

Annual Report to Congress

Compounding Quality Act

FY 2025



**U.S. FOOD & DRUG
ADMINISTRATION**

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Executive Summary

In November 2013, the President signed into law the Drug Quality and Security Act (DQSA) (Pub. L. 113-54), which contains important provisions related to the oversight of human drug compounding activities. Title I of the DQSA, the Compounding Quality Act (CQA), created a new category of compounders known as “outsourcing facilities.” A human drug compounder can elect to register with the Food and Drug Administration (FDA or Agency) as an outsourcing facility. After the initial registration, a facility that elects to continue to be registered with FDA as an outsourcing facility must re-register annually during the annual registration period of October 1 to December 31. Drug products compounded by or under the direct supervision of a licensed pharmacist in a registered outsourcing facility can qualify for exemptions from specific sections of the Federal Food, Drug, and Cosmetic Act if certain conditions are met.

CQA authorizes FDA to assess and collect fees from human drug compounders that register with the Agency as outsourcing facilities. FDA spends these fee revenues to hire, support, and maintain personnel for the oversight of these outsourcing facilities. CQA requires FDA to submit an annual report to Congress. This report covers fiscal year (FY) 2025.

In FY 2025, 97 entities registered as outsourcing facilities. Four of the 97 facilities that paid the registration fee and were initially registered as outsourcing facilities in FY 2025 withdrew their registration before the end of the fiscal year. On the last day of FY 2025, 93 facilities were registered.

In FY 2025, the total FDA spending to support its oversight of outsourcing facilities included general fund appropriations and outsourcing facility fees. These funds supported full-time equivalents (FTEs) across FDA. In particular, the outsourcing facility fees supported seven FTEs in FY 2025. This is a small fraction of the full level of effort used to support FDA’s oversight of outsourcing facilities during FY 2025. This oversight of outsourcing facilities included activities conducted by the Center for Drug Evaluation and Research, the Office of Inspections and Investigations, and FDA’s Headquarters but did not include activities conducted by the Center for Veterinary Medicine or the Center for Biologics Evaluation and Research because CQA does not cover the compounding of animal drugs or biologics.

FDA had net cash collections of \$2,219,440 in outsourcing facility fees during FY 2025. In addition, FDA had a CQA carryover balance of \$464,147, as well as \$1,858 in recoveries, from the prior fiscal year. Of the total amount of outsourcing facility fees available in FY 2025 (i.e., \$2,685,445), FDA spent \$1,728,328 to support its oversight of outsourcing facilities in FY 2025 (which is five percent of its total spending for this purpose) and carried forward a balance of \$957,117. Under CQA, fees collected, appropriated, and not obligated at the end of a fiscal year remain available to FDA in future fiscal years. FDA intends to utilize these carryover funds, as well as new fees collected, to support its oversight of outsourcing facilities. FDA will continue to ensure that the fees supplement and do not supplant any other Federal funds available for its oversight of outsourcing facilities.

In FY 2026, FDA will continue to conduct oversight of outsourcing facilities, which includes promptly investigating reports of serious adverse events and product quality issues such as drug contaminations, inspecting outsourcing facilities per a risk-based schedule, and taking regulatory action as appropriate when compounding activities violate the law. FDA

will also continue to develop policy documents and engage in outreach that will assist outsourcing facilities in complying with the law. Further, FDA will continue to coordinate and collaborate with the states.

Report Overview

A. Scope

This annual report addresses the Food and Drug Administration's (FDA's or Agency's) assessment and use of fees collected from human drug compounders registered with FDA as outsourcing facilities during the period of October 1, 2024, through September 30, 2025.

B. Report Requirements

In accordance with section 744K(h) of the Federal Food, Drug, and Cosmetic (FD&C) Act, FDA shall submit an annual report to Congress on the assessment, collection, and use of the fees collected for each fiscal year. The purpose of this report is to meet these requirements.

FDA is required to submit the annual report to Congress no later than 120 days after the end of each fiscal year (September 30).

