U.S. Government Accountability Office

FDA: Oversight Responsibilities and Funding from Fiscal Years 2008 through 2024

GAO-26-107779
Q&A Report to Congressional Addressees
February 3, 2026

Why This Matters

The Food and Drug Administration (FDA) within the Department of Health and Human Services (HHS) regulates more than $3.9 trillion worth of food, medical products, and tobacco products produced in the U.S. and abroad. Overseeing this diverse array of products is made more challenging by certain other factors, such as increased complexity in the science supporting these products and further globalization of their manufacture.

We have previously reported that FDA has faced challenges that affect its ability to perform its oversight responsibilities. These concerns contributed to us adding FDA's oversight of medical products and food safety to our High-Risk List in 2009 and 2007, respectively. Concerns with FDA's oversight also contribute to two other areas on our High-Risk List—HHS's leadership and coordination of public health emergencies and skills gaps in the federal workforce.

In 2025, government-wide directives required departments, including HHS, to downsize and reorganize. A March 2025 HHS fact sheet about its proposed reorganization noted that FDA's workforce would be decreased by approximately 3,500 full-time equivalent staff. The FDA Commissioner testified in May 2025 that FDA would centralize and streamline shared functions that were previously duplicated across the agency. Details on the extent of these changes on the structure of FDA and to the size of its workforce had yet to be publicly released as of December 2025.

To provide the Congress with context for these ongoing changes, we undertook a review, at the initiative of the Comptroller General in consultation with congressional committees, to examine information on FDA's capacity to meet its oversight responsibilities. This report provides information on changes to FDA's oversight responsibilities, funding, and staffing from fiscal year 2008 through fiscal year 2024. It also provides information on challenges affecting FDA's capacity to meet its oversight responsibilities that we and others identified prior to the 2025 proposed staff reductions and reorganization.

Key Takeaways

- From fiscal year 2008 through fiscal year 2024, there were several key changes to FDA's oversight responsibilities, including the regulation of tobacco as a new product area and new roles for the agency within existing product areas.
- While FDA's overall funding increased during that period, most of that growth came from user fees paid by industry, as opposed to discretionary appropriations derived from the U.S. General Fund of the Treasury.
- Prior to the 2025 reorganization, we and others identified capacity challenges related to staffing needs. In particular, FDA experienced difficulties in recruiting, retaining, and training staff that led to deficiencies in carrying out some of its responsibilities in overseeing food, drugs, and tobacco products. Between January 2020 and January 2025, we made a number of

recommendations to address these challenges, eight of which are discussed in this report. While FDA is taking steps in response, as of December 2025, it had not yet fully implemented most of these recommendations.

What are FDA's oversight responsibilities?

FDA regulates a wide variety of products. According to FDA, the products for which it has oversight responsibilities accounted for about 21 cents of every dollar spent by U.S. consumers in 2024. Products overseen by FDA generally fall into the following broad product categories: human drugs, biologics, and medical devices; human food and cosmetic products; veterinary medical and food products; and tobacco products.[1]

Human drugs, biologics, and medical devices. FDA is responsible for ensuring the safety and effectiveness of three areas of medical products: (1) brand-name and generic drugs, (2) biologics and biosimilars (e.g., vaccines, blood and blood components, and insulin), and (3) medical devices (e.g., diagnostic tests, syringes, pacemakers). FDA generally evaluates the safety and effectiveness of new medical products prior to marketing and monitors the safety and effectiveness of marketed products, among other things.[2] FDA carries out its oversight responsibilities through various tools and actions, such as reviewing applications for new medical products and inspecting facilities where medical products are produced.

Human food and cosmetics. FDA is responsible for ensuring the safety of nearly 80 percent of the nation's food supply, including fruits, vegetables, processed foods, dairy products, and most seafood. The agency's oversight activities focus on preventing foodborne illness, reducing diet-related chronic disease, and ensuring chemicals in food are safe. To accomplish its food safety mission, FDA uses a range of tools, including conducting inspections of domestic and foreign food facilities. In addition to food, FDA is also responsible for ensuring the safety and proper labeling of cosmetics products.

Veterinary medical and food products. FDA is responsible for ensuring animal drugs for pets and livestock are safe and effective. It is also responsible for ensuring that when food-producing animals, such as cattle and chickens, are treated with animal drugs, products that come from these animals (e.g., eggs, milk, and meat) are safe for human consumption. FDA is also responsible for ensuring the safety of animal food and medical devices. The agency conducts its oversight of these products in various ways, including but not limited to reviewing new animal drug applications and inspecting facilities that manufacture animal food and drugs for animals.

Tobacco products. FDA is responsible for regulating the manufacturing, distribution, and marketing of all tobacco products, including e-cigarettes. The focus of the agency's oversight involves preventing youth use of tobacco products, educating the public about tobacco products and the risks associated with their use, conducting research, and making decisions on whether new tobacco products can be marketed. To meet its mission, FDA oversees all pathways to legally market and distribute products including reviewing premarket applications for new products, monitoring the marketing of products, and monitoring tobacco retailers, manufacturers, importers, and distributors.

How is FDA funded?

FDA's funding to carry out its oversight responsibilities comes from two sources: discretionary appropriations derived from the U.S. General Fund of the Treasury and user fees. Discretionary appropriations are enacted through annual and supplemental appropriations acts.[3] FDA is also authorized to collect user fees from manufacturers and other regulated entities to supplement its budget

authority but only to the extent and in the amount authorized in appropriations acts. Once established, most user fees are reauthorized every 5 years.

