyond its control that could significantly affect the achievement of the strategic goals. See 5 U.S.C. § 306.

Two additional strategic planning requirements—a description of how any goals and objectives contribute to federal government priority goals, and a description of interagency collaboration to achieve the agency's goals and objectives—are not relevant to examining the structure of the SIMP because the plan is not an agency-wide document.

completeness, accuracy, and timeliness of the data. We assessed the reliability of FDA workforce data by interviewing agency officials knowledgeable about the data, reviewing related documentation, and performing electronic testing for obvious errors and accuracy and completeness, where applicable. We determined that the data were sufficiently reliable for the purposes of this report.

We conducted this performance audit from July 2015 to May 2016 in accordance with generally accepted government auditing standards. These 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 Medical Product Oversight Structure

Within FDA, the Office of Medical Products and Tobacco is responsible for providing leadership for the medical product centers and coordinating their plans, strategies, and programs.[12] Under the office's direction, three FDA centers have primary responsibility for overseeing medical products and developing strategic plans to guide their activities:[13]

- The Center for Biologics Evaluation and Research (CBER) is responsible for overseeing most biologics, such as blood, vaccines, and human tissues.
- The Center for Drug Evaluation and Research (CDER) is responsible for overseeing drugs and certain therapeutic biologics.
- The Center for Devices and Radiological Health (CDRH) is responsible for overseeing devices and for ensuring that radiation-emitting products, such as microwaves and x-ray machines, meet radiation safety standards.

[12]The Office of Medical Products and Tobacco's leadership and coordination responsibilities also extend to FDA's Center for Tobacco Products.

[13]In this report, we will use the terms "medical product centers," or "centers," to refer to the three centers responsible for medical product oversight.

Several offices within FDA provide additional oversight and management support to assist the three medical product centers. FDA's Office of Policy, Planning, Legislation, and Analysis supports strategic planning at the agency-wide, program-specific, and center levels across FDA, which included coordinating the development of the SIMP and FDA's agency-wide strategic priorities document.[14] FDA's Office of Human Resources supports recruitment and workforce management activities. Finally, FDA's Office of Regulatory Affairs conducts field activities for all of FDA's medical product centers, such as inspections of domestic and foreign establishments involved in medical products.

Medical Product Oversight Activities

The centers conduct pre- and post-market oversight of medical products, as well as formulate guidance, perform research, communicate information to industry and the public, and set priorities. Premarket oversight comprises review activities to ensure that medical products are safe and effective for use before they can be marketed in the United States. FDA's premarket oversight typically begins when companies—known as sponsors—develop a medical product.[15] Before beginning clinical trials (studies involving humans) for a new medical product, sponsors must submit an application so that FDA can preliminarily assess the product for safety.[16] As part of its premarket oversight, FDA may also choose to inspect establishments producing medical products to ensure their manufacturing processes meet quality standards.

[14]See FDA, *Strategic Priorities: 2014-2018* (2014).

[15]A sponsor is a person or entity that takes responsibility for and initiates a new medical product application. A sponsor can be an individual, company, governmental agency, academic institution, private organization, or other organization. See 21 C.F.R. §§ 312.3, 812.3(n) (2015).

In general, unless exempt by regulation, new devices are subject to FDA premarket review via either a less stringent process based on a determination that a new device is substantially equivalent to another legally marketed device (referred to as a 510(k) review), or the more stringent premarket approval process, which requires the manufacturer to supply evidence providing reasonable assurance that the device is safe and effective. See 21 C.F.R. pts. 807, subpt. E, 814 (2015).

[16]In the case of drug products, sponsors must submit an investigational new drug application before conducting clinical investigations of unapproved drug products. Similarly, sponsors seeking to conduct clinical investigations of certain devices must submit an investigational device exemption. See 21 C.F.R. pts. 312, 812 (2015).

Postmarket oversight includes review activities to both provide certainty that medical products are safe and effective after they have been marketed, and to enable FDA to take regulatory actions if a safety issue is identified, such as requiring that sponsors communicate new safety information to the public and health care providers or withdraw the product from the market. Examples of postmarket oversight include reviewing reports of adverse events to monitor the safety of marketed medical products and examining advertising and other promotional materials to ensure they are not false or misleading. FDA may require sponsors to provide additional information both before and after a product has been approved. For example, FDA may require medical product manufacturers to create a Risk Evaluation and Mitigation Strategy to ensure that the benefits of a medical product outweigh its risks.[17]

Funding for Medical Product Oversight

A significant portion of FDA's annual appropriation consists of amounts derived from user fees paid by the medical products industry. Beginning in 1992 with prescription drugs, Congress has authorized the collection of user fees from the medical products industry to provide additional resources for certain FDA oversight activities. Each user fee program is subject to reauthorization every 5 years and supports different oversight activities across each of the centers, as illustrated in figure 1. In 2012, FDASIA reauthorized or authorized four user fee programs for medical products.[18] It included the fifth reauthorization of the Prescription Drug User Fee Act of 1992 (PDUFA), which allows FDA to collect user fees from manufacturers of prescription drugs.[19] It also included the third reauthorization of the Medical Device User Fee and Modernization Act (MDUFA), which allows FDA to collect user fees from manufacturers of medical devices.[20] Congress also authorized two new user fee programs

[17]The Risk Evaluation and Mitigation Strategy is a safety strategy to manage a known or potential serious risk associated with a medicine and to enable patients to have continued access to such medicines by managing their safe use.

[18]FDA's authority to spend amounts collected as user fees is provided in annual appropriations acts. In fiscal year 2015, of the approximately $1.9 billion in appropriated funds spent by CBER, CDER, and CDRH, over half of the funds were derived from user fees.

[19]Pub. L. No. 102-571, § 103, 106 Stat. 4494 (1992) (adding Federal Food Drug and Cosmetic Act (FDCA) § 736, codified as amended at 21 U.S.C. § 379h) (fees relating to drugs).

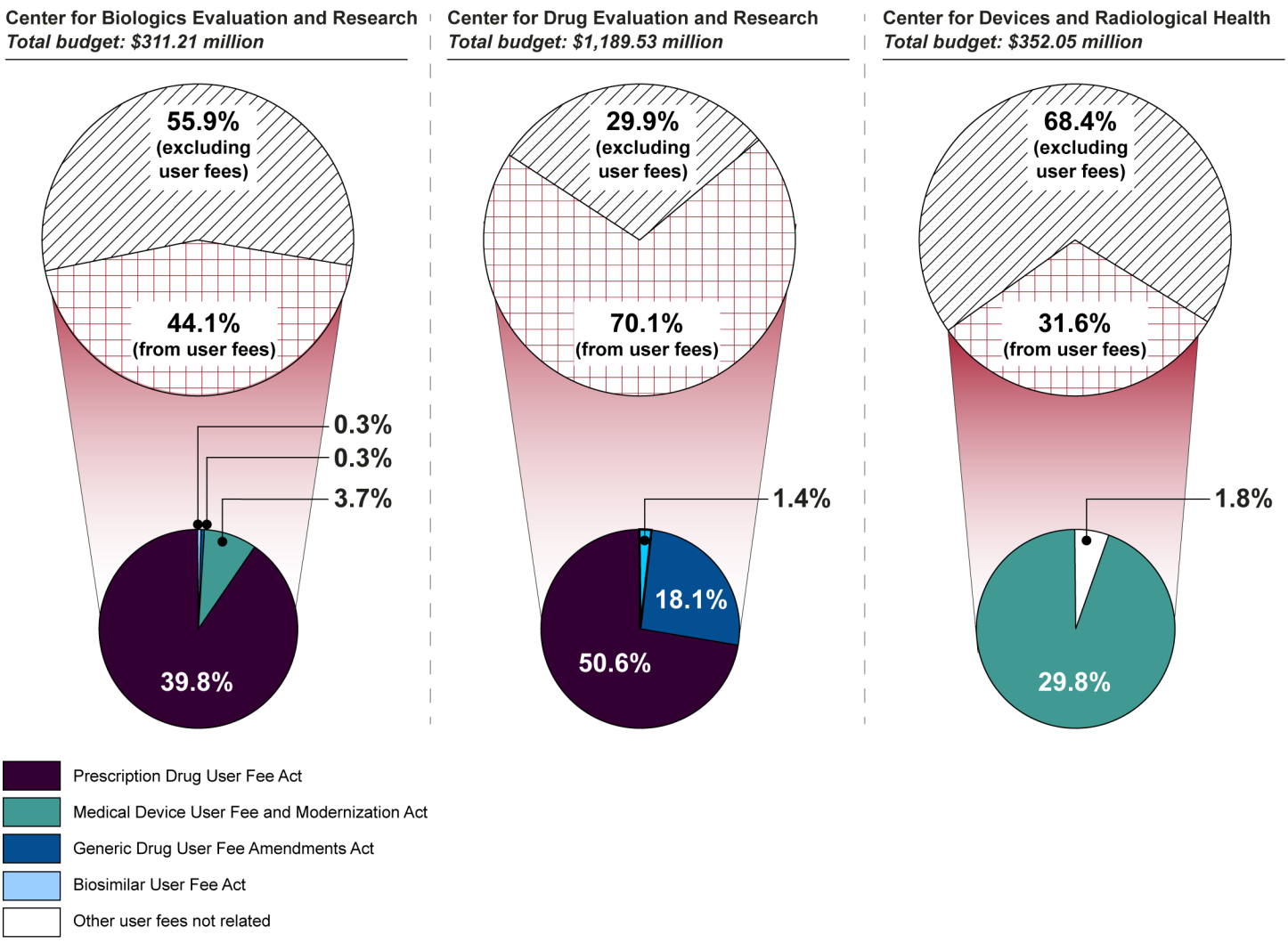
[20]Pub. L. No. 107-250, § 102(a) (2001) (adding FDCA § 738, codified as amended at 21 U.S.C. § 379j) (fees relating to medical devices).

in FDASIA: the Biosimilar User Fee Act (BsUFA), and the Generic Drug User Fee Amendments Act (GDUFA). BsUFA authorizes FDA to collect user fees from manufacturers of biosimilars, which FDA may approve based on a sponsor's ability to show that the product is highly similar to an FDA-approved biological product and has no clinically meaningful differences in terms of safety and effectiveness.[21] GDUFA authorizes FDA to collect user fees from manufacturers of generic drugs.[22]

[21]Pub. L. No. 112-144, § 402, 126 Stat. 1029 (adding FDCA § 744H, codified at 21 U.S.C. 379j-52) (fees relating to biosimilar biological products).

[22]Pub. L. No. 112-144, § 302, 126 Stat. 1011 (adding FDCA § 744B, codified at 21 U.S.C. § 379j-42) (fees relating to generic drugs).