The annual report to Congress is required to include:

1. A description of the fees assessed and collected for each fiscal year.
2. A summary description of the entities paying these fees.
3. A description of FDA's hiring and placement of new staff.
4. A description of FDA's use of fee resources to support its inspection of outsourcing facilities.
5. The number of inspections and reinspections of such facilities performed by FDA each year.

Management Discussion

C. Organization Background

FDA is responsible for protecting public health by helping to ensure the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation. FDA also has responsibility for regulating the manufacturing, marketing, and distribution of tobacco products and advancing public health. FDA helps to speed innovations that make medical products more effective, safe, and affordable and helps the public get the accurate, science-based information needed to use medical products and to consume foods to maintain and improve their health. In addition, FDA plays a significant role in the nation's counterterrorism capability. FDA fulfills this responsibility by ensuring the security of the food supply and by fostering the development of medical products to respond to deliberate and naturally emerging public health threats.

Program Organization

There are three major FDA components that support the CQA program: the Center for Drug Evaluation and Research (CDER), the Office of Inspections and Investigations (OII)¹, and FDA's Headquarters (HQ).

Exhibit 1 provides an overview of the mission for each of these components.

Exhibit 1: FDA's CQA Program Components

Component	Mission
CDER	Protects and promotes public health by helping to ensure that human drugs are safe and effective, meet established quality standards, and are available to patients.
OII	Conducts rigorous, transparent, and science-based inspections and investigations, providing real-time evidence and insight essential in empowering fact-based regulatory decisions to protect public health.
HQ	Provides FDA-wide program direction and administrative services to ensure FDA's consumer and patient safety programs are effectively and efficiently managed.

D. Fee Background and Structure

CQA authorizes FDA to assess and collect fees from outsourcing facilities to supplement the general fund appropriations that the Agency spends on outsourcing facility oversight activities.

FDA spends CQA fee collections and general fund appropriations to hire, support, and maintain personnel for the Agency's outsourcing facility oversight activities to

¹ Effective October 1st, 2024, the Office of Regulatory Affairs was restructured and renamed the Office of Inspections and Investigations (OII). This restructuring allows the field operations unit to focus on inspections, investigations, and imports as its core mission. The new enterprise-wide structure will enhance collaboration between our field investigators and other subject matter experts throughout the agency and modernize and strengthen the entire agency to work more cohesively and collaboratively in accomplishing our collective public health mission. For more information, see <https://www.fda.gov/about-fda/fda-organization/fda-modernization-efforts-establishing-unified-human-foods-program-new-model-field-operations-and>

help ensure the quality of compounded drugs available to the American public. In January 2021, FDA established CDER’s Office of Compounding Quality and Compliance to house new and existing staff that work on oversight activities related to the human drug compounding program.

Exhibit 2 outlines the CQA fee structure.

Exhibit 2: CQA Fee Structure

Fee Type		FY 2025 Fee	Definition
Annual Establishment	Non-Small Business	\$21,534	Assessed annually to entities that elect to register or re-register with FDA as outsourcing facilities. The annual establishment fee is payable upon receipt of an invoice that will be sent after FDA has determined that the registration information submitted by the entity is complete.
	Small Business	\$6,488	Assessed annually to entities that elect to register or re-register with FDA as outsourcing facilities and qualify for a small business reduction. Entities with gross annual sales totaling \$1 million or less in the 12 months ending on April 1 of the fiscal year immediately preceding the fiscal year in which the annual establishment fee is assessed may qualify for a small business reduction.
Reinspection		\$19,465	Assessed when FDA inspects an outsourcing facility more than one time because noncompliance was identified in a previous inspection. A reinspection fee will be incurred for each reinspection conducted until FDA determines that the non-compliant conditions have been adequately addressed.

