Report to Congress

Compounding Quality Act

FY 2022

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) 2022.

In FY 2022, 85 entities registered as outsourcing facilities. Nine of the 85 facilities that paid the registration fee and were initially registered as outsourcing facilities in FY 2022 withdrew their registration before the end of the fiscal year. On the last day of FY 2022, 76 facilities were registered.

In FY 2022, FDA spending to support its oversight of outsourcing facilities totaled $42,562,826. This amount included budget authority and outsourcing facility fees. These funds supported full-time equivalents (FTEs) across FDA. In particular, the outsourcing facility fees supported eight FTEs in FY 2022 out of the 80 FTEs dedicated to the oversight of outsourcing facilities. This oversight of outsourcing facilities included activities conducted by the Center for Drug Evaluation and Research, the Office of Regulatory Affairs, 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 $1,665,351 in outsourcing facility fees during FY 2022. In addition, FDA had a carryover balance of $227,922, as well as $317 in recoveries, from the prior fiscal year. Of the total amount of outsourcing facility fees available in FY 2022 (i.e., $1,893,589), FDA spent $1,423,785 to support its oversight of outsourcing facilities in FY 2022 (which is three percent of its total spending for this purpose) and carried forward a balance of $469,804. 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 the budget authority for its oversight of outsourcing facilities.

In FY 2023 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, 2022, through September 30, 2022.

B. Report Requirements

In accordance with section 744K(h) of the Federal Food, Drug, and Cosmetic Act (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 (i.e., September 30). Additional details on what is required to be included in this report are included in **Appendix A**.

Management Discussion

C. Organization Background

FDA is responsible for protecting the public's 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 the public's health by helping speed innovations that make medical products more effective, safe, and affordable and by helping the public get the accurate, science-based information needed to use medical products and consume foods to maintain and improve their health.

FDA similarly 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 Compounding Quality Act (CQA) program: the Center for Drug Evaluation and Research (CDER), the Office of Regulatory Affairs (ORA), and Headquarters (HQ).

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

Exhibit 1: 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.
ORA	Protects consumers and enhances public health by maximizing compliance of FDA-regulated products and minimizing the risk associated with those products.
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. These fees supplement FDA's budget authority (BA) appropriations to support activities related to the Agency's outsourcing facility oversight.

FDA spends CQA fee collections and BA appropriations to hire, support, and maintain personnel for the Agency's outsourcing facility oversight activities to 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. The CQA fee structure is outlined in **Exhibit 2**.

Exhibit 2: CQA Fee Structure

Fee Type		FY 2022 Fee	Definition
Annual Establishment	*Non-Small Business*	$18,999	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	$5,824	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		$17,472	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 FD&C Act specifies how the fees must be calculated each fiscal year, including the annual adjustments that must be made for inflation and small businesses. The fee amounts are to be published in the *Federal Register* each year, typically at the beginning of August.[1, 2]

E. 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."

[1] CQA fee rates for fiscal year (FY) 2022 (86 FR 40588) and FY 2023 (87 FR 45335) are available at https://www.fda.gov/industry/fda-user-fee-programs/human-drug-compounding-outsourcing-facility-fees.

[2] For more information, please see FDA's guidance for industry on *Fees for Human Drug Compounding Outsourcing Facilities* Under sections 503B and 744K of the FD&C Act.

F. Performance Summary

In FY 2022, FDA advanced the following two major documents regarding compounding: a guidance document and a Federal Register notice.[3]

Regarding the first major document, FDA published a revised draft guidance document on hospital and health system compounding.[4]

Regarding the second major document, FDA issued a *Federal Register* notice[5] adding four bulk drug substances to the list of bulk drug substances (i.e., active pharmaceutical ingredients) for which there is a clinical need (the 503B Bulks List); these substances may be used in compounding by outsourcing facilities. The four bulk drug substances are diphenylcyclopropenone (DPCP) for topical use only, glycolic acid for topical use only in concentrations up to 70 percent, squaric acid dibutyl ester (SADBE) for topical use only, and trichloroacetic acid (TCA) for topical use only. In the same *Federal Register* notice, FDA determined that eight bulk drug substances will not be added to the 503B Bulks List.