The funding FDA receives from each source is subject to certain statutory limitations. For example, FDA can only use the funding it receives from prescription drug user fees for activities specified in the legislation authorizing these fees, such as reviewing human drug applications and monitoring the safety of drugs on the market. In contrast, while medical device user fees can be used for application review, the legislation authorizing such user fees does not explicitly allow their use for post-market safety activities but does allow their use for a narrower set of monitoring activities, such as evaluating post-market studies required as a condition of approval.

As part of receiving most user fee funding, FDA also commits to meeting performance goals established in negotiated agreements between FDA and industry, such as commitments to review marketing applications within certain time frames or commitments for FDA to publish guidance on topics of interest to industry. These performance goals are negotiated on 5-year cycles as part of the reauthorization process.

What have been key changes to FDA's oversight responsibilities from fiscal years 2008 through 2024?

Our review of relevant statutes, agency documentation, and other publicly available documents identified several key changes to FDA's oversight responsibilities from fiscal year 2008 through fiscal year 2024. These changes added new types of products for FDA to regulate and expanded the agency's roles or activities within existing product areas. Examples include the following.

New types of products

- **Tobacco.** In 2009, the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) authorized FDA to regulate the manufacturing, marketing, and distribution of tobacco products, including cigarettes and smokeless tobacco.[4] The act also authorized FDA to collect user fees from manufacturers and importers of such products. FDA later extended its oversight through rulemaking (authorized by the act) to include all other products meeting the definition of tobacco product, including cigars, pipe tobacco, and e-cigarettes, in 2016.[5] The Consolidated Appropriations Act, 2022, further extended FDA's authority to include the regulation of tobacco products containing nicotine from any source—including synthetic nicotine.[6]
- **Biosimilars.** In 2010, the Patient Protection and Affordable Care Act established new authority for FDA to review and approve products known as biosimilars or interchangeable biosimilars.[7]
- **Over-the-counter hearing aids.** The FDA Reauthorization Act of 2017 required FDA to establish by regulation a new medical device category for over-the-counter hearing aids.[8] Previously, hearing aids were only available from a licensed professional.

Expanded roles or activities within existing product areas

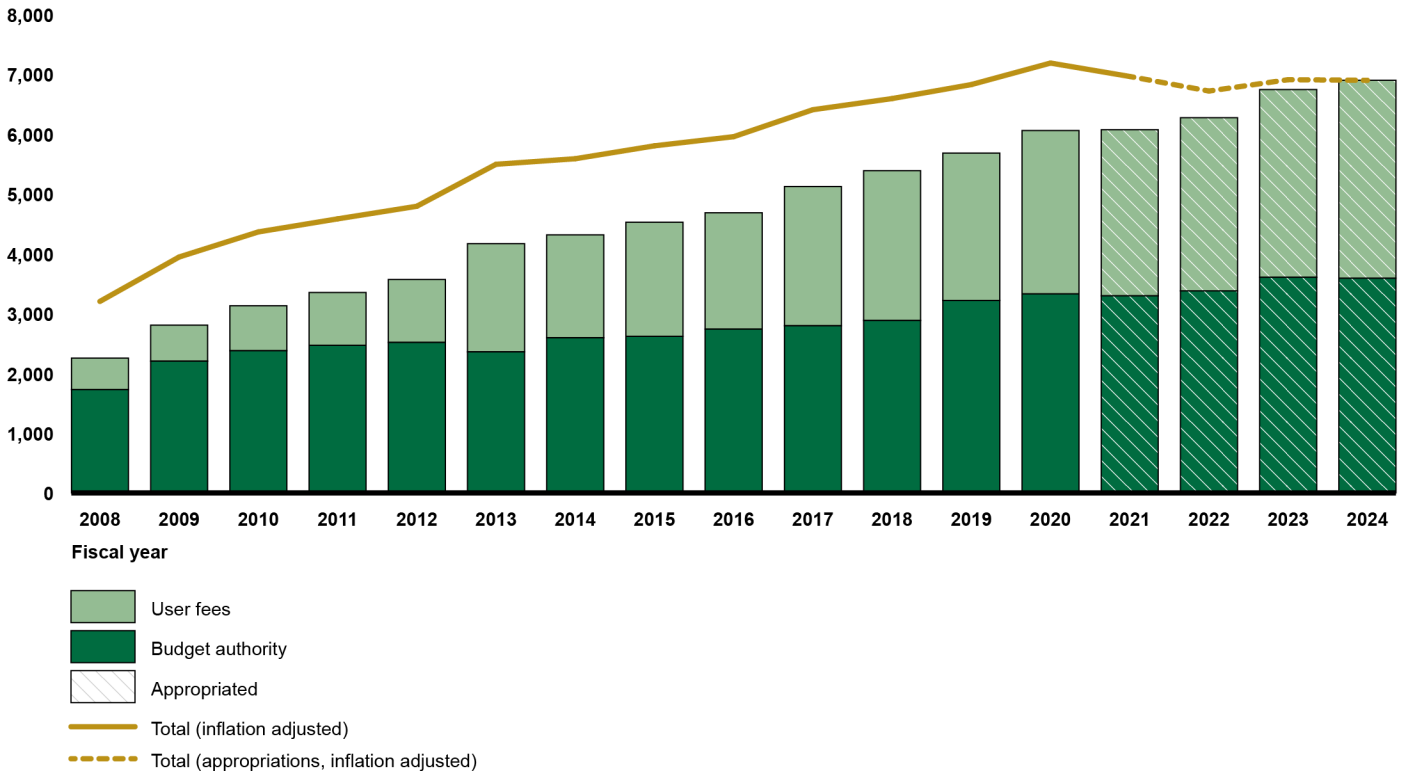
- **Expanding food safety authority with increased foreign inspections.** In 2011, the FDA Food Safety Modernization Act significantly increased FDA's responsibilities for overseeing human and animal foods. For example, the act directed FDA to conduct an increasing number of foreign food safety inspections each year, starting with 600 inspections in 2011 and reaching 19,200 inspections in 2016.[9]