The statute specifies how the fees must be calculated each fiscal year, including adjustments for inflation and small businesses. The fee amounts are published in the *Federal Register* 60 days before the start of each fiscal year.^{2,3}

Legal Conditions

The FD&C Act, as amended by CQA, specifies that for fiscal year (FY) 2014 and each subsequent fiscal year, fees authorized to be appropriated are in “an amount equivalent to the total amount of fees assessed for such fiscal year.”

² CQA fee rates for FY 2025 (89 FR 61470 (July 31, 2024)) and FY 2026 (90 FR 35903 (July 30, 2025)) are available at <https://www.fda.gov/industry/fda-user-fee-programs/human-drug-compounding-outsourcing-facility-fees>.

³ For more information, please see FDA’s guidance for industry document titled *Fees for Human Drug Compounding Outsourcing Facilities Under Sections 503B and 744K of the FD&C Act*, available at <https://www.fda.gov/media/136683/download>.

Performance Summary

CQA fees are used to support the costs of FDA's oversight of outsourcing facilities and represent a small portion of FDA's overall outsourcing facility oversight program. Oversight of outsourcing facilities includes activities related to inspections and enforcement, policy development and implementation, stakeholder outreach, and state collaboration and coordination.

In FY 2025, FDA used available fee revenues to implement the CQA regulatory framework for outsourcing facilities, conduct stakeholder outreach with currently registered outsourcing facilities and compounders interested in registering as outsourcing facilities, respond to inquiries about compounding, develop policies related to outsourcing facilities, perform inspections, promote compliance with current good manufacturing practice (CGMP) standards and other requirements for outsourcing facilities, and take enforcement actions when appropriate.

In FY 2025, FDA issued three final guidance documents. Two of the final guidance documents published in January 2025, Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug and Cosmetic Act and Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug and Cosmetic Act, describe FDA's interim policies regarding the use of bulk drug substances in compounding by outsourcing facilities, and by licensed pharmacists in State-licensed pharmacies and Federal facilities and licensed physicians that are not registered with FDA as outsourcing facilities, while FDA develops the lists of bulk drug substances that can be used in compounding under sections 503B and 503A of the FD&C Act. The third final guidance document published in October 2024, Temporary Policies for Compounding Certain Parenteral Drug Products, describes FDA's regulatory and enforcement priorities regarding the compounding of certain parenteral drug products by outsourcing facilities and by State-licensed pharmacies and Federal facilities that are not registered with FDA as outsourcing facilities.

In addition to publishing these policy documents, in FY 2025, FDA held several training sessions and conferences. Through the Compounding Quality Center of Excellence, FDA sponsored 15 instructor-led training sessions in areas related to CGMP with over 160 participants. The Compounding Quality Center of Excellence also offered 10 self-guided online trainings that were completed over 5,100 times in FY 2025. More than 65 percent of registered outsourcing facilities took one or more of those training sessions. Further, FDA held its sixth annual Compounding Quality Center of Excellence Conference; this conference garnered nearly 900 participants (virtual and in-person), including approximately 66 percent of registered outsourcing facilities, and aimed to engage outsourcing facilities and other stakeholders on key topics and best practices. FDA also held its 13th annual intergovernmental meeting on drug compounding with state regulators.

In FY 2025, 109 entities requested to register as outsourcing facilities. Of these 109 facilities, 97 registered as outsourcing facilities (with 88 paying the non-small business establishment fee and nine paying the small business establishment fee), and 12 submitted information to register but failed to pay the fee. Further, four of these facilities withdrew their registration prior to the end of FY 2025. On the last day of FY 2025, 93 facilities were registered.

Table 1 shows the geographical locations of the firms registered as outsourcing facilities in FY 2025.