FDA also held a meeting of the Pharmacy Compounding Advisory Committee to discuss four substances that were nominated for inclusion on the list of bulk drug substances that may be used in compounding under section 503A of the FD&C Act and one substance for addition to a list of drugs that have been withdrawn or removed from the market for reasons of safety or effectiveness.[6]

In FY 2022, FDA held several training sessions and conferences. Through the Compounding Quality Center of Excellence, FDA sponsored 18 virtual interactive training sessions in FY 2022, with over 500 total attendees, that were led by technical experts. The Compounding Quality Center of Excellence also offered 10 self-guided online trainings that were completed over 2,200 times in FY 2022. Nearly 80 percent of registered outsourcing facilities took one or more of the trainings offered through the Compounding Quality Center of Excellence. In addition, FDA held its third annual conference, The Shared Pursuit of Compounding Excellence, through the Compounding Quality Center of Excellence; this conference garnered more than 800 participants and aimed at engaging outsourcing facilities and other stakeholders on key topics and best

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[3] For more information on FDA's compounding policy documents, visit https://www.fda.gov/drugs/human-drug-compounding/regulatory-policy-information.

[4] FDA published this revised draft guidance document, titled "Hospital and Health Systems Compounding Under Section 503A of the Federal Food, Drug, and Cosmetic Act," on October 6, 2021; it is available at https://www.fda.gov/media/97353/download.

[5] List of Bulk Drug Substances for Which There Is a Clinical Need Under Section 503B of the Federal Food, Drug, and Cosmetic Act, 87 FR 4240 (January 27, 2022), available at https://www.govinfo.gov/content/pkg/FR-2022-01-27/pdf/2022-01558.pdf.

[6] For more information on the Pharmacy Compounding Advisory Committee meeting, visit https://www.fda.gov/advisory-committees/advisory-committee-calendar/june-8-2022-meeting-pharmacy-compounding-advisory-committee-meeting-announcement-06082022

practices. FDA also held its 11th intergovernmental meeting on drug compounding with state regulators.

In FY 2022, 85 entities registered as outsourcing facilities. Of these 85 facilities, 74 paid the non-small business establishment fee, 11 paid the small business establishment fee, and 4 submitted information to register but failed to pay the fee. Further, nine facilities withdrew their registration prior to the end of FY 2022. On the last day of FY 2022, 76 facilities were registered.

Table 1 shows the geographical locations of the firms registered as outsourcing facilities in FY 2022.

Table 1: Number of Firms Registered as Outsourcing Facilities During FY 2022 by Geographical Location

Geographical Location	States Included	Number of Registered Outsourcing Facilities
Northeast	Connecticut, Massachusetts, New Jersey, New York, Pennsylvania, Maryland, and Vermont	25
Southeast	Alabama, Arkansas, Florida, North Carolina, South Carolina, and Tennessee	21
Midwest	Kansas, Missouri, Minnesota, Illinois, Nebraska, Indiana, and Ohio	12
Southwest	Arizona, Arkansas, Oklahoma, and Texas	16
West	California, Colorado, Idaho, Nevada, and Washington	11
	Total	**85**

Outsourcing facilities vary widely in terms of scope of distribution and the types of products compounded. 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. For example, 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 2021 to FY 2022.

Table 2: Number of Entities That Registered and De-Registered as Outsourcing Facilities (as of September 30, 2022)

Fee Type	FY 2021	FY 2022
Registered and Remained Registered Through the End of the Fiscal Year	74	76
Registered But Then De-Registered	8	9

Financial Information

This section provides an overview of the program financials for CQA for the 2 most recent fiscal years. These financials include fee collections, obligations, carryover, and full-time equivalents (FTEs).

G. Fee Program Financials

Table 3 represents a summary of the CQA financial position as it relates to fee resources (i.e., collections and carryover). This table also provides an overview of the obligations for which the fee resources were used. The financial notes can be found in **Appendix B**.

Table 3: CQA Fee Collections, Obligations, and Carryover for FYs 2021 and 2022 (as of September 30, 2022)

Budgetary Resources	Notes	FY 2021	FY 2022
Total Carryover, Beginning of Year		$235,104	$227,922
Net Collections		$1,433,751	$1,665,351
Recoveries	Note 1	$0	$317
Total Budgetary Resources		**$1,668,855**	**$1,893,589**

Obligations	Notes	FY 2021	FY 2022
Total Payroll & Operating	Note 2	$1,406,184	$1,388,689
Total Rent	Note 3	$34,749	$35,096
Total Shared Services	Note 4	$0	$0
Total Obligations		**$1,440,933**	**$1,423,785**

Carryover	Notes	FY 2021	FY 2022
Total Carryover, End of Year		**$227,922**	**$469,804**

Numbers have been rounded to the nearest dollar.