Figure 1: User Fee Program Support for the Food and Drug Administration (FDA) Medical Product Centers' Oversight Activities, Fiscal Year 2016



Source: GAO analysis of FDA budget data. | GAO-16-500

Prior to each user fee program reauthorization, FDA negotiates with representatives of each medical products industry to identify goals for how FDA should spend those user fees over the next 5-year authorization period. Once FDA and the industry reach agreement, the Secretary of Health and Human Services submits letters containing these

commitments to Congress.[23] The user fee commitments contain performance goals for FDA's review activities, such as reviewing and acting upon a certain number of received medical product applications within certain time frames. User fee commitments may also require FDA to undertake certain actions, such as implementing agreed upon efficiency enhancements by a given date. FDA reports annually to Congress on progress made in achieving performance goals identified in each of the user fee commitments.[24] These reports contain both descriptions of each center's relevant oversight activities over the previous year, and data on its performance toward meeting user fee commitments.[25]

FDA Did Not Fully Document a Comprehensive Strategy for Medical Product Oversight in its Strategic Integrated Management Plan

We found that the SIMP does not contain key elements of strategic planning and therefore does not present a comprehensive strategy across the medical product centers. Our previous work has shown that strategic planning for activities below the agency-wide level is a leading practice for successful agencies, and can help agencies integrate activities, align goals, and coordinate performance management across different parts of their organization.[26] However, the SIMP does not fully contain several of these leading practices. Of the seven relevant strategic planning elements from GPRA, the SIMP fully contains two elements, partially contains four elements, and does not contain one element. In particular, we found that the SIMP contains a mission statement and describes how FDA incorporated input from Congress; it partially contains a description

[23]Pub. L. No. 112-144, §§ 101(b), 201(b), 301(b), 401(b), 126 Stat. 996, 1002, 1008, 1026 (codified as notes at 21 U.S.C. §§ 379g, 379i, 379j-41, 379j-51). In this report, when we refer to agency commitments under various user fee statutes, we are referring to commitments contained in the letters submitted pursuant to these statutes.

[24]For MDUFA commitments, FDA reports its progress on both a quarterly and annual basis.

[25]See, for example, FDA, *FY 2014 Performance Report to the President and Congress for the Generic Drug User Fee Amendments* (Silver Spring, Md.: 2014); *FY 2014 Performance Report to the President and Congress for the Biosimilar User Fee Act* (Silver Spring, Md.: 2014); *FY 2014 Performance Report to Congress for the Medical Device User Fee Amendments* (Silver Spring, Md.: 2014); and *FY 2014 Performance Report to Congress for the Prescription Drug User Fee Act* (Silver Spring, Md.: 2014).

[26]For example, see GAO, *Environmental Protection: EPA Should Develop a Strategic Plan for its New Compliance Initiative*, GAO-13-115 (Washington, D.C.: Dec. 10, 2012); *Managing for Results: Strengthening Regulatory Agencies' Performance Management Practices*, GAO/GGD-00-10 (Washington, D.C.: Oct. 28, 1999); and GAO/GGD-96-118.

of its general goals and objectives, the strategies needed to achieve its goals and objectives, how its performance goals related to its general goals and objectives, and program evaluations used to review its goals and objectives; and it does not identify external factors that could significantly affect the achievement of its goals and objectives.

Specifically, the SIMP presents high-level information on goals and performance measures for medical product oversight, but lacks detail on how it will be used or implemented. Each of the SIMP's first two sections describes a goal—improving efficiency and developing the workforce, respectively—and lists planned or ongoing initiatives to achieve that goal. For most of these initiatives, rather than describe the necessary steps, planned accomplishments, or time frames for implementation, the SIMP provides a high-level description of what FDA expects to achieve. In addition, the SIMP's summary states that the plan reflects coordination and cooperation among the centers to address their program-specific needs, share best practices, and share common solutions. However, FDA officials told us that they do not use the SIMP to address issues requiring center collaboration, and acknowledged that the plan did not represent the full range of working relationships among the centers. Moreover, the SIMP does not fully link its performance goals to its general goals and objectives. The SIMP instead describes performance measures related to FDA's user fee commitments, even though several of the initiatives included in the plan are unrelated to these commitments. FDA officials explained that they focused the SIMP's performance measures on user fee commitments rather than, for example, tying performance measures to each initiative, because user fee commitments are the main vehicle by which FDA assesses the efficiency of each medical product center's premarket review.

Additionally, groups we spoke with that represent the medical products industry did not view the SIMP as an effective strategic planning document for FDA. Of the five industry groups we interviewed, two were unfamiliar with the SIMP and the others did not see how its contents related to strategic planning. For example, representatives from one industry group said that the SIMP was neither integrated nor strategic, because it merely described the different activities of the centers rather than establishing one overarching strategic approach for all of the centers. Additionally, representatives from another industry group said that the SIMP lacked detail on how FDA would use it or implement the initiatives it described.

FDA officials said that due to the circumstances around FDASIA's enactment in 2012, they chose to develop the SIMP as a point-in-time

document to address legislative requirements rather than as a strategic plan for medical product oversight. For example, agency officials said FDASIA required FDA to submit the SIMP within a year of enactment, during which time FDA was also developing its agency-wide strategic priorities document.[27] Officials said that more time would have better enabled FDA to align the SIMP with agency-wide goals, and helped the agency to structure the plan as a strategic planning document. Officials also told us that leadership gaps in the Office of Medical Products and Tobacco, caused in part by turnover in the Deputy Commissioner position, created challenges when developing the SIMP. Officials said that, given these factors, the agency chose to develop a more limited document. Despite acknowledging that the SIMP was not intended to be an effective strategic planning document, FDA officials said that the SIMP's development process was useful because it facilitated coordination and information sharing between the centers on how to achieve certain user fee goals.

Nonetheless, FDA officials acknowledged the growing need for strategic planning across the medical product centers to improve center collaboration and address emerging issues, but said that it may not require a separate strategic plan. Officials said that some issues, such as staffing vacancies and coordination with other agencies, were better addressed at an agency-wide level. However, they indicated that integration and collaboration across the medical product centers are important for other issues that the agency is working to address, such as data sharing, evidence generation, biomarker integration, combination products, consistent terminology, patient engagement, and the medical product review process.[28] FDA officials also said that these types of issues have become more important as the complexity of medical products has increased, and that coordination can help the centers share leading practices to address these issues. For example, officials said that collaboration could help the centers develop more effective clinical trials, improve their decision-making, and improve the quality of evidence and

[27]See FDA, *Strategic Priorities: 2014-2018*.

[28]Combination products are therapeutic and diagnostic products that combine drugs, devices, and/or biological products.

clarity of guidance.[29] For these issues, FDA officials said that they continue to strategically plan across the centers without a written document specifically for medical products by using other planning documents. Although they noted that the agency's resources have been better spent working toward goals in existing plans, rather than putting together a new strategic plan specific to medical product oversight, they indicated that more formal planning in the future may be useful as resources become available.

FDA officials said that they did not structure the SIMP as a strategic plan, because they thought it would be duplicative of other FDA strategic plans; however, we found that none of these other plans comprehensively describes FDA's long-term plan for addressing key issues amongst the centers, as summarized below:

- FDA has an overarching strategic priorities document that includes strategic goals and objectives for medical product activities.[30] This document describes a broad level of activities, but does not specifically discuss strategies across the centers. For example, one FDA goal is partially aimed at improving coordination within FDA, and the agency also describes some activities that may require the centers' collaboration, such as developing comprehensive regulatory approaches for integrating approval and compliance functions.

- FDA officials said that they use the annual budget process as an opportunity for strategic planning. While FDA's fiscal year 2017 budget justification describes planned activities specific to each center, its planning across the centers is limited to a few specific initiatives, such as developing scientific workshops to advance the development of pediatric therapeutic products.[31]

[29]FDA's Science Board also identified collaboration as essential for the agency to be successful in driving innovation in product development, particularly for new diagnostic and preventive tools, treatments, and cures. The Science Looking Forward Committee, Report of the Science Looking Forward Committee, prepared for FDA Science Board, *Mission Possible: How FDA Can Move at the Speed of Science* (Washington, D.C.: September 2015).

[30]See FDA, *Strategic Priorities: 2014-2018*.

[31]See Department of Health and Human Services, *Fiscal Year 2017: Food and Drug Administration Justification of Estimates for Appropriations Committees*.

- FDA officials identified strategic plans for specific initiatives that involve each center, such as FDA's strategic plan for advancing regulatory science and FDA's strategic plan for information technology.[32] However, we recently reported on FDA's strategic plan for information technology, finding a lack of goals and performance measures for determining whether its implementation is successful in supporting FDA's mission.[33]

- Each center also has its own strategic plan, but they differ in structure and content.[34] While the center-specific plans include activities, goals, and objectives relevant to each individual center, they do not describe crosscutting issues or include plans for collaboration across the centers to address them. Officials from each center said that they also relied on performance measures in other documents, such as user fee commitments, to plan their activities and measure their performance.[35]

The growing importance of areas that cut across medical product centers highlights the importance of FDA's strategic planning for medical product oversight. The absence of a documented long-term plan for medical product oversight may hinder FDA's efforts to address emerging issues that require center collaboration, such as access to quality data and developing requirements for combination products. Also, the absence of a documented strategy is inconsistent with leading practices for strategic

[32]See FDA, *A Strategic Plan: Advancing Regulatory Science at FDA* (2011); FDA, *Information Technology Strategic Plan 2015-2018* (2015). For additional example, see FDA, *FDA's Strategic Plan for Risk Communication* (2009).

[33]To address these issues, we recommended that FDA establish schedules and milestones for completing an updated version of the information technology, and then implement the plan. GAO, *Information Technology: FDA Has Taken Steps to Address Challenges, but Needs a Comprehensive Strategic Plan*, GAO-16-182 (Washington, D.C.: Dec. 17, 2015). In addition, we expect to soon issue a companion report on FDA's regulatory science efforts related to medical products, in which we examine the agency's strategic planning, funding, and achievements related to these efforts.

[34]See CBER, *Strategic Plan: 2012-2016* (2011); CDER, *Strategic Plan 2013-2017*; CDRH, *2016-2017 Strategic Priorities*.

[35]The user fee commitments contain performance goals for FDA's review activities, such as reviewing and acting upon a certain number of received medical product applications within certain time frames. Officials said that these commitments are generally focused on FDA's premarket review process.

planning based on prior GAO work.[36] These practices indicate that formal strategic planning is needed for medical products by identifying crosscutting issues and ensuring that collaborative center goals, measures, and activities are effectively integrated with FDA's overall organizational mission and goals. Documenting a strategic plan for medical products—whether it occurs in a freestanding document or as part of existing documents the centers are already using—would also enable FDA to oversee its activities in a consistent and transparent manner, help the agency communicate its priorities to key stakeholders, and help align its activities to support mission-related outcomes.

FDA Included Mostly a Compilation of Preexisting Efficiency and Workforce Development Initiatives in its Strategic Integrated Management Plan

In FDA's SIMP, the agency compiled 30 efficiency initiatives under three different themes and included 19 different types of workforce development initiatives for each center on training, recruitment, and retention. FDA had fully implemented about a third of the efficiency initiatives and most of the workforce development initiatives prior to the SIMP's issuance in 2013.