Table 1: Number of Firms Registered as Outsourcing Facilities During FY 2025 by Geographical Location

Geographical Location	States Included	Number of Registered Outsourcing Facilities
Northeast	Connecticut, Massachusetts, New Jersey, New York, Maryland, and Pennsylvania	20
Southeast	Alabama, Arkansas, Florida, North Carolina, South Carolina, Virginia, Mississippi, and Tennessee	31
Midwest	Kansas, Missouri, Minnesota, Nebraska, Wisconsin, Ohio, and Montana	11
Southwest	Arizona, Oklahoma, and Texas	21
West	California, Colorado, and Nevada	14
Total		97

Outsourcing facilities vary widely in terms of scope of distribution and the types of products compounded. For example, some outsourcing facilities distribute drugs primarily within the state in which they are located. Other outsourcing facilities operate on a larger scale, distributing drug products to healthcare facilities nationwide. One firm may compound and distribute only three drug products, while another firm may compound and distribute thousands of different drug products. In addition, one firm may compound five units (e.g., vials or syringes) of a single drug product, while another firm may compound over 100,000 units of a single drug product. Many outsourcing facilities are state-licensed pharmacies, but some are not. In addition, although outsourcing facilities are by definition compounding sterile drugs (e.g., injectables for various routes of administration), many also compound non-sterile drugs (e.g., solid oral dosage forms). The types of drug products compounded by outsourcing facilities may include, for example, ophthalmics, anesthetics, antibiotics, hormones, steroids, dermatologic products, and vitamin injections.

Table 2 lists the number of entities that (1) registered and remained registered and (2) registered, then de-registered, as an outsourcing facility during the two most recent fiscal years. The number of outsourcing facilities that registered and remained registered increased from FY 2024 to FY 2025.

Table 2: Number of Entities Registered and De-Registered as Outsourcing Facilities

Fee Type	FY 2024	FY 2025
Registered and Remained Registered Through the End of the Fiscal Year	83	93
Registered But Then De-Registered	7	4

E. Outsourcing Facility Inspections and Reinspections

CQA authorizes FDA to assess and collect a reinspection fee from outsourcing facilities that are reinspected under certain circumstances (section 744K(a)(1)(B) of the FD&C Act). The statute defines “reinspection” as

[One] or more inspections conducted under section 704 subsequent to an inspection conducted under such provision which identified noncompliance materially related to an applicable requirement of this Act, specifically to determine whether compliance has been achieved to the Secretary's satisfaction (section 744(J)(4) of the FD&C Act).

Moreover, the statute provides that an outsourcing facility subject to multiple reinspections in a fiscal year shall be subject to a reinspection fee for each reinspection (section 744K(a)(2) of the FD&C Act) until FDA finds that the noncompliant conditions have been adequately addressed.

In FY 2025, FDA conducted 42 inspections of outsourcing facilities. Of these 42 inspections, 17 were "reinspections" as defined in CQA. As of September 30, 2025, FDA had collected eleven reinspection fees, and six facilities were invoiced but failed to pay the fee for FY 2025.

Table 3 provides a summary of 503B outsourcing facility inspections, which includes surveillance, follow up, or for-cause inspections (no fees collected) and 503B reinspections (fees collected) for the 2 most recent fiscal years.

Table 3: Outsourcing Facility Inspection Summary by Type During FYs 2024 and 2025

Inspection Type	FY 2024	FY 2025
503B Inspections	20	25
503B Reinspections	13	17
Total Inspections	33	42

The number of inspections and reinspections increased from FY 2024 to FY 2025. Outsourcing facility inspections were funded by outsourcing facility fees and FDA's general fund appropriations.

Financial Information

This section provides an overview of the program financials for CQA for FY 2024 and FY 2025. These financials include fee revenue, obligations, carryover, and full-time equivalents (FTEs).

F. Fee Program Financials

Table 4 represents a summary of the CQA financial position for FY 2024 and FY 2025.