Budgetary Resources: The "Budgetary Resources" component of **Table 3** is the sum of available fee funding (i.e., the existing available carryover balance and additional fee collections) that will be used to fund obligations. The "Cash Collections" component is the actual amount collected during the fiscal year, net of any refunds that have taken place.

CQA specifies how the fees must be calculated each fiscal year, including any annual inflation and small business adjustment factors.

Obligations: The "Obligations" component of **Table 3** shows the annual expenditure of CQA fees broken out into major expense categories. Per section 744K of the FD&C Act, CQA fees can only be used "to pay for the costs of oversight of outsourcing facilities."

Carryover: CQA fees are available until expended. This means the fees that are collected, appropriated, and not obligated at the end of the fiscal year remain available to FDA for use in future fiscal years. The unobligated CQA fees at the end of each fiscal year are referred to as the "carryover balance." Maintaining an appropriate level of carryover enables FDA to mitigate financial risks to the program, including, for example, the risk of collecting less fees than estimated for a fiscal year and the risk of a lapse in appropriations.

H. 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 inflation adjustment utilized in FY 2022 was 1.164796 percent.

- **Small Business Adjustment Factor:** This adjustment takes into account 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 2022 was $1,527.

Table 4 provides the annual collections by fee type.

Table 4: CQA Fee Collections by Fee Type for FYs 2021 and 2022 (as of September 30, 2022)

Fee Collected	FY 2021	FY 2022
Non-Small Business Establishment Fees	$1,262,079	$1,405,926
Small Business Establishment Fees	$56,950	$64,064
Reinspection Fees	$136,680	$157,248
Total Cash Collections	**$1,455,709**	**$1,627,238**

Fees Receivable	FY 2021	FY 2022
Non-Small Business Establishment Fees	$0	$0
Small Business Establishment Fees	$0	$0
Reinspection Fees	$17,085	$17,472
Total Fees Receivable	**$17,085**	**$17,472**

Numbers have been rounded to the nearest whole dollar.

The number of reinspection fees collected increased from FY 2021 to FY 2022 as restrictions due to the COVID-19 public health emergency were lifted. Outsourcing facility inspections were funded by outsourcing facility fees and FDA's BA appropriations.

I. Fee Obligations

Table 5 provides a breakout of fee obligations by expense category. The financial notes can be found in **Appendix B**.

Table 5: CQA Fee Obligations by Expense Category for FY 2021 and FY 2022

User Fee Obligations	Notes	FY 2021	FY 2022
Payroll & Operating	Note 2		
CDER		$900,753	$820,464
ORA		$505,432	$537,016
HQ		$0	$31,209
Total Rent	Note 3	$34,749	$35,096
Total Shared Services	Note 4	$0	$0
Total Obligations		**$1,440,933**	**$1,423,785**

Numbers have been rounded to the nearest whole dollar.

Total obligations include payroll and operating, rent, and shared services costs. The details of each component are as follows:

- **Payroll and Operating:** 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.

- **Rent:** This is paid to the General Services Administration for the federal buildings that FDA occupies, as well as to non-federal sources for direct leases and services. Rent is charged at different rates depending on the type and location of the space provided.