FDA's Strategic Integrated Management Plan Included User Fee and Center Initiatives to Improve Efficiency, About a Third of Which Were Implemented Prior to the Plan's Issuance

We found that FDA grouped the SIMP's 30 efficiency initiatives into three themes: (1) business modernization, (2) process improvement, and (3) smarter regulation. (See appendix I for a full description of each efficiency initiative.)

- Under business modernization, FDA included 3 initiatives on each center's workload measurement activities, 3 initiatives focused on data standards efforts, and 2 initiatives specific to staff location and ability to use electronic functions to complete their work. For the initiatives on the centers' workload measurement activities, the centers each updated their time reporting systems to record user fee

[36]For example, see GAO/GGD-00-10; GAO-13-115; and GAO, *Maritime Administration: Ship Disposal Program Needs Improved Communications and Updated Strategic Planning*, GAO-14-223 (Washington, D.C.: Feb. 12, 2014).

activities, which employees are required to do in 2-week increments four times during the fiscal year.[37]

- Under process improvement, FDA included 11 efficiency initiatives specific to an agency-wide or center-specific need. CBER included initiatives to improve its review mechanisms and move to more electronic processes. CDER included efforts to streamline processes for its formal communication mechanisms with the industry and manufacturing facilities. CDRH included pilot programs for certain device types and manufacturers, and a postmarket program for identifying new device risks.

- Under smarter regulation, FDA included 11 initiatives—8 initiatives that stem from each user fee program, as well as 3 initiatives for medical devices that respond to other statutory requirements. The majority of the 11 initiatives are focused on the premarket review process of medical products. Specifically, the initiatives are related to improving communication between FDA and the industry, providing additional guidance to industry for how FDA will assess medical products, providing its plans for health information technology, and defining FDA's approach to and requirements for facilities that manufacture drug products.

The SIMP notes that these three themes reflect the strategic goals and priorities that the medical product centers are all pursuing to improve efficiency. FDA officials further explained that the three themes helped to connect seemingly unrelated center-specific and user fee program responsibilities and initiatives presented in the SIMP.

We found that FDA fully implemented about a third of the 30 efficiency initiatives within the 12 to 18 months prior to the SIMP's issuance in July 2013, and implemented another half of the initiatives since then. As of March 2016, the remaining initiatives had yet to be fully implemented, the majority of which are related to developing data standards for electronic submissions or efforts to move to an electronic review process. For example, CDRH specified that its initiative to establish a unique device

[37]In GAO-10-279, we recommended that FDA track its workload by strategic goals. While FDA provided information on its efforts to estimate resources for medical product responsibilities, it has yet to fully address this recommendation through the agency's various employee time reporting systems.

identification system started with the highest risk medical devices and will be fully implemented in 2020 once all medical devices have identifiers in electronic health records. (See table 1.)

Table 1: Efficiency Initiatives in the Food and Drug Administration's (FDA) Strategic Integrated Management Plan, by Implementation Status

Efficiency initiative	Implementation status		
	Prior to July 2013	By March 2016	Not fully implemented
1. Biosimilar User Fee Act (BsUFA) meeting types	✓		
2. Center for Biologics Evaluation and Research's (CBER) new approach to time reporting	✓		
3. Center for Drug Evaluation and Research's (CDER) new approach to work tracking and time reporting	✓		
4. Center for Devices and Radiological Health (CDRH) 510(k) triage program	✓		
5. CDRH's management of premarket device review process and workload	✓		
6. FDA's new authorities related to electronic submissions and data standardization	✓		
7. Prescription Drug User Fee Act (PDUFA) enhanced communication with sponsors during drug development	✓		
8. PDUFA meeting minutes	✓		
9. PDUFA new review program for the most innovative new drugs and biologics	✓		
10. CBER's move to FDA White Oak headquarters		✓	
11. CDER Risk Evaluation and Mitigation Strategies review		✓	
12. CDER warning letters		✓	
13. CDRH changes to investigational device exemption decision program		✓	
14. CDRH's modernized infrastructure and processes for the review of premarket device applications		✓	
15. CDRH regulatory framework for health information technology		✓	
16. CDRH signal management program		✓	
17. FDA User Fee Council		✓	
18. Generic Drug User Fee Amendments Act (GDUFA) commitments, complete review, and easily correctable deficiencies		✓	
19. GDUFA risk-based and parity of foreign and domestic inspection frequency		✓	
20. GDUFA self-identification of generic drug facilities, sites, and organizations		✓	
21. Medical Device User Fee and Modernization Act (MDUFA) improved review experience		✓	
22. PDUFA data standards plan goals		✓	
23. PDUFA enhancing benefit-risk assessment		✓	
24. CBER electronic managed review process tool			✓
25. CBER electronic review templates			✓

Efficiency initiative	Implementation status		
	Prior to July 2013	By March 2016	Not fully implemented
26. CBER quality system for Managed Review Process			✓
27. CDRH Medical Device Single Audit Program			✓
28. CDRH parallel review pilot program			✓
29. CDRH unique device identification system			✓
30. Data standards efforts jointly pursued by the medical product centers			✓

Source: GAO analysis of FDA documents. | GAO-16-500

FDA Included Different Types of Workforce Development Initiatives for Each Center, and Most Initiatives Were Implemented Prior to the Strategic Integrated Management Plan's Issuance

We found that FDA included 19 workforce development initiatives in the SIMP—11 training initiatives, 7 recruitment initiatives, and 1 retention initiative. (See appendix II for a full description of each workforce development initiative.) FDA officials told us that the majority of the workforce development initiatives are specific to each center's activities, reflecting differences in program responsibilities and procedures. Industry officials we spoke with emphasized the importance of recruitment, retention, and training efforts on the agency's ability to meet user fee commitments. (For more information on the size and characteristics of FDA's overall and center-specific workforce, see appendix III.)

The 11 training initiatives FDA included in the SIMP describe multiple training courses or programs.[38] As part of these initiatives, FDA included programs for the new reviewer trainings offered by each of the medical product centers and initiatives covering training for each of the user fee programs, which may be taken by staff from multiple centers. The initiatives also included training courses dedicated to specific topics for each medical product center. For example, CBER included training courses covering medical device review and project management, and CDRH included two leadership experience programs for future and current managers. The first CDRH program gives certain staff an opportunity to explore a supervisory career path; the second is to help

[38]Some training initiatives have several components. For example, CBER's reviewer training and review management updates initiative contains four different training courses or programs.

staff in management positions learn about CDRH's management competencies and satisfy federal supervisory training requirements.[39]

We found that the seven recruitment initiatives FDA included in the SIMP are intended to streamline recruitment processes at both the agency and center levels.[40] For example, CDER included initiatives to manage and fill vacancies in executive-level positions and critical occupations, such as chemists and project managers.[41] Each of the centers also included initiatives to improve outreach to potential job candidates, such as through job fairs, alumni networks, and institutional partnerships.

For retention, we found that FDA included a single initiative in the SIMP—CDRH's efforts to address the center's high attrition rate by reducing individual workloads, decreasing staff-to-manager ratios, and providing employees with a better work environment. To reduce staff workloads and decrease staff-to-manager ratios, CDRH increased the number of review and management staff.[42] To provide a better work environment, CDRH developed and improved performance evaluation tools and employee recognition processes. For example, CDRH created a resource guide to educate staff on the center's performance management system. FDA did not include retention initiatives for CBER or CDER in the SIMP; however,

[39]Federal agencies are required to have policies to ensure the implementation of leadership development programs and training for individuals in supervisory, managerial, and executive positions in support of the agency's management succession planning. 5 C.F.R § 412.202 (2015).

[40]While FDA's Office of Human Resources has ultimate hiring authority, the centers can initiate their own programs to recruit and retain potential candidates.

[41]FDA indicated that it could not provide vacancy data for each fiscal year by center, because the agency does not currently have a system of record to accurately track this information and cannot validate the data. Each center uses a different methodology, and vacancy data changes on a routine basis. FDA previously reported center vacancies as of September 1, 2014 as part of correspondence documented in a congressional report. See, A Report by Sen. Lamar Alexander (R-Tenn.) and Sen. Richard Burr (R-N.C.), *Innovation for Healthier Americans: Identifying Opportunities for Meaningful Reform to Our Nation's Medical Product Discovery and Development* (Washington, D.C.: Jan. 29, 2015).

[42]As part of MDUFA negotiations, CDRH committed to hire more staff, which is scheduled to continue through 2017.

officials from both centers told us that each center uses some retention tools and processes.[43]

Among the 19 workforce development initiatives included in the SIMP, 15 initiatives were implemented prior to the plan's issuance in July 2013. By March 2016, FDA implemented 2 additional workforce development initiatives, bringing the total to 17 initiatives. Of the remaining 2 initiatives, 1 is still being implemented. CDRH is in the process of reducing staff workloads as part of the center's retention initiative—an activity related to hiring plans that are to be phased in through fiscal year 2017. The final one, CDER's alumni network initiative, was terminated. CDER planned to pilot the initiative in four of its offices beginning in 2013, but it was never piloted or implemented due to a lack of employee activity in alumni associations. (See table 2.)

Table 2: Workforce Development Initiatives in the Food and Drug Administration's (FDA) Strategic Integrated Management Plan, by Implementation Status

	Implementation status		
Workforce development initiative	**Prior to July 2013**	**By March 2016**	**Not fully implemented**
1. Biosimilar User Fee Act trainings	✓		
2. CDER's Blue Ribbon Executive Recruitment Program	✓		
3. CDER's comprehensive training program[a]	✓		
4. CDER's continuing education program	✓		
5. CDER's corporate recruitment process	✓		
6. CDRH's Experiential Learning Program	✓		
7. CDRH's Leadership Enhancement and Development Program	✓		
8. CDRH's Leadership Readiness Program	✓		
9. CDRH's Reviewer Certification Program	✓		
10. CDRH's strategic communication and outreach	✓		
11. FDA's hiring authorities	✓		

[43]CBER officials told us that retention activities in the center are minimal, but the center does use incentives and awards. CBER's 2012-2016 Strategic Plan highlights retention as a part of its management goals. From 2012 to 2015, the center had the highest percentage of retirement-eligible staff of the three medical product centers. While attrition rates for CDER and CDRH have decreased, CBER's attrition rate has increased from 4.7 percent in 2012 to 7.8 percent in 2015. CDER officials also told us that they have retention tools, including a student loan repayment program, retention incentives, as well as center- and office-level honors and awards.

Workforce development initiative	Implementation status		
	Prior to July 2013	By March 2016	Not fully implemented
12. FDA's re-established human resources responsibility	✓		
13. Generic Drug User Fee Amendments Act trainings	✓		
14. Medical Device User Fee and Modernization Act trainings	✓		
15. Prescription Drug User Fee Act trainings	✓		
16. CBER's comprehensive recruitment strategy		✓	
17. CBER's reviewer training and review management updates[b]		✓	
18. CDRH's retention initiatives[c]			✓
19. CDER's alumni network			N/A[d]

Source: GAO analysis of FDA documents. | GAO-16-500

[a]The Center for Drug Evaluation and Research's (CDER) comprehensive training program initiative includes a description of the New Reviewer Blended Learning Program.