Table 4: CQA Fee Program Financials for FYs 2024 and 2025

Budgetary Resources	FY 2024	FY 2025
Total Carryover, Beginning of Year	\$306,790	\$464,147
Net Collections	\$1,929,249	\$2,219,440
Recoveries	\$744	\$1,858
Total Budgetary Resources	\$2,236,783	\$2,685,445
Obligations	FY 2024	FY 2025
Total Payroll	\$1,737,189	\$1,692,881
Total Operating	\$0	\$0
Total Rent	\$35,447	\$35,447
Total Shared Services	\$0	\$0
Total Obligations	\$1,772,636	\$1,728,328
Carryover	FY 2024	FY 2025
Total Carryover, End of Year	\$464,147	\$957,117

Budgetary Resources: Total Budgetary Resources is the total fee funding (i.e., the existing total carryover, fee collections, and recoveries). Net Collections are the amounts collected during the fiscal year, net of refunds that have taken place. Recoveries account for funds de-obligated from prior year obligations. For example, recoveries could include funding from a contract that ended in a prior year and was not expended. See **Section G** for more on fee revenue.

Obligations: Total Obligations is the annual expenditure of CQA fee funds broken out by major expense categories. Per section 744K(d) of the FD&C Act, CQA fees may be expended only “to pay for the costs of oversight of outsourcing facilities.”

Carryover: CQA fees collected, appropriated, and not obligated at the end of the fiscal year remain available to support the oversight of outsourcing facilities in future fiscal years. In this report, such fee funds are referred to as the “total carryover” or “CQA carryover.” See **Section I** for more on carryover.

G. Fee Revenue

The process for fee setting is defined in the statute. Fees are to be adjusted for the following factors:

Inflation Adjustment Factor: This adjustment is a composite measure based on the sum of (1) operating expenses by changes in the Consumer Price Index (CPI) and (2) payroll-related expenses by changes in FDA’s average personnel compensation and benefits amounts.

The FY 2025 inflation adjustment factor was 1.297679, compounded for the 10 years since FY 2015. For FY 2025, the inflation adjustment was 29.7679 percent (rounded).

Small Business Adjustment Factor: This adjustment considers estimates of the number of small businesses that will pay a reduced fee for that year and the positive adjustment to the establishment fee of the remaining entities needed to achieve total fees equalling the amount that FDA would have collected if no entity qualified for the small business reduction.

The small business adjustment amount in FY 2025 was \$2,069.

Collections

Cohort Year Collections: Fee collections are generally recognized and reported in the fiscal year that the fee was originally due (referred to as the “cohort year”).⁴ Totals reported are after any refunds for the cohort year. To ensure the quality of the information provided in this annual report, FDA annually updates prior years’ numbers reported in the current report to account for any collections or refunds processed after publication of the prior year reports.

Table 5 outlines CQA collections by fee type and cohort year. The “Fees Receivable” component shows the outstanding amounts that are still owed for Cohort Years 2024 and 2025. Refer to **Section D** for more background and information on the CQA fee structure.

**Table 5: CQA Fee Collections by Fee Type FYs 2024 and 2025
(as of September 30, 2025)**

Fees Collected	FY 2024	FY 2025
Non-Small Business Establishment Fees	\$1,723,096	\$1,873,458
Small Business Establishment Fees	\$24,784	\$58,392
Reinspection Fees	\$201,487	\$231,826
Total Cash Collections	\$1,949,367	\$2,163,676

Fees Receivable	FY 2024	FY 2025
Non-Small Business Establishment Fees	\$0	\$589,470
Small Business Establishment Fees	\$0	\$6,488
Reinspection Fees	\$40,157	\$154,843
Total Fees Receivable	\$40,157	\$750,801

The number of reinspection fees collected increased from FY 2024 to FY 2025. Outsourcing facility inspections were funded by outsourcing facility fees and FDA’s general fund appropriations.

H. Fee Obligations

CQA fees may be expended only “for the costs of oversight of outsourcing facilities,” per section 744K(d) of the FD&C Act.

⁴ For example, a fee originally due in FY 2024, but received in FY 2025, is attributed to FY 2024 cohort year collections.

Table 6 provides a comparison of fee obligations by expense category during the past 2 fiscal years.