- **Additional user fee programs.** The Food and Drug Administration Safety and Innovation Act in 2012 created user fee programs for generic drugs and biosimilars and the CARES Act in 2020 created user fee programs for over-the-counter drugs.[10] As with most other FDA user fee programs, FDA commits to meeting certain performance goals and reporting to Congress. For example, FDA has goals to review and act on applications within specified time frames.
- **Expanding authority for cosmetics.** The Modernization of Cosmetics Regulation Act of 2022 expanded FDA's authority to regulate cosmetics.[11] For example, the act gave FDA the authority to mandate that companies recall cosmetics if FDA determines there is a reasonable probability that the product is adulterated or misbranded and will cause serious adverse events.[12]
- **Strengthening cybersecurity of medical devices.** The Consolidated Appropriations Act, 2023, expanded FDA's authority to ensure medical devices meet minimum cybersecurity standards, including that manufacturers address post-market vulnerabilities.[13] FDA formally established a Division of Medical Device Cybersecurity in 2024 and dedicated resources to support strengthening medical device cybersecurity, according to agency officials.

How did FDA's overall funding and staffing change from fiscal years 2008 through 2024?

FDA's overall funding grew from fiscal year 2008 through fiscal year 2024, largely from user fees paid by manufacturers and other regulated entities.[14] Over this 17-year period, the source of FDA's overall funding changed from being mostly funded by budget authority to being funded in nearly equal amounts by budget authority and user fees. (See fig. 1.)

Figure 1: Food and Drug Administration (FDA) Overall Funding, by Funding Source, Fiscal Year 2008 through Fiscal Year 2024



Source: GAO analysis of FDA Justification of Estimates for Appropriations Committees for fiscal years 2010 through 2026. | GAO-26-107779

Note: According to FDA officials, funding for fiscal year 2008 through fiscal year 2020 represents obligations (i.e., definite commitments that create a legal liability of the U.S. government for payment of goods and services ordered or received). Funding for fiscal year 2021 through fiscal year 2024

represents appropriations with congressionally approved adjustments, such as reallocations of appropriated funds within or among appropriations accounts, according to agency officials. Budget authority data show federal funding through discretionary appropriations derived from the U.S. General Fund of the Treasury. User fee data show funding from user fees paid by manufacturers and other regulated entities. Total amounts represent total funding each fiscal year adjusted for inflation using the gross domestic product price index in 2024 dollars.

Increases in FDA's funding from user fees during this time came from both new user fee authorizations and growth in established user fees.

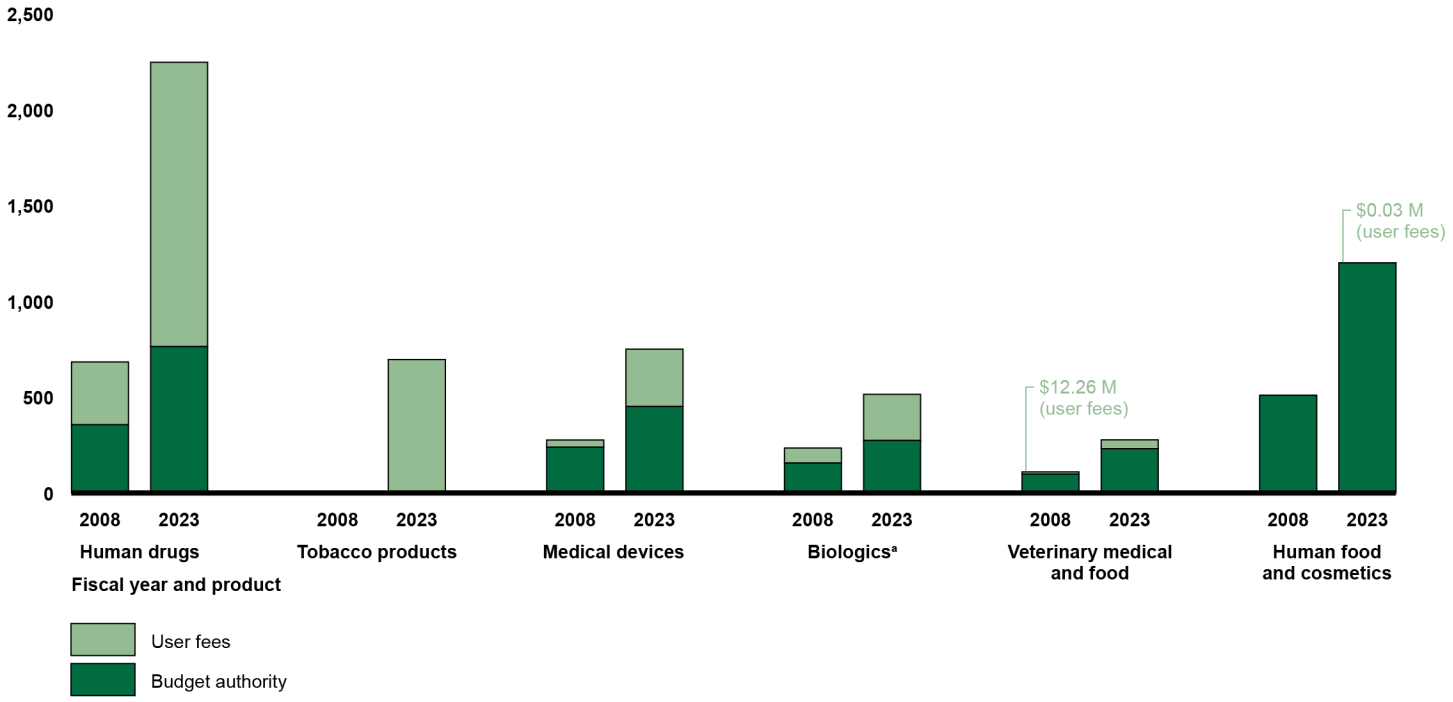
- **New user fee authorizations.** Since fiscal year 2008, FDA has received new authorities to collect user fees to support certain activities related to its oversight of over-the-counter drugs, generic drugs, biosimilar products, and human foods. Additionally, in 2009, the Tobacco Control Act authorized FDA to collect user fees from the tobacco industry which provide all the funding for FDA's tobacco oversight. FDA is authorized to collect user fees from manufacturers and importers of certain regulated tobacco products identified in the act.[15] Although FDA regulates all tobacco products, the agency currently lacks the authority to assess and collect user fees from manufacturers and importers of e-cigarettes and certain other tobacco products.
- **Growth in existing user fees.** FDA has also seen an increase in the total amount of user fees it is authorized to collect for existing programs. For example, the total amount of user fees FDA was authorized to collect from manufacturers of prescription drugs increased from about $459 million in fiscal year 2008 to about $1.4 billion in fiscal year 2024.