[b]The Center for Biologics Evaluation and Research's (CBER) reviewer training and review management updates includes new reviewer, device reviewer, and project management trainings, and review management updates.

[c]The Center for Devices and Radiological Health's (CDRH) retention initiatives include efforts to reduce staff workloads and provide employees with a better work environment.

[d]CDER's alumni network initiative was never piloted or implemented due to a lack of employee activity in alumni associations.

FDA Identified Mechanisms for Evaluating the Effectiveness of the Majority of Its Strategic Integrated Management Plan Initiatives

We found that FDA had already established or has plans to establish formal and informal mechanisms to assess the effectiveness of just over half of the 30 efficiency initiatives in the SIMP. For the SIMP's workforce development initiatives, FDA identified mechanisms to assess most of the 19 initiatives, and each center's approach to assess training is different.

FDA Identified Formal and Informal Mechanisms to Evaluate the Effectiveness of Just Over Half of Its Efficiency Initiatives

FDA stated that the agency had assessed or has plans to assess just over half of the 30 efficiency initiatives for effectiveness, although these plans are generally not described in the SIMP. In its plan, FDA identified formal measures of effectiveness for 3 initiatives, each of which is based on a MDUFA or PDUFA commitment, but does not specify any additional measures in the plan itself for the remaining 27 initiatives.[44] (See table 3.) However, we found that FDA has formal or informal measures that do not appear in the SIMP for a majority of these initiatives.

Table 3: Evaluations Included in the Food and Drug Administration's (FDA) Strategic Integrated Management Plan (SIMP) for the Initiatives to Improve Efficiency

Evaluation	Description and results
Interim and final assessment of the new review program for the most innovative drugs and biologics	FDA completed the interim assessment in March 2015 that it committed to under the Prescription Drug User Fee Act (PDUFA). It found that the program has been successful in enhancing review transparency, communication, and predictability. The interim report also made 10 recommendations to FDA, including a recommendation to analyze the expected burden on the agency's reviewers when adding new review process requirements to ensure timeliness and thoroughness. The final assessment is scheduled to be completed in December 2016.
Evaluation of the benefit-risk framework in regulatory decision-making	FDA selected a third-party contractor in October 2015 to begin the assessment of the benefit-risk framework that it committed to under PDUFA. Center officials expect the evaluation to be completed in mid-2017.
Medical Device User Fee and Modernization Act comprehensive examination of the device review process	A third-party contractor completed an initial assessment of the program in June 2014 and issued a final evaluation of the Center for Devices and Radiological Health's (CDRH) progress in meeting its recommendations in February 2016. The initial assessment made 11 overarching recommendations touching on CDRH's review process, infrastructure, guidance, workload tools, training, and staff turnover. CDRH officials told us that the assessment is also the mechanism by which they assess the SIMP initiative to move the premarket device application review process to a modernized infrastructure. The final evaluation reported that CDRH had satisfied FDA's commitment to fulfill the recommendations.

Source: GAO analysis of FDA documents. | GAO-16-500

Note: FDA did not include in the SIMP any evaluation studies for the two user fee programs—the Biosimilar User Fee Act and the Generic Drug User Fee Amendments Act—for medical products authorized in 2012.

[44]While FDA also listed other evaluations in the SIMP, these were not related to a specific initiative for improving efficiency. The evaluations that FDA committed to under PDUFA, but not related to a specific initiative to improve efficiency are: (1) an evaluation of rare disease drug development activities, (2) an evaluation of the impact of electronic submissions and data standards for postmarket safety surveillance, (3) a fiscal year 2013 evaluation of the review activity adjustment methodology, and (4) a fiscal year 2015 evaluation of the review activity adjustment methodology.

For five initiatives, FDA officials identified formal measures of effectiveness that were not described in the SIMP. The officials explained that these initiatives are assessed through periodic user fee program reports or center strategic goals. For example

- CDER officials told us that the GDUFA initiative on commitments, complete review, and easily correctable deficiencies is assessed against the user fee commitments. For example, FDA committed to review and act on 90 percent of complete, electronic abbreviated new drug applications within 10 months after the date of submission. FDA does not have to meet some of these commitments until 2017, but the agency indicated that it faces challenges meeting them due to a large backlog of applications.[45]

- CDRH officials told us that they assessed the investigational device exemption decision program using center-specific strategic goals related to reducing the number of review cycles needed before full approval, and reducing the overall median time to full approval. CDRH met each of these goals in fiscal year 2015.

For nine initiatives, officials from each center described efforts they took to informally examine effectiveness. For example, CBER uses staff feedback to assess implementation of its electronic review templates, and incorporates revisions as appropriate. For CDRH's initiative to establish a unique device identification system, officials said they track certain metrics, such as numbers of vendors certified to participate in the program and visits to the program's website.

FDA officials told us that, for the remaining 13 effectiveness initiatives in the SIMP, they are either exploring effectiveness measures or do not have plans to measure effectiveness. In some cases, officials described ways in which effectiveness could be measured or efforts to develop assessments. For example, CDRH officials told us that they did not currently have, but were exploring, ways to measure the impact of its signal management program initiative through industry responses or actions taken. In other instances, such as with CBER's two initiatives on

[45]Prior to GDUFA, FDA had accumulated a backlog of 2,866 original amended new generic drug applications. In addition, FDA received more of this type of application than expected in fiscal years 2013 and 2014. These high numbers led to a generic drug applications backlog, where FDA has approximately 3,300 pending applications in addition to post-approval studies.

improving its managed review process tool, officials indicated that they were unclear about the best way to measure effectiveness. Additionally, FDA does not have current plans to measure effectiveness of some initiatives and officials noted that such measurement would be either unnecessary or impractical. For example, FDA is not measuring effectiveness for the PDUFA meeting minutes initiative, because officials said it would be a challenge to survey sponsors and the agency wants to be selective about choosing that option.

FDA Identified Mechanisms to Assess Most of the Workforce Development Initiatives, including Centers' Different Approaches to Assess Training

FDA identified mechanisms to assess the effectiveness of 12 of the 19 workforce development initiatives. Specifically, the agency identified mechanisms to assess 4 of 7 recruitment initiatives, the 1 retention initiative, and 7 of 11 training initiatives. In the SIMP, FDA generally did not describe assessments for specific initiatives, but rather described each user fee program's hiring and training commitments as broad measures of the agency's workforce development efforts. For example, in order to reach the committed GDUFA level of 923 full-time equivalent staff by the end of fiscal year 2015, FDA committed to hire and then train at least 25 percent of staff in fiscal year 2013 and 50 percent in fiscal year 2014. FDA reported that it met this commitment by October 2014, 11 months ahead of schedule. (As previously noted, appendix III provides additional information on the size and characteristics of FDA's overall and center-specific workforce.)

FDA officials described the mechanisms in place to assess the effectiveness of 4 of the 7 recruitment initiatives described in the SIMP. For the two that are FDA-wide recruitment initiatives, FDA uses agency- and department-wide tools to measure the overall effectiveness. Specifically, FDA developed the FDA Accelerated Staffing Track 80-day hiring metric in early fiscal year 2015 to measure the time it takes to hire a new employee once the need is identified.[46] However, officials said that data quality and data entry issues limited the accuracy and validity of the data available at the time of our review.[47] In addition, FDA uses HHS

[46]The FDA Accelerated Staffing Track metric is tracked in the automated Human Resources Employee Personnel System, and has 11 steps from start to finish, with performance indicators at each step.

[47]With the fiscal year 2015 data currently available to the Office of Human Resources, FDA's average overall time to hire was 91 days. For the same fiscal year, the average time to hire for each medical product center was 77 days for CDER, 68 days for CDRH, and 67 days for CBER.

personnel information systems to track monthly and quarterly hire and separation data for each medical product center.[48] Officials also described performance metrics that CBER and CDRH track to assess effectiveness for two center-specific recruitment initiatives. For CBER's comprehensive recruitment strategy, the center tracks the number of resumes received and hires from targeted populations. For example, CBER hired four veteran; five minority; and 31 science, technology, engineering, and mathematics candidates during fiscal year 2015. For CDRH's initiative on strategic communication and outreach for recruitment, the center uses monthly reports to track the number of applicants responding to the center's job postings, including data on the number of applicants that apply to and are eligible for each position. For the three recruitment initiatives that do not currently have mechanisms to assess effectiveness, CDER officials described the center's current plans or what it had already done. For one initiative, officials said that the center is developing an automated project management and tracking tool. Officials expect that the tool will be implemented in spring 2016. For another initiative, CDER met its overall hiring objectives, but did not measure the number of selections made as a result of the initiative itself. Finally, CDER's alumni network initiative was never implemented, and thus FDA did not put in a place a mechanism to assess its effectiveness.

To assess the effectiveness of the one retention initiative in the SIMP, CDRH officials told us they measure the number of full-time equivalent staff supporting MDUFA activities, changes in staff-to-manager ratios, and survey results. CDRH's total full-time equivalent staff supporting MDUFA increased from 1,133 in fiscal year 2013 to 1,293 in fiscal year 2015. At the same time, CDRH reduced the staff-to-manager ratio in its two offices with medical device review responsibilities.[49] CDRH also analyzes changes in federal Employee Viewpoint Survey responses to

[48]FDA uses HHS's Business Intelligence Information System, which tracks and consolidates attrition data on a quarterly basis. These consolidated data include information on rates of new hires and separations (i.e., staff turnover) by pay grade and demographics, and can be broken down to the FDA and center levels. FDA also uses Capital HR, the personnel system for the civilian population used by HHS. FDA's Office of Human Resources and center officials with "need to know" access can use the system for personnel actions, such as retrieving staffing lists. Officials also use this system to track retention data, whether for categorical or individual retention activities.

[49]In the CDRH office responsible for device evaluation, staff-to-manager ratios decreased from 14:1 in fiscal year 2011 to 11:1 in fiscal year 2015. In the CDRH office responsible for evaluation of diagnostic tests and radiological devices, staff-to-manager ratios decreased from 27:1 in fiscal year 2011 to 12:1 in fiscal year 2015.

assess its efforts to provide a better workplace for its employees. From 2011 to 2014, CDRH observed positive changes for three of six critical indicators it identified for providing recognition and all six critical indicators it identified for performance evaluation.

Of the 11 training initiatives, CBER, CDER, and CDRH officials each identified mechanisms to assess the effectiveness of 7 initiatives.[50] Specifically, each center indicated that it uses participant surveys to assess effectiveness. CBER also delivers a test at the conclusion of some, but not all, of the programs included in its training initiative.[51] Furthermore, as described in the SIMP, CDRH conducts an audit process for its Reviewer Certification Program through which new reviewers are evaluated by an experienced reviewer. During the audit process, new reviewers are rated against six criteria, including the appropriate use of guidance and strength of final review decision analyses.[52]

The four remaining training initiatives described in the SIMP were related to each user fee program and the centers use different approaches to assess the extent to which all reviewers required to complete training have done so. CBER and CDER track the names of staff who register for training and do not measure the number of medical product reviewers required to complete the trainings. CBER and CDER officials said that FDA was not required to report on training completion rates, and they assume that required staff completed user fee training, because it is

[50]In addition to initiative-specific evaluations, CBER and CDER officials told us that they each conduct overall training program assessments, which include the training initiatives described in the SIMP. CDER's training needs assessment helps determine the extent to which current trainings fit into staff needs and center-wide training priorities. In 2010, CDER conducted a center-wide survey and developed recommendations for five training program areas. CDER conducted another assessment in 2014 to evaluate training needs for center-specific competencies. CBER uses an annual training assessment to establish training priorities and support the achievement of the center's strategic goals. CBER's 2016 assessment included an online survey of center staff, a follow-up survey of high-interest subject areas, and interviews with center offices.