Table 6: CQA Fee Obligations by Expense Category for FYs 2024 and 2025

Fee Obligations	FY 2024	FY 2025
Payroll	\$1,737,189	\$1,692,881
CDER	\$1,176,145	\$1,253,437
OII	\$561,044	\$439,444
HQ	\$0	\$0
Operating	\$0	\$0
Total Rent	\$35,447	\$35,447
Total Shared Services	\$0	\$0
Total Obligations	\$1,772,636	\$1,728,328

Payroll and Operating Costs: These obligations provide for payroll and operating costs that support oversight of outsourcing facilities. Payroll and operating includes, for example, core regulatory review functions, inspections, guidance and policy development activities, scientific activities, and management and administrative functions that support the CQA program. The payroll and operating costs associated with the outsourcing facility oversight activities are based on obligations attributed to CDER, OII, and HQ.

Center employees are required to report their time in an activity-based reporting system. This allows FDA to ensure that CQA fee funds are only supporting payroll proportional to the time invested in outsourcing facility oversight activities.

For operating activities (e.g., certain contracting services), CQA fee funds are allocated based on the proportion to which those activities support the CQA program. If an operating activity solely supports CQA, it can be fully funded by CQA fees (and/or general fund appropriations). If the operating activity is shared, CQA fees may fund the activity up to the appropriate proportion of the benefit from such activity that accrues to outsourcing facility oversight activities.

Rent Costs: The General Services Administration charges rent to FDA for the federal buildings that FDA occupies. This rent is charged at different rates depending on the type and location of the space provided. Since rent is an essential support cost for the oversight of outsourcing facilities, a portion of those charges is paid from general fund appropriations, and a portion is paid from CQA fees.

Shared Services: FDA has several shared service programs, supported by the Working Capital Fund (WCF), that provide support for activities across the Agency, such as human resources and information technology (IT). **Appendix A.1** provides a full list of the offices that constitute the WCF.

I. Fee Carryover

CQA fees collected, appropriated, and not obligated at the end of a fiscal year remain available to support the CQA program in future fiscal years. This balance is referred to as the “CQA carryover.”⁵

⁵ Per section 744k(f) of the FD&C Act, fees are authorized to remain available until expended.

The net change in CQA carryover each year is equal to net collections minus net obligations. This is demonstrated best in **Table 7**.

Table 7: Historical CQA Fee Collections, Obligations, and Carryover Balances by Fiscal Year

Historical Carryover	FY 2021	FY 2022	FY 2023	FY 2024	FY 2025
Total Carryover, Beginning of Year	\$235,104	\$227,922	\$469,804	\$306,790	\$464,147
Net Collections	\$1,433,751	\$1,665,351	\$1,349,257	\$1,929,249	\$2,219,440
Recoveries	\$0	\$317	\$295	\$744	\$1,858
Obligations	(\$1,440,933)	(\$1,423,785)	(\$1,512,567)	(\$1,772,636)	(\$1,728,328)
Total Carryover, End of Year	\$227,922	\$469,804	\$306,790	\$464,147	\$957,117

Maintaining an appropriate level of carryover enables FDA to mitigate financial risks to the program, including, for example, the risk of under collecting fees and the financial challenges associated with a potential lapse in appropriations, so that FDA can continue its oversight of outsourcing facilities under such financial constraints, to the extent carryover remains available.

J. Full-Time Equivalents

“FTE employment” (often referred to as “staff year”), as defined by section 85 of the Office of Management and Budget (OMB) Circular A-11, means the total number of regular straight-time hours—not including overtime or holiday hours—worked by employees, divided by the number of compensable hours applicable to each fiscal year. Annual leave, sick leave, compensatory time off, and other approved leave categories are considered “hours worked” for purposes of defining FTE employment.

In FY 2025, FDA’s outsourcing facility fees supported approximately five CDER FTEs and two OII FTEs out of the 122 FTEs dedicated to the oversight of outsourcing facilities.

Table 8 presents total fee-paid FTE levels that supported outsourcing facility oversight by FDA organizational components for the past 5 fiscal years. The table displays data for CDER, OII, and HQ.