FDA's overall staffing also grew during this period. Staffing levels are based on the number of full-time equivalents (FTE). One FTE represents an estimate of labor hours contributed by one person working full time for one year (rather than an accounting of an individual person). FDA's FTEs grew from 9,818 in fiscal year 2008 to 19,744 in fiscal year 2024.[16]

How did FDA's funding by product area change from fiscal years 2008 through 2024?

FDA funding generally increased across product areas from fiscal year 2008 through fiscal year 2024, though the extent of increase varied by product area.[17] Growth in funding from user fees outpaced growth in funding from budget authority in FDA's human medical product areas—human drugs, medical devices, and biologics. In contrast, growth in budget authority outpaced growth in user fees for both veterinary medical and food products and for human foods and cosmetics products. FDA's funding for tobacco oversight also grew and was entirely funded by user fees. (See fig. 2 for obligations in fiscal year 2008 and fiscal year 2023.)

Figure 2: Food and Drug Administration (FDA) Funding, by Product Area and Funding Source, Fiscal Year 2008 and Fiscal Year 2023



Source: GAO analysis of FDA Justification of Estimates for Appropriations Committees for fiscal years 2010 and 2026. | GAO-26-107779

Note: According to FDA officials, funding for fiscal year 2008 and fiscal year 2023 represents obligations (i.e., definite commitments that create a legal liability of the U.S. government for payment of goods and services ordered or received) in each of these product areas. FDA's funding by product area does not include funding for other areas of FDA operations—such as FDA headquarters, building and facilities, and rent. Budget authority data show federal funding amounts through discretionary appropriations derived from the U.S. General Fund of the Treasury. User fee data show funding from user fees paid by manufacturers and other regulated entities. Obligation data for fiscal year 2024 were not available in FDA's Justification of Estimates for Appropriations Committees at the time of our review.

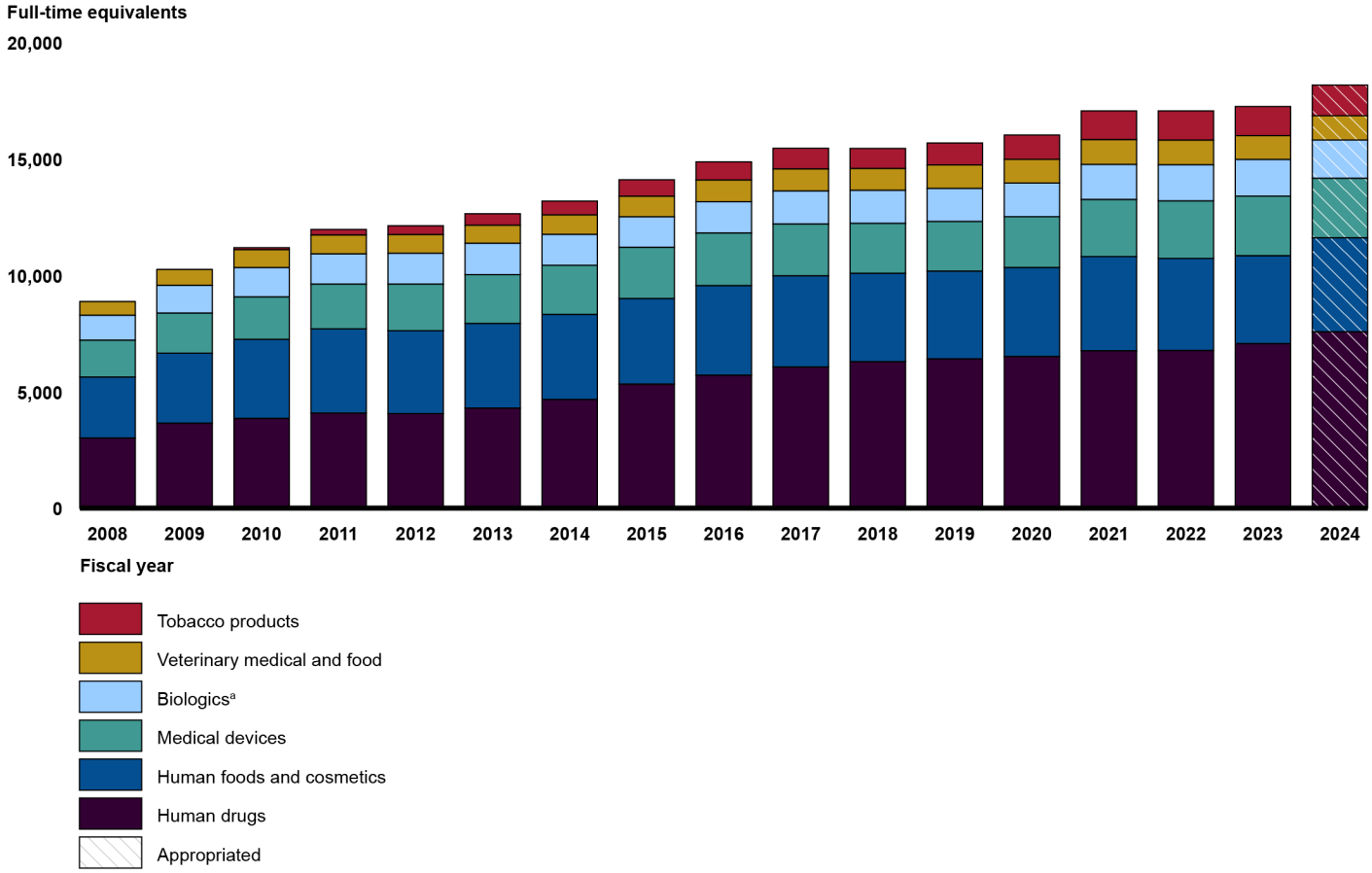
[a]Biologics include such products as vaccines, blood and blood components, and insulin.