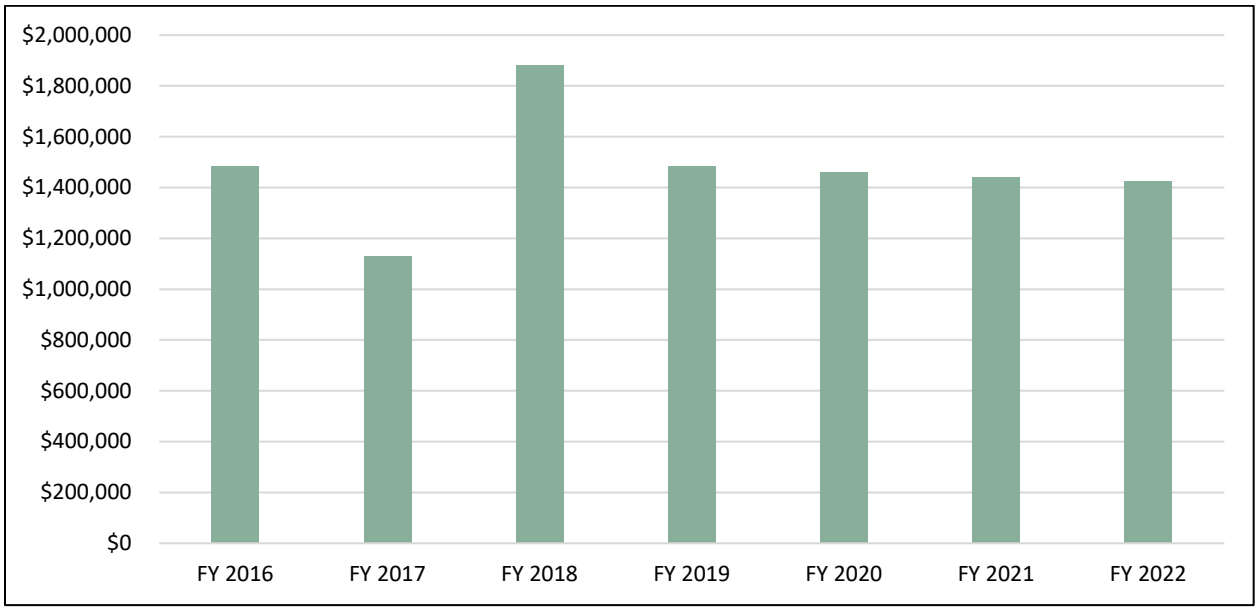
- **Shared Services:** FDA has several shared service organizations that provide support across various fee programs, such as human resources and information technology (IT).

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. During the COVID-19 public health emergency, this oversight also included performing remote regulatory assessments of eight outsourcing facilities.

In FY 2022, 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, perform inspections to the extent possible in light of the COVID-19 pandemic, and conduct regulatory oversight to promote compliance with CGMP standards and other requirements for outsourcing facilities, as well as take enforcement actions when appropriate.

Exhibit 3 displays FDA's level of spending to support the staff and activities related to the oversight of outsourcing facilities.

Exhibit 3: Historical CQA Fee Obligations by Fiscal Year



J. 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 "fee carryover."[7]

The net change in carryover balance each fiscal year is equal to cash collections minus net obligations. This is demonstrated best in **Table 3** above.

Table 6 provides CQA carryover balances for the 6 most recent fiscal years. The financial notes can be found in **Appendix B**.

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

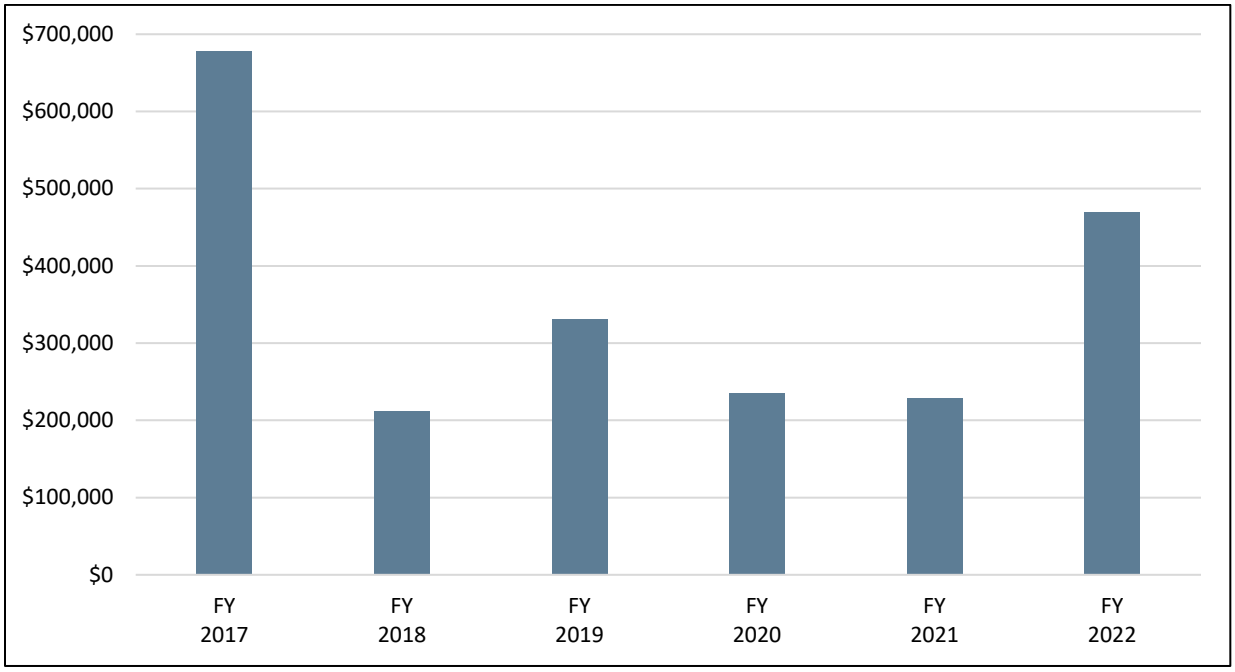
Table 6: Historical CQA Fee Collections, Obligations, and Carryover Balances by Fiscal Year