Table 8: Historical Trend of FTEs Supported by CQA Fees as of September 30 for FYs 2021 to 2025

Organization	FY 2021	FY 2022	FY 2023	FY 2024	FY 2025
CDER	5	4	6	5	5
OII	4	4	3	3	2
HQ	0	0	0	0	0
Total FTEs	9	8	9	8	7

Management Assurance

The FDA maintains a strong internal control culture in order to support data-driven decision making, reliable financial forecasting, accountability for resource use and to ensure compliance with laws, including:

- Federal Managers' Financial Integrity Act (FMFIA) – This act requires agencies to establish internal controls that provide a reasonable assurance of effective and efficient operations, compliance with applicable laws, and reliable financial reporting. This act requires agencies to comply with federal financial management systems requirements, ensuring that transactions are properly recorded, and financial reports are reliable.
- Office of Management and Budget (OMB) Circular A-123 – It sets the standards for internal controls and requires agencies to implement internal control assessments, including the management of risks and ensuring accountability.
- Government Accountability Office (GAO) Standards for Internal Control (Green Book) – Provides the framework for designing, implementing, and operating an effective internal control system within the federal government.
- Improper Payments Elimination and Recovery Act (IPERA) – IPERA requires agencies to identify and reduce improper payments and recover overpayments when they occur.
- Federal Information Security Modernization Act (FISMA) – Addresses internal controls related to information security, ensuring the protection of federal information systems.

Additionally, FDA established a council to govern oversight and accountability:

- User Fee Financial Management Committee (UFFMC): The UFFMC oversees and ensures FDA's compliance with sound financial management practices and statutory provisions governing user fees, providing oversight for resource needs, financial planning, and forecasting. The CFO serves as the Chairman, a Program Representative serves as the Program Vice Chairman, and voting members include all Center Directors from across the Agency.

A. Supplemental Financial Information

A.1. Shared Services Costs

FDA has several shared service programs, supported by the WCF, that provide support for activities across the Agency. The shared service programs in FY 2025 include:

- **Office of Digital Transformation:** Provides the vision and leadership in IT, data, and cybersecurity needed to advance FDA's mission and strategic priorities.
- **Office of Equal Employment Opportunity:** Promotes a work environment that ensures equal employment opportunity and fosters a professional culture that values and empowers individuals so they can participate and contribute to their fullest potential.
- **Office of Ethics and Integrity:** Protects the integrity of FDA's programs and operations by promoting an ethical culture and ensuring compliance with applicable federal ethics laws.
- **Office of Facilities, Engineering, and Mission Support Services:** Provides FDA employees with office and laboratory facilities.
- **Office of Finance, Budget, and Acquisitions:** Leads FDA's budget, acquisitions, and financial management functions while ensuring the financial integrity of FDA's resources.
- **Office of Human Capital Management:** Provides human resource services that promote collaboration and a work environment that is characterized by open communication, personal accountability, trust, and mutual respect.
- **Office of Management and Enterprise Services:** Provides strategic and tactical enterprise-wide services through development and implementation of administrative policies, programs, and initiatives.
- **Office of Occupational Safety and Health:** Reinforces FDA's expectations for workplace health and safety, laboratory safety and security, laboratory quality and efficiency, enhances communications among FDA safety staff, and provides program support.
- **Office of Planning, Evaluation and Risk Management:** Partners with FDA's leaders to achieve organizational excellence by improving program performance, governance, operational efficiency, and risk management.
- **Office of Security and Passport Operations:** Develops and implements the Agency-wide security policies and programs by providing leadership and guidance to managers and staff on all aspects of security. Delivers efficient passport and visa services and administers vital security functions that contribute to the Agency's mission of protecting public health by enhancing the safety and security of all personnel, facilities, and information.
- **Office of Talent Solutions:** Provides high quality and efficient solutions that enable FDA to hire a talented and qualified workforce.

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