How did FDA's staffing by product area change from fiscal years 2008 through 2024?

FDA staffing, as measured by FTEs, generally increased across product areas from fiscal year 2008 through fiscal year 2024.[18] The extent of increase varied by product area.

For each of FDA's product areas, growth in FTEs was also largely funded by user fees. The exceptions to this were for the veterinary medical and food and the human foods and cosmetics product areas, where most of the FTE growth was funded by budget authority. (See fig. 3.)

Figure 3: Food and Drug Administration (FDA) Full-Time Equivalents, by Product Area, Fiscal Year 2008 through Fiscal Year 2024



Source: GAO analysis of FDA Justification of Estimates for Appropriations Committees for fiscal years 2010 through 2026. | GAO-26-107779

Note: FDA's staffing by product area, as measured by full-time equivalents (FTE), does not include staffing for other areas of FDA operations—such as FDA headquarters. FTEs represent an estimate of labor hours contributed by one person working full time for one year (and does not represent an accounting of an individual person). FTEs for fiscal year 2008 through fiscal year 2023 reported in FDA's Justification of Estimates for Appropriations Committees represent obligations (i.e., definite commitments that create a legal liability of the U.S. government for payment of goods and services ordered or received). FTEs for fiscal year 2024 represent appropriations with congressionally approved adjustments, such as reallocations of appropriated funds within or among appropriations accounts, according to agency officials.

[a]Biologics include such products as vaccines, blood and blood components, and insulin.

What staffing challenges affecting FDA's capacity to meet its oversight responsibilities have GAO and others identified since 2020?

In reports issued between January 2020 and January 2025, we and others reported that FDA faced staffing challenges related to recruiting, retaining, and training staff. These reports have identified examples of FDA not having the capacity to meet, or facing potential challenges in meeting, its oversight responsibilities for multiple product areas. Capacity, according to our high-risk framework, is having the skilled staff and other resources—such as adequate funding, management organization and infrastructure, and technology—that an agency needs to address the risks that result from not meeting its mission.[19]

The following are previously identified examples of FDA not being able to fulfill or facing potential challenges in fulfilling its responsibilities for multiple products that it oversees.

Recruiting and retaining

We have reported in multiple previously issued reports that recruitment and retention challenges have limited the number of drug and food inspections FDA could complete, potentially compromising FDA's oversight of food and drug manufacturing. We have made related recommendations, which FDA agreed with but had not yet implemented as of December 2025.

- In February 2024 and November 2024, we reported that investigator attrition—due to low compensation and frequent travel, among other issues—reduced the number of clinical research and drug manufacturing inspections FDA could conduct, compared to previous years.[20] Across the two reports, we made two recommendations for FDA to take action to address its attrition challenges. FDA agreed with our recommendations, but as of December 2025, these recommendations had not yet been implemented.
- In January 2025, we reported that challenges related to recruiting and retaining investigators limited the number of food safety inspections FDA could conduct.[21] We recommended that FDA develop and implement a performance management process that includes information on FDA's progress in recruiting and retaining food safety investigators and the agency agreed with this recommendation.

Others have also reported staffing challenges that have limited FDA's ability to carry out its oversight responsibilities. According to a November 2023 report by the Department of Health and Human Services' Office of Inspector General (HHS OIG), FDA struggled to hire and maintain staff, which affected its ability to process tobacco product applications in a timely manner.[22] As a result, FDA's decisions on tobacco product applications were delayed, and more than 50,000 tobacco products remained on the market as of October 19, 2022, while waiting for FDA's decision on their premarket applications. HHS OIG recommended FDA work with the Office of Personnel Management (OPM) to help the agency reach its staffing goal. FDA agreed and indicated that it addressed the recommendation, as HHS, on behalf of FDA, submitted a request to OPM to use a streamlined hiring process for certain positions. In January 2025, FDA officials told us they had worked with OPM to establish such a process, but that the agency was still facing challenges with recruiting and retaining staff for its tobacco program.

Training

We have also previously reported that challenges in training staff have affected FDA's progress in meeting its oversight responsibilities. Examples include the following.