	Notes	FY 2017	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Total Carryover, Beginning of Year		$342,593	$678,186	$211,527	$330,150	$235,104	$227,922
Net Collections		$1,465,529	$1,415,523	$1,600,982	$1,363,839	$1,433,751	$1,665,351
Recoveries	Note 1	$392	$828	$2,839	$315	$0	$317
Obligations		($1,130,328)	($1,883,011)	($1,485,197)	($1,459,200)	($1,440,933)	($1,423,785)
Total Carryover, End of Year		**$678,186**	**$211,527**	**$330,150**	**$235,104**	**$227,922**	**$469,804**

Numbers have been rounded to the nearest whole dollar.

Exhibit 4 provides a historical perspective of FDA's CQA carryover for the last 6 fiscal years. FDA implemented strategies to minimize the amount of carryover while maintaining oversight of outsourcing facilities. FDA intends to utilize these carryover funds as well as new fees collected to further support its oversight of outsourcing facilities.

Exhibit 4: Historical CQA Fee Carryover by Fiscal Year



K. Full-Time Equivalents

"FTE employment" (often referred to as "staff year"), as defined by the Office of Management and Budget (OMB) Circular A-11, section 85, reflects 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 2022, FDA’s outsourcing facility fees supported approximately four CDER FTEs and four ORA FTEs. This is a small fraction of the full level of effort required to support FDA’s oversight of outsourcing facilities during FY 2022.

Table 7 presents total fee-paid FTE levels that supported outsourcing facility oversight by FDA organizational components for the past 6 fiscal years. The table displays data for CDER, ORA, and HQ.

Table 7: Historical Trend of FTEs Supported by CQA Fees (as of September 30 of Each Fiscal Year)

Organization	FY 2017	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
CDER	4	8	6	6	5	4
ORA	3	4	3	3	4	4
HQ	0	0	0	0	0	0
Total FTEs	**7**	**12**	**9**	**9**	**8**	**8**

All numbers in Table 7 have been rounded to the nearest whole FTE.

Exhibit 5 provides the historical trend of fee-paid FTE distribution levels across FDA organizations for the past 6 years.

Exhibit 5: Historical CQA Fee-Paid FTE Levels by FDA Organization

L. 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 2022, FDA conducted 27 inspections of outsourcing facilities. Of these 27 inspections, 11 were "reinspections" as defined in CQA. As of September 30, 2022, FDA had collected nine reinspection fees for FY 2022. FDA is pending the collection of one reinspection fee for FY 2022, and one reinspection fee for FY 2021. In addition, one FY 2022 reinspection will be invoiced in FY 2023.

Table 8 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 8: Outsourcing Facility Inspection Summary by Type During FYs 2021 and 2022
(as of September 30, 2022)

Inspection Type	FY 2021	FY 2022
503B Inspections	11	16
503B Reinspections	9	11
Total Inspections	**20**	**27**

The number of inspections and reinspections increased from FY 2021 to FY 2022 as restrictions due to the COVID-19 public health emergency were lifted. Outsourcing facility inspections were funded by outsourcing facility fees and FDA's BA appropriations.