[51]CBER officials also told us they review completed tests for commonly missed test questions, as well as use real-time answers during some training classes. If commonly missed questions are identified, the course instructor will be asked to rewrite the question or allocate more course time to explaining the question and the correct answer. Some courses incorporate real-time feedback, where question answers are aggregated and projected on a screen. Instructors then identify the topics or concepts for which follow-up is needed.

[52]The SIMP also describes the agency's commitment to assess some CDRH workforce activities, such as leadership and reviewer trainings.

made available in different settings, such as CBER's review management updates and CDER's new employee orientation. For example, CDER officials told us that 99 percent of the staff hired under the GDUFA commitment had completed training, as all hired staff take mandatory online training once hired. Training completion rates are not included in GDUFA performance reports. In contrast, CDRH measures user fee training completion rates among its required staff and reports on these rates in MDUFA quarterly performance reports, as required by their user fee commitments. CDRH reported a 99 percent staff completion rate among its review staff required to complete MDUFA training.

Center officials did not identify any mechanisms to assess how effective participants were in applying the information learned during these user fee trainings (known as training comprehension). CBER officials said its user fee trainings were delivered and recorded in special training sessions, such as in monthly review management updates, and that these trainings do not have mechanisms to assess comprehension. CDER officials were unable to show that staff who took user fee trainings were given post-completion tests. CDRH officials told us that a post-completion test was not disseminated for the initial MDUFA trainings. However, CDRH has since incorporated the user fee trainings into the center's Reviewer Certification Program, which has multiple mechanisms for assessment.

Conclusions

Emerging issues—including increasingly complex medical products such as combination products, the need for integrated information systems, and the increased hiring demands for specific scientific knowledge—go beyond the expertise of a single medical product center and highlight the growing importance of strategic planning across medical products. Advances involving new diagnostic tools, treatments, and cures require collaboration in order to be successful. However, FDA has faced longstanding challenges in carrying out the many responsibilities necessary for the oversight of medical products. While FDA engaged each of the medical product centers in the development of the SIMP, this narrowly focused plan is not used by the agency or centers. Moreover, it highlights gaps in the agency's management across FDA's medical product centers by not fully linking its performance goals to its general goals and objectives, and having limited information on implementation time frames. While FDA has various other strategic planning documents for medical product oversight, these documents also do not set a long-term strategy for the centers, because they are focused on narrower issues or do not have details specific to center-level collaboration. Using leading practices identified as essential for strategic planning can help

ensure the agency is prepared to address challenges requiring coordination across the centers in a consistent and transparent manner. Documenting measurable goals, objectives, and a long-term strategy for areas resulting from this planning—whether it is through a freestanding document or as part of existing documents—can help the agency ensure its priorities are communicated among key stakeholders, even in times of leadership turnover.

Recommendation for Executive Action

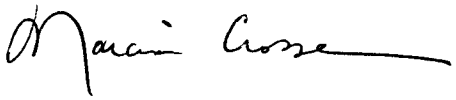
To ensure that FDA can effectively coordinate and integrate its medical product centers' programs and emerging issues, we recommend that the Secretary of Health and Human Services direct the Commissioner of FDA to engage in a strategic planning process to identify challenges that cut across the medical product centers and document how it will achieve measurable goals and objectives in these areas.

Agency Comments and Our Evaluation

We provided a draft of this report to HHS. The agency agreed with our recommendation and provided written comments, which are reprinted in appendix IV. In its written comments, HHS described the context surrounding the development of the SIMP and the progress FDA has made regarding its medical product review activities under its four user fee programs. It noted the importance of coordinating and integrating the activities that are common among FDA's medical product centers. In agreeing with our recommendation, HHS indicated that FDA has already started a process to identify key crosscutting themes for the medical products centers, which it will then use to develop an overarching strategic planning framework to guide the work of these centers. We encourage FDA to use leading practices to ensure this framework has measurable goals and objectives.

As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution of it until 30 days from its date. At that time, we will send copies to the Secretary of Health and Human Services. In addition, the report will be available at no charge on the GAO website at http://www.gao.gov.

If you or your staffs have any questions about this report, please contact me at (202) 512-7114 or crossem@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.



Marcia Crosse
Director, Health Care

Appendix I: Description of Efficiency Initiatives in FDA's Strategic Integrated Management Plan

Table 4 shows each efficiency initiative that the Food and Drug Administration (FDA) included in its strategic integrated management plan. FDA described 30 efficiency initiatives in its plan, including those specific to a medical product center or to a user fee program. FDA also grouped the initiatives into three themes: (1) business modernization, (2) process improvement, and (3) smarter regulation.

Table 4: Efficiency Initiatives in the Food and Drug Administration's (FDA) Strategic Integrated Management Plan

Efficiency initiative	Description
Business modernization	
CBER's move to FDA White Oak headquarters	CBER will centralize its staff from multiple sites to FDA's headquarters in White Oak, Maryland.
CBER's new approach to time reporting	CBER updated the system for its workload measurement tool, which will enable the center to track user fee efforts.
CDER's new approach to work tracking and time reporting	CDER modernized its workload tracking system, in part, to track time spent on user fee regulatory activities.
CDRH's management of premarket device review process and workload	CDRH began using information technology tools to better facilitate its premarket device review process. In doing so, CDRH revised its time reporting codes to better align with the current user fee requirements.
CDRH's modernized infrastructure and processes for the review of the premarket device applications	CDRH implemented new electronic tools to improve premarket reviews, including a move to allow digital signatures and increased telecommuting. CDRH also implemented a standard electronic filing structure for its internal records management activities.
Data standards efforts jointly pursued by the medical product centers	The medical product centers collaborate in the areas of data standards governance, data management, and electronic submissions. Each center participates on each other's councils, as well as FDA's Data Standards Council. The centers also work with standards development organizations to develop and issue guidance on electronic submissions.
FDA's new authorities related to electronic submissions and data standardization	FDA is using its new statutory authority to require electronic transmission using standardized data formats for certain submission types.
PDUFA data standards plan goals	In the PDUFA data standards plan, CBER and CDER have defined an approach to developing clinical trials study data terminologies and content standards for over 50 disease and therapeutic areas. The centers work with a standards development organization to then develop the standards.
Process improvement	
CBER electronic managed review process tool	CBER is developing an electronic tool to provide review staff with more access to standard operating procedures, checklists, and guidance in the review process.
CBER electronic review templates	CBER is implementing electronic review templates for staff to use when reviewing biological product license applications. The electronic review templates include links to relevant guidance and standard operating procedures.
CBER quality system for Managed Review Process	CBER is putting into place a quality system to be able to perform quality assurance audits of its review process. CBER is also evaluating specific processes of the review process for efficiency and to ensure consistent application.

Efficiency initiative	Description
CDER Risk Evaluation and Mitigation Strategies review	CDER is identifying ways to improve the consistency and timeliness of the Risk Evaluation and Mitigation Strategies reviews that it is required by law to conduct when it identifies that additional risk management is necessary to assess if the benefits of a drug outweigh its risks.
CDER warning letters	Along with FDA's Office of Regulatory Affairs, CDER is streamlining its process for issuing warning letters to pharmaceutical manufacturing facilities when it finds compliance issues.
CDRH 510(k) pilot program	CDRH is deploying a triage program to place good quality 510(k) submissions into a quicker 30-day review track. Sponsors may submit a 510(k) submission when the sponsor can demonstrate to FDA that the new device is substantially equivalent to a device already legally on the market. Using a streamlined memo, reviewers can rely on FDA experience with devices to focus on the key elements of the submission.
CDRH Medical Device Single Audit Program	CDRH, working with a coalition of regulatory authorities representing four countries and 13 auditing organizations, is piloting a program that will allow a single audit of a device manufacturer's quality management system to meet the needs of each participating regulatory authority.
CDRH parallel review pilot program	CDRH, along with the Centers for Medicare & Medicaid Services, will conduct parallel review to address the needs of both agencies when voluntarily requested by sponsors of innovative devices.
CDRH signal management program	CDRH re-assessed its postmarket activities to address new and unexpected risks for marketed devices and put into place signal review teams that evaluated newly identified safety signals for devices in the pilot program.
FDA User Fee Council	FDA established a User Fee Council to coordinate and oversee agency-wide user fee programs, including those for medical products. The council serves as the mechanism to communicate with FDA management.
PDUFA meeting minutes	CDER is streamlining its approach to the meeting minutes it must send drug sponsors after their meetings in order to more consistently and timely capture the advice and discussion that took place.
Smarter regulation	
BsUFA meeting types	FDA established five premarket meeting types that sponsors can choose to match their drug development needs.
CDRH changes to investigational device exemption decision program	FDA revised its premarket decision policy for approving investigational device exemptions, modified decision letters, and issued guidance on the new decision policy. In addition, FDA will issue regulations on clinical hold authority for when use of a device poses an unreasonable safety risk.
CDRH regulatory framework for health information technology	FDA is required to publish a report for a risk-based regulatory framework for health information technology, including mobile medical applications.[a]
CDRH unique device identification system	FDA is required to finalize and implement regulations that establish a postmarket unique device identification system for medical devices.[b] This system—phased in by medical device class and characteristic over a 7-year period—will enable FDA to adequately identify a medical device throughout its distribution and use.
GDUFA commitments, complete review, and easily correctable deficiencies	FDA agreed to performance goals for premarket review of original unamended abbreviated new drug applications, to issue complete response letters to all applicants in a more timely manner, to communicate promptly with applicants on easily correctible deficiencies in the submissions, and to clarify issues and answer questions during first review cycle meetings.

Efficiency initiative	Description
GDUFA risk-based and parity of foreign and domestic inspection frequency	FDA will use a risk-based approach to prioritize premarket inspections of foreign and domestic drug manufacturing establishments. As appropriate, FDA will use relatively recent routine surveillance inspections in lieu of application-specific inspections for drug application approvals.
GDUFA self-identification of generic drug facilities, sites, and organizations	Generic drug facilities, sites, and organizations must electronically submit identification information on an annual basis to FDA.
MDUFA improved review experience	In order to provide more complete feedback to industry earlier in the premarket regulatory process, FDA implemented a structured presubmission process, submission acceptance reviews, and substantive interaction goals. Among other activities, FDA issued communications guidance in February 2014 on presubmission feedback to sponsors and meetings with FDA review staff.
PDUFA enhanced communication with sponsors during drug development	FDA agreed to strengthen premarket communication with sponsors during drug development, including selected points of contact for general questions or for communication challenges. In addition, FDA published guidance in December 2015 on best practices for communication.
PDUFA enhancing benefit-risk assessment	FDA was required to implement a structured benefit-risk framework for the new drug and biologics approval process.[c] The agency plans to base this framework on the benefit-risk assessment it developed over the past several years and phase in the framework throughout the current PDUFA reauthorization. In addition, FDA initiated patient-focused drug development meetings on certain disease areas to gain patient perspectives.
PDUFA new review program for most innovative drugs and biologics	FDA agreed to develop a new premarket review program for the most innovative new drugs and biologics that includes new meeting types for communication between FDA and the drug sponsor, as well as more review time in the first review cycle.