- In February 2024, we reported that it can take 2 to 3 years to fully train a new clinical research investigator, according to FDA officials. This lead time needed to get staff trained can result in delays in meeting goals.[23]
- Similarly, in January 2025, we reported that FDA officials said it takes about 2 years to fully train food investigators. This training time, combined with the large number of investigators eligible to retire, limits FDA's ability to meet its food inspection goals.[24]
- We reported in July 2023 that FDA had challenges training staff working in regenerative medicine—which involves restoring, replacing, or recreating cells, tissues, or organs to treat or mitigate disease.[25] As we noted in our report, without sufficient training, it will be harder for FDA reviewers to assess and respond to applications that include novel and complex emerging regenerative medicine technologies—which include cell therapies and gene and tissue engineering products used to treat cancer, heart disease, diabetes, and more.

FDA has also identified recruiting, retaining, and training as challenges to maintaining staff with skills critical to overseeing its regulated products. In its January 2024 Strategic Workforce Plan, FDA reported that it needed to maintain staff with certain identified skills—such as data analytics, artificial intelligence

learning, and inspections—and outlined goals for addressing such staffing needs. FDA's plan noted that it would address a requirement in the Consolidated Appropriations Act, 2023, and our January 2022 recommendation to develop an agency-wide strategic workforce plan to ensure it can monitor and evaluate progress toward its workforce goals.[26]

FDA implemented our recommendation in January 2024 when it submitted its Strategic Workforce Plan to Congress. However, in early 2025, FDA officials told us that the plan was no longer current. In August 2025, FDA officials indicated efforts were underway to ensure the agency's workforce approach aligned with the administration's priorities and available resources.

What other challenges affecting FDA's capacity to meet its oversight responsibilities have GAO and others identified since 2020?

In reports issued between January 2020 and January 2025, we and others have reported challenges with how FDA has managed its resources. These have further affected the agency's capacity to meet, or introduced potential challenges in meeting, its oversight responsibilities for multiple product areas. We have made recommendations related to these challenges, which FDA agreed with but had not yet implemented as of December 2025.

- In January 2025, we reported that FDA could make more effective use of its resources by reducing incidences of attempted domestic inspections.[27] Attempted inspections occur when FDA investigators arrive to conduct an inspection of a food facility, but the inspection cannot be completed because, for example, the facility is not operating on the day of inspection. Attempted inspections represented nearly one-third of the domestic food inspections that FDA counted toward meeting its FDA Food Safety Modernization Act mandate from 2018 to 2023.[28] We recommended FDA take action to address this issue.[29] FDA agreed with our recommendation and said that it planned to evaluate its existing policies and procedures and explore options to minimize the number of attempted inspections.
- In September 2020, we reported that FDA lacked standardized processes for overseeing equipment (e.g., scientific equipment, computers, and office furniture) across its centers that regulate medical products, which could potentially affect its ability to effectively manage property.[30] For example, while one center maintained a personal property database, another center did not generally collect personal property maintenance data. To help the agency make sound decisions about the use of its funding, we recommended that FDA establish and implement formal policies to manage its personal property across the centers. Doing so would help FDA effectively manage its property's useful life and plan for and respond to potential changes to the centers' funding and priorities. FDA agreed with the recommendations and HHS stated that it plans to develop standard operating procedures related to personal property for FDA's medical-product regulatory centers. As of December 2025, FDA had not yet implemented our recommendations.
- In December 2022, the Reagan-Udall Foundation for the FDA reported that the agency had challenges with its information technology system.[31] Specifically, the Foundation reported that FDA did not have an information technology system that allowed the individual systems that collect product safety and quality complaints to connect with each other. According to the Foundation, this gap in technology contributed to FDA's delayed response to the outbreaks of illness from infant formula, which led to multiple deaths. The Foundation recommended that FDA invest in and adequately resource the building of a cohesive system that replaces the various independent information collection systems that do not interact with each other.

Agency Comments

We provided a draft of this report to FDA for review and comment. FDA provided technical comments, which we incorporated as appropriate.

How GAO Did This Study

To describe FDA's oversight responsibilities, we reviewed key laws and regulations to identify changes that have affected FDA's responsibilities from fiscal year 2008 through fiscal year 2024. We defined key changes as those resulting in new product categories or product types subject to FDA regulation, new FDA roles for overseeing product categories, or significant modifications to FDA activities for overseeing product categories. Key changes also could have included changes resulting in a reduction in FDA oversight roles. In addition, we looked at data included in publicly available documents describing the number of entities FDA must regulate and medical product applications FDA received. Based on this review, we did not identify a clear trend suggesting an increase or decrease over the time frame in our review.

To describe FDA's funding and staffing, we reviewed FDA's *Justification of Estimates for Appropriations Committees* for fiscal years 2010 through 2026, which reported data on FDA funding, including budget authority and user fee funding, as well as FTEs for fiscal years 2008 (the last year we previously reported) through 2024 (prior to the 2025 proposed reorganization at HHS).[32] Based on the data included in the justifications, we report obligations or appropriations as available. According to FDA officials, the budget authority and user fee funding amounts reported as "actuals" in the justifications were obligations and amounts reported as "final" were appropriations. To determine the reliability of FDA funding and staffing data, we interviewed knowledgeable agency officials about the steps taken to ensure data are accurate and reliable, reviewed related documentation, and examined the data for consistency. We found these data to be sufficiently reliable for our purposes.

To identify staffing and other capacity challenges affecting FDA's ability to meet its oversight responsibilities that we and others identified from January 2020 through January 2025, we analyzed reports that reviewed the agency's operations, programs, and systems. We chose this 5-year time frame to identify challenges that are likely still relevant. We also included reports issued in January 2025 that reported on information collected in 2024. For this analysis, we reviewed our reports and third-party assessments of FDA's programs and operations, such as those completed by HHS OIG and the Reagan-Udall Foundation for the FDA. We identified third-party assessments by searching public websites and interviewing FDA officials for reports commissioned by the agency.

We conducted this performance audit from August 2024 to February 2026 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

List of Addressees

The Honorable Bill Cassidy, M.D.
Chair
The Honorable Bernard Sanders
Ranking Member
Committee on Health, Education, Labor and Pensions
United States Senate

The Honorable John Hoeven
Chair
The Honorable Jeanne Shaheen
Ranking Member
Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies
Committee on Appropriations
United States Senate

The Honorable James Comer
Chairman
Committee on Oversight and Government Reform
House of Representatives

The Honorable Andy Harris
Chairman
The Honorable Sanford Bishop, Jr.
Ranking Member
Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies
Committee on Appropriations
House of Representatives

GAO Contact Information

For more information, contact: Mary Denigan-Macauley and John Dicken, Directors, Health Care, DeniganMacauleyM@gao.gov and DickenJ@gao.gov.

Public Affairs: Sarah Kaczmarek, Managing Director, Media@gao.gov.

Congressional Relations: David A. Powner, Acting Managing Director, CongRel@gao.gov.

Staff Acknowledgments: William Hadley (Assistant Director), Katherine L. Amoroso (Analyst-in-Charge), Matthew Bond, Kaitlin Farquharson, Benjamin T. Feldman, Carolyn Garvey, Nkenge Gibson, Rebecca Hendrickson, Derry Henrick, David Jones, Laurie Pachter, and Sarah Resavy.

Endnotes

[1]FDA is also responsible for ensuring the protection of public health and safety by overseeing radiation-emitting products (e.g., microwaves and x-ray machines). Some of its oversight responsibilities of these products include assessing radiation emission levels from products and providing guidance to the general public and users of radiation-emitting products.

[2]FDA also has oversight responsibilities with respect to human drugs that are not evaluated for safety and effectiveness prior to marketing, such as compounded drugs and over-the-counter monograph drug products.

[3]FDA refers to discretionary appropriations derived from the U.S. General Fund of the Treasury as "budget authority" and, in keeping with the conventions used in FDA budget documents, we use that term throughout this report. The authority to obligate user fees is also generally considered budget authority, but for purposes of this report, the term budget authority is only being used to describe FDA's discretionary appropriations derived from the U.S. General Fund of the Treasury.

[4]Pub. L. No. 111-31, div. A, 123 Stat. 1776 (2009). For more information, see GAO, *Tobacco Product Regulation: Most FDA Spending Funded Public Education, Regulatory Science, and Compliance and Enforcement Activities*, GAO-14-561 (Washington, D.C.: June 20, 2014). Prior to 2009, restrictions on the distribution of tobacco products were largely enforced at the state level, and promotion of cigarettes and smokeless tobacco was largely overseen by the Federal Trade Commission.

[5]81 Fed. Reg. 28,974 (May 10, 2016) (codified in relevant part at 21 C.F.R. § 1100.1).

[6]Pub. L. No. 117-103, div. P, tit. I, subtit. B, § 111, 136 Stat. 49, 789-90.

[7]Pub. L. No. 111-148, § 7002, 124 Stat. 119, 804-21 (2010) (codified, as amended, at 42 U.S.C. § 262(k)).

[8]Pub. L. No. 115-52, § 709, 131 Stat. 1005, 1065-67. FDA issued the final rule establishing such regulations in 2022. See 87 Fed. Reg. 50,698 (Aug. 17, 2022). For more information, see GAO, *Over-the-Counter Hearing Aids: Information on the New Medical Device Category*, GAO-24-106854 (Washington, D.C.: May 7, 2024).

[9]Pub. L. No. 111-353, tit. II, § 201, 124 Stat. 3885, 3923-24 (2011) (codified at 21 U.S.C. § 350j). For more information, see GAO, *Food Safety: FDA Should Strengthen Inspection Efforts to Protect the U.S. Food Supply*, GAO-25-107571 (Washington, D.C.: Jan. 8, 2025).

[10]Food and Drug Administration Safety and Innovation Act, Pub. L. No. 112-144, tit. III, IV, 126 Stat. 993, 1008-39 (2012); CARES Act, Pub. L. No. 116-136, §§ 3861-62, 134 Stat. 281, 458-69 (2020).

[11]Pub. L. No. 117-328, div. FF, tit. III, subtit. E, 136 Stat. 4459, 5847. For more information, see GAO, *Cosmetic Safety: Better Planning Would Enhance FDA Efforts to Implement New Law*, GAO-24-105542 (Washington, D.C.: Dec. 6, 2023).

[12]See 21 U.S.C. § 364g. See also 21 U.S.C. § 364(5) (defining serious adverse event).

[13]Pub. L. No. 117-328, § 3305, 136 Stat. 4459, 5832 (2022) (codified at 21 U.S.C. § 360n-2).

[14]According to FDA officials, overall funding reported as “actuals” in the agency’s Justification of Estimates for Appropriations Committees for fiscal year 2008 through fiscal year 2020 represents obligations (i.e., definite commitments that create a legal liability of the U.S. government for payment of goods and services ordered or received). Overall funding for fiscal year 2021 through fiscal year 2024 reported as “final” represents appropriations with congressionally approved adjustments, such as reallocations of appropriated funds within or among appropriations accounts.

[15]Under the Tobacco Control Act, FDA is authorized to assess user fees on tobacco products that fall within the following six product classes: cigars, pipe tobacco, cigarettes, snuff, chewing tobacco, and roll-your-own tobacco. See 21 U.S.C. § 387s.