Source: GAO analysis of FDA documents. | GAO-16-500

Notes: Three FDA centers have primary responsibility for overseeing medical products: the Center for Biologics Evaluation and Research (CBER), the Center for Drug Evaluation and Research (CDER), and the Center for Devices and Radiological Health (CDRH). A significant portion of FDA's annual appropriation consists of amounts derived from user fees paid by the medical products industry. Each user fee program supports different oversight activities across each of the centers. In 2012, the Food and Drug Administration Safety and Innovation Act of 2012 reauthorized or authorized four user fee programs for medical products: the Prescription Drug User Fee Act of 1992 (PDUFA), the Medical Device User Fee and Modernization Act (MDUFA), the Biosimilar User Fee Act (BsUFA), and the Generic Drug User Fee Amendments Act (GDUFA).

[a]Pub. L. No. 112-144, § 618(a), 126 Stat. 1063.

[b]Pub. L. No. 112-144, § 614, 126 Stat. 1061. (codified at 21 U.S.C. § 360i(f).

[c]Pub. L. No. 112-144, § 905, 126 Stat. 1092. (codified at 21 U.S.C. § 355(d).

Appendix II: Description of Workforce Development Initiatives in FDA's Strategic Integrated Management Plan

Table 5 shows each workforce development initiative the Food and Drug Administration (FDA) included in its strategic integrated management plan. FDA described 19 workforce development initiatives in its plan specific to recruitment, retention, or training.

Table 5: Workforce Development Initiatives in the Food and Drug Administration's (FDA) Strategic Integrated Management Plan

Workforce development initiative	Description
Recruitment initiatives	
CBER's comprehensive recruitment strategy	CBER targets candidates in specific populations, such as veterans and minorities. CBER interacts with these candidates at career fairs and scientific conferences, and posts job announcements in journals, on the center's website, and on diversity-focused job boards. The center also uses open and continuous announcements to recruit for mission critical positions, such as biologists.
CDER's alumni network	CDER intended to establish an alumni network of its current employees in order to develop relationships with academic institutions and recruit for vacant student and executive-level positions.
CDER's Blue Ribbon Executive Recruitment Program	CDER uses the recruitment program to manage and fill vacancies in executive positions. Each executive vacancy is managed as a separate project and overseen by a steering committee.
CDER's corporate recruitment process	CDER established a corporate recruitment model to streamline its processes for hiring scientific and non-scientific positions. CDER uses open and continuous announcements and other activities to hire for hard-to-fill positions—chemists, consumer safety officers, and mathematical statisticians. CDER also interacts with potential candidates at conferences and hiring events, trains its staff on how to recruit for the center, operates a website with information on open positions and other vacancies, and uses social media to inform FDA's followers of open job announcements.
CDRH's strategic communication and outreach	CDRH will, depending on annual hiring needs, perform outreach at career fairs, or visit professional and military associations and academic institutions. CDRH may also post job openings in print ads, industry journals, job boards, and career search engines, and network through former and current FDA employees.
FDA's hiring authorities	FDA uses special direct-hiring authorities to fill vacancies with a severe shortage of candidates or critical positions, including medical officer, nurse, and pharmacist positions. FDA also had temporary streamlined hiring authority to fill positions to carry out activities under MDUFA and GDUFA.[a]
FDA's re-established human resources responsibility	The Department of Health and Human Services returned human resources responsibility to FDA in 2012. FDA's Office of Human Resources was then created to provide human resources services to the agency and work closely with the centers on workforce development activities. Among other activities, this office has responsibility for recruitment, merit promotions, various personnel actions, human resources data collection and analysis, and chairing an FDA council on training.
Retention initiatives	
CDRH's retention initiatives	CDRH carried out a number of activities to reduce staff workloads and staff-to-manager ratios in its review divisions, and to provide employees with an improved work environment. CDRH committed to hiring additional reviewers and managers as part of user fee negotiations with the medical device industry. The center also developed and improved performance evaluation resources and employee recognition programs and processes.
Training initiatives	

Workforce development initiative	Description
BsUFA trainings	CDER's BsUFA training was a 2-hour program providing an overview of the new user fee requirements. CBER delivered BsUFA trainings at one of the center's review management updates.[b]
CBER's reviewer training and review management updates	CBER trainings include new reviewer training, device reviewer training, project management training, and monthly review management updates. CBER's new reviewer training is a 4-day program required for new review staff. The device reviewer training is a 2- to 3-day training that orients staff to the key device review elements. Project management training helps staff learn how to manage medical product submissions and may be offered through different academic institutions. CBER's review management updates serve as refreshers or introductions to policies, standard operating procedures, and other current issues impacting the review process.
CDER's comprehensive training program	The program represents the full range of training opportunities available to CDER staff, including CDER's learning program for new reviewers, which is delivered during a new reviewer's first 6 to 9 months at the agency. The learning program consists of six online modules and three corresponding workshops.
CDER's continuing education program	CDER awards continuing education hours and credits to physicians, pharmacists, and nurses for attending the center's seminars, workshops, and other activities that enhance the skills and knowledge of staff that support FDA's regulatory mission. CDER has considered expanding this program to include other professions, such as legal professionals.
CDRH's Experiential Learning Program	CDRH provides review staff with the opportunity to learn more from the medical device industry, the clinical community, and academic institutions on topics such as medical device design and manufacturing. Focus areas for fiscal year 2015 included refractive lasers, electrophysiology catheters, and good manufacturing practices.
CDRH's Leadership Enhancement and Development Program	This program is mandatory for CDRH supervisors, managers, and non-bargaining unit team leaders, and designed to satisfy federal supervisory training requirements. Training conducted in fiscal year 2015 included building strong customer relations, critical thinking for better decision-making, and non-verbal communication for managers.
CDRH's Leadership Readiness Program	This program is an opportunity for eligible staff to explore a supervisory career path. Once accepted into the program, participants engage in classroom training, practical activities, mentoring exercises, and shadowing sessions. Each program cohort consists of about 20 selected participants.
CDRH's Reviewer Certification Program	This program is a mandatory 10-month training for new reviewers in CDRH's two offices with medical device review responsibilities. It includes 38 courses, 140 training hours, hands-on exercises, knowledge assessments, and an audit process. Trainings conducted in fiscal year 2015 included basic food and drug law, how to write effective premarket consulting reviews, and signal management training.
GDUFA trainings	CDER offers GDUFA trainings every two weeks through its new employee orientation program in coordination with new employee hiring.
MDUFA trainings	CDRH developed MDUFA training modules, including information on changes to clinical laboratory laws and electronic workload management. These trainings were mandatory for all CDRH staff involved in premarket review and were incorporated into the center's Reviewer Certification Program. CBER reviewers were also required to complete the MDUFA trainings.
PDUFA trainings	CDER included PDUFA training in the center's mandatory new employee orientation. CBER reviewers were also required to complete PDUFA training. FDA also offered special PDUFA programs, such as trainings on the development and review of drugs for rare diseases.

Source: GAO analysis of FDA documents. | GAO-16-500

Notes: Three FDA centers have primary responsibility for overseeing medical products: the Center for Biologics Evaluation and Research (CBER), the Center for Drug Evaluation and Research (CDER), and the Center for Devices and Radiological Health (CDRH). A significant portion of FDA's annual appropriation consists of amounts derived from user fees paid by the medical products industry. Each user fee program supports different oversight activities across each of the centers. In 2012, the Food and Drug Administration Safety and Innovation Act of 2012 reauthorized or authorized four user fee programs for medical products: the Prescription Drug User Fee Act of 1992 (PDUFA), the Medical Device User Fee and Modernization Act (MDUFA), the Biosimilar User Fee Act (BsUFA), and the Generic Drug User Fee Amendments Act (GDUFA).

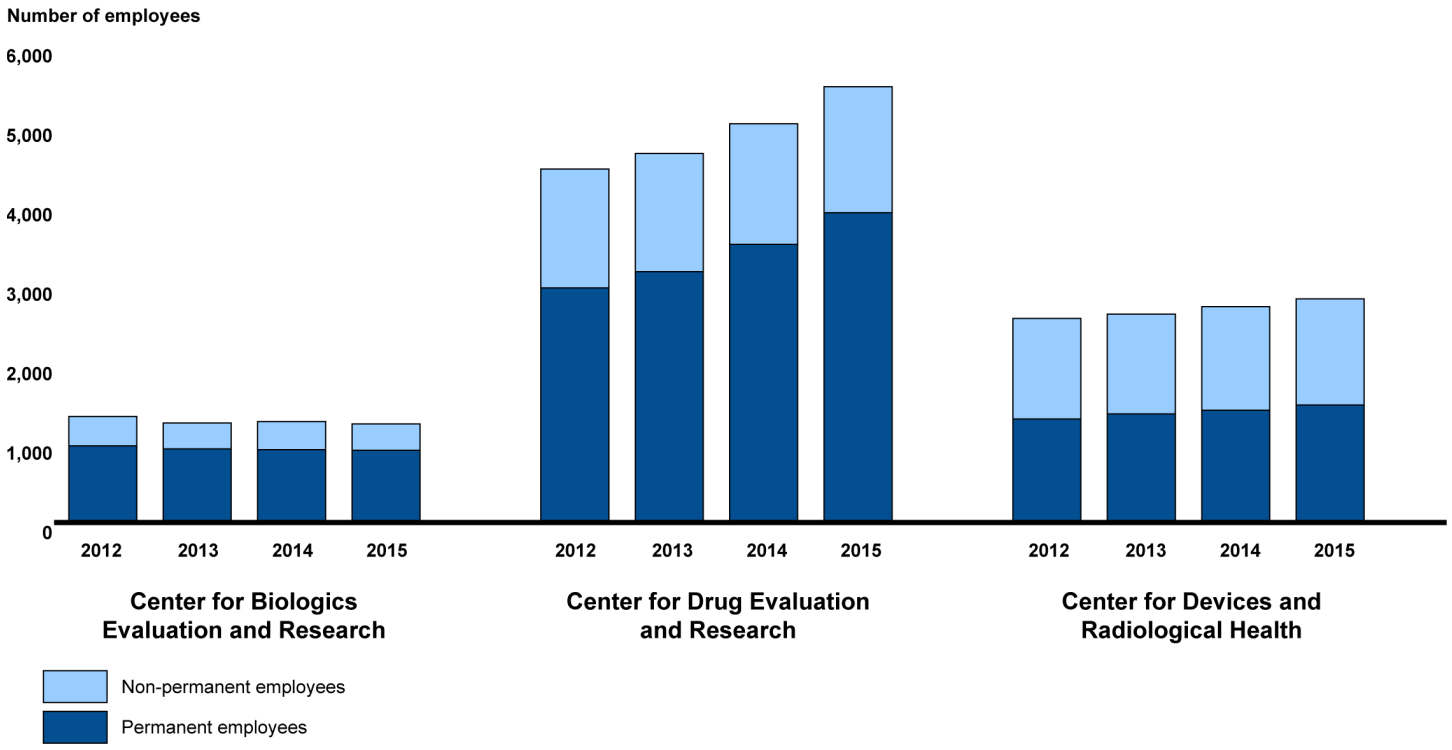
[a]Federal agencies, including FDA, may use special direct-hire authority upon a determination that a severe shortage or a critical hiring need exists. 5 C.F.R. §§ 337.204, 337.205 (2015). FDA's temporary streamlined authority to appoint employees for GDUFA and MDUFA review activities was provided in FDASIA. Pub. L. No. 112-144, §§ 208, 307, 126 Stat.1007, 1025 (codified at 21 U.S.C. §§ 379d-3). This streamlined authority expired July 9, 2015.