[16]Like the funding data, overall FTEs for fiscal year 2008 reported in FDA’s Justification of Estimates for Appropriations Committees represent obligations, and overall FTEs for fiscal year 2024 represent appropriations with congressionally approved adjustments, according to agency officials.

FDA also hires contractors and works with state, local, tribal, and territorial partners to conduct work, such as some food safety inspections and tobacco retailer inspections. These individuals are not accounted for in the FTE data.

[17]According to FDA officials, funding for product areas reported as “actuals” in the agency’s Justification of Estimates for Appropriations Committees for fiscal year 2008 through fiscal year 2023 represents obligations. Funding for product areas for fiscal year 2024 reported as “final” represents appropriations with congressionally approved adjustments. While the justifications present actuals data by product areas for fiscal year 2021 through fiscal year 2023, overall funding (as discussed in the prior section) is presented as final data for the same time period.

[18]According to FDA officials, FTEs for product areas reported as “actuals” in the agency’s Justification of Estimates for Appropriations Committees for fiscal year 2008 through fiscal year 2023 represent obligations. FTEs for product areas for fiscal year 2024 reported as “final” represent appropriations with congressionally approved adjustments.

[19]Capacity entails an agency having sufficient staff and resources to address its risks. Capacity also includes the management and organizational infrastructure necessary for an agency to achieve its mission. Human capital is a particularly important aspect of capacity and skills gaps are affecting progress on many high-risk areas. In addition to having sufficient skilled staff, agencies must also build capacity by ensuring that adequate funding, internal controls, systems, structures, and technology are present to effectively carry out their mission. See, GAO, *High-Risk Series: Key Practices to Successfully Address High-Risk Areas and Remove Them from the List*, GAO-22-105184 (Washington, D.C.: Mar. 3, 2022).

[20]GAO, *Clinical Research: FDA Should Evaluate Its Efforts to Recruit and Retain Its Inspection Workforce,* GAO-24-106383 (Washington, D.C.: Feb. 22, 2024); *Drug Safety: FDA Should Implement Strategies to Retain Its Inspection Workforce*, GAO-25-106775 (Washington, D.C.: Nov. 13, 2024).

[21]GAO, *Food Safety: FDA Should Strengthen Inspection Efforts to Protect the U.S. Food Supply,* GAO-25-107571 (Washington, D.C.: Jan. 8, 2025).

[22]Department of Health and Human Services, Office of Inspector General, *The Food and Drug Administration Needs To Improve the Premarket Tobacco Application Review Process for Electronic Nicotine Delivery Systems To Protect Public Health,* A-06-22-01002 (Washington, D.C.: Nov. 8, 2023).

[23]See, for example, *Prescription Drug User Fee Act Reauthorization Performance Goals and Procedures Fiscal Years 2023 through 2027*, accessed June 30, 2025. FDA's goal is to review and act on 90 percent of standard new drug applications that involve a new molecular entity within 10 months following a 60-day filing review period that begins on the date of FDA's receipt of the application (so the goal is a total of 12 months from receipt). Priority review reduces this time to 6 months following the 60-day filing date (so the goal is a total of 8 months from receipt). FDA's goal is to review and act on 90 percent of standard new drug applications that do not involve a new molecular entity within 10 months of receipt. Priority review reduces this time to within 6 months of receipt.

[24]GAO-25-107571. According to FDA officials, nearly one-quarter of food investigators were eligible to retire as of July 2024.

[25]GAO, *Regenerative Medicine: Therapeutic Applications, Challenges, and Policy Options,* GAO-23-105430 (Washington, D.C.: July 13, 2023).

[26]Consolidated Appropriations Act, 2023, Pub. L. No. 117-328, § 3623, 136 Stat. 4459, 5878 (2022) (codified at 21 U.S.C. § 379d-3b) and GAO, *FDA Workforce: Agency-Wide Workforce Planning Needed to Ensure Medical Product Staff Meet Current and Future Needs*, GAO-22-104791 (Washington, D.C.: Jan. 14, 2022).

[27]GAO-25-107571.

[28]GAO-25-107571. Our analysis in this report focused on FDA's routine surveillance food safety inspections intended to monitor a food facility's compliance with regulatory requirements. The report did not cover other types of FDA inspections, such as those conducted when there is reason to believe a facility has serious manufacturing problems or to investigate a specific problem or complaint that has come to FDA's attention.

[29]Recent work by HHS OIG also found that FDA attempted to inspect thousands of food facilities that were not in operation and recommend that it take steps to improve methods for identifying facilities that are not in operation. See HHS OIG, *FDA Food Safety Inspections of Domestic Food Facilities*, OEI-02-23-00300, (Washington, D.C.: June 2025).

[30]GAO, *Federal Property: Formal Policies Could Enhance FDA's Property Management Efforts*, GAO-20-689 (Washington, D.C.: Sept. 23, 2020).

[31]Reagan-Udall Foundation for the FDA, *Operational Evaluation of the FDA Human Foods Program* (Washington, D.C.: Dec. 6, 2022). The foundation is an independent organization created by Congress to advance the mission of FDA to modernize product development, accelerate innovation, and enhance product safety.

[32]See HHS, *Fact Sheet: HHS' Transformation to Make America Healthy Again* (Washington, D.C.: Mar. 27, 2025). As of September 2025, several states had challenged HHS's March 27 announcement on statutory and constitutional grounds. *New York v. Kennedy*, No. 25-cv-00196 (D.R.I. May 5, 2025). In addition, several other groups had challenged government-wide directives requiring federal departments to downsize and reorganize. *Am. Fed'n of Gov't Emps., AFL-CIO v. Trump*, No. 25-cv-3698 (N.D. Ca. Apr. 28, 2025). At the time of reporting, both lawsuits were ongoing.