[b]In FDA's strategic integrated management plan, the agency described communication-related activities for BsUFA trainings, such as the development of a comprehensive BsUFA website containing answers to frequently asked questions and other resources.

Appendix III: Size and Characteristics of FDA and Medical Product Center Workforce, Fiscal Years 2012 to 2015

We analyzed Food and Drug Administration (FDA) data on the agency's workforce population and attrition for fiscal years 2012 to 2015. Our analysis includes detail on the three medical product centers: the Center for Biologics Evaluation and Research (CBER), the Center for Drug Evaluation and Research (CDER), and the Center for Devices and Radiological Health (CDRH). FDA's total workforce grew from 16,716 employees in 2012 to 19,043 employees in 2015—a 14 percent increase. FDA measures year-to-year changes in its total workforce by subtracting the employee losses from the employee gains of permanent and non-permanent staff. Figure 2 shows the number of medical product center employees—permanent and non-permanent—for each fiscal year.[1]

Figure 2: Total Number of Food and Drug Administration (FDA) Medical Product Center Employees, Fiscal Years 2012 to 2015



Source: GAO analysis of FDA data. | GAO-16-500

[1]Non-permanent employees include advisory committee members; consultants; staff fellows; visiting scientists; and other temporary, part-time, or intermittent employees.

Some losses and gains reported by the centers are due to employees that transferred within the agency, such as from one center to another. Tables 6, 7, and 8 show information on transfers within FDA for each medical product center in fiscal years 2012 to 2015.[2]

Table 6: Number of Center for Biologics Evaluation and Research (CBER) Employee Transfers Within Food and Drug Administration (FDA), Fiscal Years 2012 to 2015

	Transfers to CBER				Transfers from CBER			
	2012	2013	2014	2015	2012	2013	2014	2015
Center for Devices and Radiological Health	0	2	3	7	0	1	2	1
Center for Drug Evaluation and Research	8	2	2	6	7	7	6	12
Center for Food Safety and Applied Nutrition	0	0	2	4	0	0	1	2
Center for Tobacco Products	1	1	1	2	4	6	0	5
Center for Veterinary Medicine	1	1	0	1	0	1	0	0
Office of Regulatory Affairs	1	2	2	0	0	1	1	3
Other FDA office	3	4	6	4	6	3	3	6
Total	**14**	**12**	**16**	**24**	**17**	**19**	**13**	**29**

Source: GAO analysis of FDA data. | GAO-16-500

Note: The number of employee transfers includes only permanent employees. Transfers do not include employees who move externally to another federal agency outside of FDA.

Table 7: Number of Center for Drug Evaluation and Research (CDER) Employee Transfers Within Food and Drug Administration (FDA), Fiscal Years 2012 to 2015

	Transfers to CDER				Transfers from CDER			
	2012	2013	2014	2015	2012	2013	2014	2015
Center for Biologics Evaluation and Research	7	7	6	12	8	3	4	8
Center for Devices and Radiological Health	11	13	17	10	7	14	12	8
Center for Food Safety and Applied Nutrition	1	1	4	2	2	7	3	1
Center for Tobacco Products	5	7	7	9	5	8	9	9
Center for Veterinary Medicine	1	3	4	2	0	2	1	4
Office of Regulatory Affairs	4	5	9	11	1	16	11	17
Other FDA office	23	23	17	33	21	17	20	24

[2]FDA categorizes transfers as either an employee who transfers externally to another federal agency, or an employee who transfers internally to a different center or office within FDA.

	Transfers to CDER				Transfers from CDER			
	2012	2013	2014	2015	2012	2013	2014	2015
Total	**52**	**59**	**64**	**79**	**44**	**67**	**60**	**71**

Source: GAO analysis of FDA data. | GAO-16-500

Note: The number of employee transfers includes only permanent employees. Transfers do not include employees who move externally to another federal agency outside of FDA.

Table 8: Number of Center for Devices and Radiological Health (CDRH) Employee Transfers Within Food and Drug Administration (FDA), Fiscal Years 2012 to 2015

	Transfers to CDRH				Transfers from CDRH			
	2012	2013	2014	2015	2012	2013	2014	2015
Center for Biologics Evaluation and Research	0	1	2	1	0	2	3	7
Center for Drug Evaluation and Research	7	8	10	3	11	13	17	10
Center for Food Safety and Applied Nutrition	2	0	1	2	1	0	0	1
Center for Tobacco Products	1	0	2	4	1	1	8	0
Center for Veterinary Medicine	0	0	1	2	1	0	1	0
Office of Regulatory Affairs	2	2	6	9	2	4	4	5
Other FDA office	15	15	9	7	9	8	4	5
Total	**27**	**26**	**31**	**28**	**25**	**28**	**37**	**28**

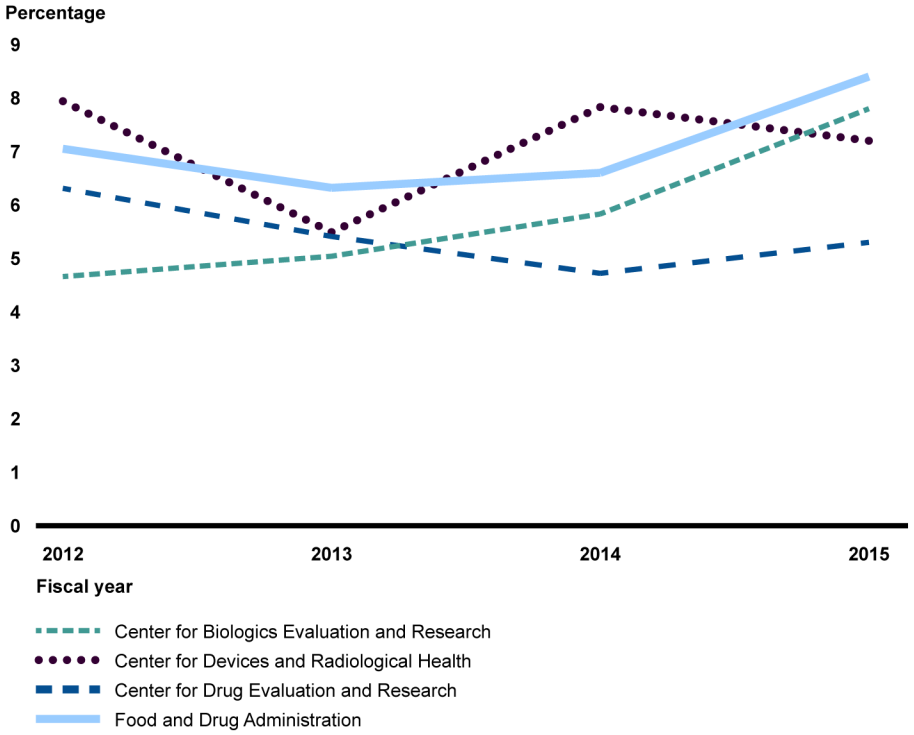
Source: GAO analysis of FDA data. | GAO-16-500

Note: The number of employee transfers includes only permanent employees. Transfers do not include employees who move externally to another federal agency outside of FDA.

FDA also tracks the percentage of retirement-eligible staff. In fiscal year 2015, 12.4 percent of FDA's overall permanent workforce was retirement-eligible. In the same fiscal year, the retirement eligibility for each medical product center was 15.9 percent for CBER, 10.9 percent for CDER, and 11.8 percent for CDRH.

Figure 3 shows the FDA-wide and center-specific attrition rates from fiscal year 2012 to 2015. FDA calculates attrition rates by dividing the number of voluntary personnel losses by the average number of employees for each fiscal year. Voluntary personnel losses include retirements, resignations, and employees who transfer externally to another federal agency or internally to a different center or office within FDA.

Figure 3: Food and Drug Administration (FDA) and Medical Product Center Attrition Rates, Fiscal Years 2012 to 2015



Source: GAO analysis of FDA data. | GAO-16-500

The following tables show the number of employees, personnel gains, and attrition rates for FDA and each medical product center. The tables also include information on mission-critical occupations, which may vary by center.

Table 9: Number of Food and Drug Administration (FDA) Employees, Personnel Gains, and Attrition Rate for Fiscal Years 2013 to 2015, by Mission Critical Occupation

	Number of employees			Personnel gains			Attrition rate		
	2013	2014	2015	2013	2014	2015	2013	2014	2015
Total workforce	13,712	14,289	15,187	1,123	1,332	1,626	6.32%	6.60%	8.40%
Biologist	538	553	578	36	53	96	5.06%	3.48%	5.82%
Chemist	1,032	1,084	1,177	97	171	139	3.71%	4.35%	4.05%
Consumer safety officer	3,018	3,085	3,220	95	148	236	4.04%	3.64%	7.70%
IT specialist	487	472	478	78	17	29	3.54%	5.21%	5.89%
Mathematical statistician	239	241	248	23	24	42	5.00%	7.92%	7.39%

Medical officer	633	634	642	42	40	58	5.93%	6.63%	5.50%
Microbiologist	584	597	631	25	44	45	3.45%	3.39%	4.80%
Pharmacist	157	189	266	56	69	112	14.62%	8.67%	2.99%
Veterinary medical officer	110	112	119	11	8	10	1.88%	2.70%	1.63%

Source: GAO analysis of FDA data. | GAO-16-500

Note: The number of employees and personnel gains includes only permanent employees. Personnel gains are also reflected in the number of employees for the same fiscal year.

Table 10: Number of Center for Biologics Evaluation and Research (CBER) Employees, Personnel Gains, and Attrition Rate for Fiscal Years 2013 to 2015, by Mission Critical Occupation

	Number of employees			Personnel gains			Attrition rate		
	2013	2014	2015	2013	2014	2015	2013	2014	2015
Total CBER workforce	924	915	906	40	66	78	5.04%	5.83%	7.80%
Biologist	193	188	189	10	11	23	4.16%	4.72%	7.43%
Chemist	51	52	49	1	2	4	5.83%	5.83%	5.94%
Consumer safety officer	170	172	164	2	6	10	4.12%	2.92%	5.36%
Mathematical statistician	23	26	25	3	3	1	12.24%	12.24%	7.84%
Medical officer	105	107	108	8	12	6	4.83%	4.72%	4.65%
Microbiologist	68	65	67	2	6	4	2.99%	9.02%	3.03%
Pharmacologist	13	12	11	1	1	0	0.00%	16.00%	17.39%
Toxicologist	5	4	4	0	0	0	0.00%	22.22%	0.00%

Source: GAO analysis of FDA data. | GAO-16-500

Note: The number of employees and personnel gains includes only permanent employees. Personnel gains are also reflected in the number of employees for the same fiscal year. Personnel gains include employees who transferred to CBER from another Food and Drug Administration (FDA) center or office.

Table 11: Number of Center for Drug Evaluation and Research (CDER) Employees, Personnel Gains, and Attrition Rate for Fiscal Years 2013 to 2015, by Mission Critical Occupation

	Number of employees			Personnel gains			Attrition rate		
	2013	2014	2015	2013	2014	2015	2013	2014	2015
Total CDER workforce	3,155	3,498	3,897	389	576	623	5.41%	4.72%	5.30%
Biologist	61	62	84	5	11	35	13.11%	3.25%	8.22%
Chemist	340	377	426	57	118	61	4.04%	4.74%	4.98%
Consumer safety officer	261	284	295	11	36	18	4.68%	4.04%	5.18%
Mathematical statistician	129	134	132	15	15	24	5.49%	10.65%	6.02%
Medical officer	402	411	416	31	32	42	6.53%	6.40%	4.59%
Microbiologist	48	56	69	1	12	12	3.85%	1.92%	8.00%
Pharmacist	154	184	261	62	67	115	15.07%	7.69%	3.60%

	Number of employees			Personnel gains			Attrition rate		
	2013	2014	2015	2013	2014	2015	2013	2014	2015
Pharmacologist	305	323	348	23	57	54	3.05%	2.23%	4.47%
Toxicologist	31	34	39	2	5	10	3.28%	12.31%	2.74%

Source: GAO analysis of FDA data. | GAO-16-500

Note: The number of employees and personnel gains includes only permanent employees. Personnel gains are also reflected in the number of employees for the same fiscal year. Personnel gains include employees who transferred to CDER from another Food and Drug Administration (FDA) center or office.

Table 12: Number of Center for Devices and Radiological Health (CDRH) Employees, Personnel Gains, and Attrition Rate for Fiscal Years 2013 to 2015, by Mission Critical Occupation

	Number of employees			Personnel gains			Attrition rate		
	2013	2014	2015	2013	2014	2015	2013	2014	2015
Total CDRH workforce	1,365	1,412	1,477	140	204	217	5.49%	7.83%	7.20%
Biologist	86	100	98	5	17	16	4.79%	4.30%	6.06%
Biomedical engineer	203	232	262	28	60	50	3.81%	7.36%	6.07%
Chemist	30	30	36	2	6	7	13.79%	6.67%	9.09%
Consumer safety officer	113	116	116	2	9	8	5.31%	6.99%	6.03%
Electrical engineer	23	21	22	3	1	6	0.00%	9.09%	9.30%
Mathematical statistician	46	42	43	2	8	5	6.38%	4.55%	7.06%
Mechanical engineer	13	13	14	2	3	5	0.00%	15.38%	7.41%
Medical officer	76	71	71	8	14	16	10.96%	16.33%	14.08%
Microbiologist	37	39	44	3	5	6	8.82%	7.89%	7.23%
Toxicologist	10	9	10	0	2	1	10.53%	10.53%	10.53%

Source: GAO analysis of FDA data. | GAO-16-500

Note: The number of employees and personnel gains includes only permanent employees. Personnel gains are also reflected in the number of employees for the same fiscal year. Personnel gains include employees who transferred to CDRH from another Food and Drug Administration (FDA) center or office.

Appendix IV: Agency Comments from the Department of Health and Human Services

DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

APR 22 2016

Ms. Marcia Crosse
Director, Health Care Team
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Ms. Crosse:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, *"FDA: Comprehensive Strategic Planning Needed to Enhance Coordination Between Medical Product Centers"* (GAO-16-500).

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

Sincerely,

Jim R. Esquea
Assistant Secretary for Legislation

Attachment

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED, "FOOD AND DRUG ADMINISTRATION: COMPREHENSIVE STRATEGIC PLANNING NEEDED TO ENHANCE COORDINATION BETWEEN MEDICAL PRODUCT CENTERS" (GAO-16-500)

The Department of Health and Human Services (HHS) appreciates the opportunity to review and comment on this draft report.

The Food and Drug Administration's (FDA) Office of Medical Products and Tobacco (OMPT) provides FDA with high level coordination and leadership across the medical product centers. Although each center must address a different portfolio of products, which are subject to different statutes and regulations, they are all affected by an increasing number of cross-cutting issues, including the increase in the number of combination products. These issues offer opportunities to improve the level of coordination needed to best fulfill the Agency's role of protecting and promoting the health and safety of the American people, and to do so in a manner that optimizes the benefits to be realized from economies of scale.

The Food and Drug Administration Safety and Innovation Act (FDASIA), signed into law on July 9, 2012, includes the fifth authorization of the Prescription Drug User Fee Act (PDUFA) and the third authorization of the Medical Device User Fee Amendments (MDUFA). It also established two new user fee programs: the Generic Drug User Fee Amendments (GDUFA) and the Biosimilar User Fee Act (BsUFA), which build on the successes of these two established user fee programs.

Because the 2013 Strategic Integrated Management Plan was developed in the context of the FDASIA legislation and the user fee programs authorized under FDASIA, the plan focused on assuring that FDA's resources are managed as efficiently and effectively as possible. The plan (1) identifies strategic institutional goals, priorities and mechanisms to improve efficiency for the medical product centers; (2) describes actions to recruit, retain, train and develop the workforce needed to fulfill the Agency's public health mission; and (3) identifies results-oriented, outcomes-based measures to assess progress in achieving # 1 and #2 above and appropriately and consistently apply FDASIA's statutory requirements, including the new user fee programs. The plan also focused on harmonizing the methods and systems necessary to monitor, analyze, and report the Agency's progress in achieving the performance goals established as part of the user fee commitments. Over the past year, GAO has learned about the significant progress of FDA's medical product centers in implementing the plan, as evidenced by highly successful product review time metrics related to user fee goals.

User fees are a critical source of stable funding that strengthens the regulation of medical products. Each program is distinct and requires a different implementation approach, but also provides a framework for matching resources to performance commitments. This approach bolsters FDA's medical product centers' ability to meet more effectively and efficiently the mission of the Agency, including protecting the public health by accelerating innovation and ensuring that medical products are safe and effective.

As described below, FDA user fee programs have resulted in major increases in year-over-year efficiency – while unequivocally maintaining the Agency's position as the "gold standard" in the quality of medical product review in the world.

PDUFA
The most established user fee program, the PDUFA program, approved 45 novel new drugs in 2015, almost double the 10-year average for approvals. A great majority of these drugs (39 of 45, 87%) were approved on the "first cycle" of review, meaning without requests for additional information that would delay approval and lead to another cycle of review.

Over the years, the PDUFA program has achieved increasingly demanding performance commitments, improved communication with sponsors, improved post-market surveillance, and implemented IT enhancements, among other improvements. The most recent reauthorization, PDUFA V, added a new program to enhance the review of new molecular entities and biologics as well as a focus on increasing the utilization of the electronic submissions system.

MDUFA
In 2015, FDA approved 61 original PMAs and Panel Track supplements, the most since the start of the MUDFA program. FDA also established and publicly reported Investigational Device Exemption (IDE) performance metrics and succeeded in reducing the number of IDEs requiring more than two cycles to a full approval decision by 53% compared to FY 2013. In addition, FDA reduced the overall median time to full IDE approval to 30 days from 442 days in 2011. In addition, FDA completed 14 premarket process improvement projects, resulting in the implementation of all eleven recommendations stemming from the MDUFA III independent assessment of the premarket review process. Among the many actions undertaken under this effort were issuance of revised eCopy and refuse to accept (RTA) guidance documents, improved procedures for premarket review file management, adoption of the Kirkpatrick methodology for training evaluation, a plan for incorporating quality management into premarket review activities, adoption of a review tool that promotes consistency of reviews, and the collection and management of suggestions for improvement and quality issues.

GDUFA
Since the enactment of GDUFA, FDA has rapidly built new operational, policy, regulatory science and staffing infrastructure (meeting/exceeding the FY15 hiring goal) to implement the program. As a result, FDA has made significant progress toward the goal of reviewing 90% of the pre-GDUFA backlog applications by September 30, 2017 and issuing a first action on about 80% through FY 2015. In addition, FDA reduced the approval time for generic drugs by well over half (from 738 to 316 days for original ANDAs; and from 322 to 96 for Prior Approval Supplements) in the three-year existence of the program.

BSUFA
Since the initiation of BsUFA, FDA has approved the first two biosimilar products: Zarxio (filgrastim-sndz) and Inflectra (infliximab-dyyb). To date, five companies have submitted a total of eight applications for proposed biosimilar products. FDA is actively engaged with biosimilar sponsors holding development-phase meetings and providing written advice for ongoing development programs. As of December 31, 2015, 59 proposed biosimilar products linked to 18 different reference products were enrolled in the Biosimilar Product Development Program.

FDA is developing rigorous scientific standards to ensure that biosimilar and interchangeable products are safe and effective – and provide guidance documents for industry. Still very new, the BsUFA program continues to show year-over-year improvement and is on track to meet a majority of its performance goals.

GAO Recommendation

The Government Accountability Office recommends that the Secretary of Health and Human Services take action on the following:

- FDA should engage in a strategic planning process to identify challenges that cut across the medical product centers and document how it will achieve measurable goals and objectives in these areas.

HHS Response

The Department appreciates GAO's efforts to review and analyze FDA's Strategic Integrated Management Plan. FDA will carefully consider the findings as it plans and implements future improvements to the user fee programs. Based on the distinct missions of the FDA's medical product centers, it is not always possible to directly integrate processes across them. Still, HHS agrees with GAO's recommendation that "the Commissioner of FDA should engage in a strategic planning process to identify challenges that cut across the medical product centers and document how it will achieve measurable goals and objectives in these areas." We recognize that there are certain infrastructure issues that call out for working across the centers, including workforce development, information technology, contracting, and financial systems. Over the past year, FDA has identified the key cross-cutting themes for the medical product centers, and eventually, FDA's Office of Medical Products and Tobacco will use this process to develop an overarching strategic planning framework to help guide its centers.

Appendix V: GAO Contact and Staff Acknowledgments

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Staff Acknowledgments

In addition to the contact named above, William Hadley, Assistant Director; George Bogart; Jennel Lockley; Drew Long; Matt Lowney; Dan Powers; and E. Jane Whipple made key contributions to this report.