Management Assurance

M. Internal Controls

The Federal Managers' Financial Integrity Act of 1982 (FMFIA) is intended to strengthen internal controls and accounting systems. OMB Circular A-123, Management's Responsibility for Enterprise Risk Management and Internal Control, implements the FMFIA requirements. FMFIA requires that management establish and maintain effective internal control to achieve the following objectives:

1. Effective and efficient operations,
2. Reliable reporting, and
3. Compliance with applicable laws and regulations.

The Department of Health and Human Services (HHS) provides guidance to its operating divisions (OpDivs) to implement FMFIA through its FMFIA Guidelines. OpDivs, including FDA, are responsible for developing and maintaining internal control and compliance programs that include programmatic and operational controls, as well as reporting controls to support sound financial management. The Government Accountability Office's Standards for Internal Control in the Federal Government (Green Book) states: "Management is responsible for an effective internal control system. As part of this responsibility, management sets the entity's objectives, implements controls, and evaluates the internal control system." OMB Circular A-123 requires an annual internal control assessment, and FMFIA requires the head of each executive agency to report annually on the effectiveness of the internal controls and any identified material weaknesses in those controls.

In alignment with FMFIA, OMB Circular A-123, OMB Circular A-11, the Green Book, and HHS guidelines, FDA established an Enterprise Risk Management (ERM) Program, with an ERM Council as the governance body responsible for providing overall oversight and accountability. The Council's purview includes deciding on and managing the Agency's Enterprise Risk Profile and ensuring integration with FDA's FMFIA, budget formulation, and strategic planning activities. The ERM Council has senior executive representatives from each FDA Center and Office, and is chaired by the Chief Operating Officer, with a Center Director as Co-Chair and Chief Financial Officer (CFO) as President Pro Tempore. FDA's ERM Program supports the Council in managing the Agency's Enterprise Risk Profile, facilitates risk response planning, collaborates with Center and Office senior leaders and staff in conducting a range of analyses to manage risks, and provides communications and training opportunities that promote a risk-informed culture.

Additionally, FDA has an established Senior Assessment Team (SAT) to act as the governance body responsible for providing oversight and accountability for FDA's internal control over reporting, including overseeing the FMFIA and OMB Circular A-123 assessments, and for fostering an environment that promotes strong internal controls and reduces the risk of fraud, waste, and abuse. The SAT is chaired by FDA's CFO and co-chaired by the Deputy CFO and Director of the Office of Financial Management,

as well as a Program Co-Chair who is a Center Deputy Executive Officer appointed by the CFO. The SAT members are representatives from each FDA Center and Office.

FDA's internal control program includes integrated management controls covering the OMB A-123 appendices. Specifically:

1. Reporting controls to include business and IT controls are implemented in accordance with Appendix A, Management of Reporting and Data Integrity Risk;

2. Charge card controls are implemented in accordance with Appendix B, A Risk Management Framework for Government Charge Card Programs;

3. Controls over financial disbursements are implemented in accordance with Appendix C, Requirements for Payment Integrity Improvement; and

4. Financial system controls are implemented in accordance with Appendix D, Compliance with the Federal Financial Management Improvement Act of 1996.

In FY 2022, FDA's annual assessment of internal controls included tests of 95 business and IT controls across 14 major transaction cycles and 27 transaction sub-cycles to identify recommendations to strengthen internal controls and compliance. This assessment included 36 IT controls related to the User Fee System. Further, FDA has enhanced its integration with HHS to include a focus on IT controls, align with HHS's standardized IT controls guidance, and overall collaborate with HHS (Appendices A and B).

Annually, FDA conducts an improper payments risk assessment and performs improper payment testing to assess financial disbursements. In FY 2022, FDA completed the FDA FY 2022 Improper Payments risk assessment to identify FDA Programs that were susceptible to significant improper payments. The FDA Programs—FDA User Fees (Non-General Fund), Animal Drugs and Feed, FDA Other Activities (FDA Headquarters), Payment to FDA Innovation Account, National Center for Toxicological Research, Coronavirus Emergency Funding Supplemental and FDA Buildings and Facilities—were deemed to not be susceptible to significant improper payments. The Biologics and Devices & Radiological Health programs were selected for transactional testing (Appendix C).

The Unified Financial Management System FDA-set-of-books and the User Fee System are compliant with HHS guidelines and with OMB Circular A-123, Appendix D, Compliance with the Federal Financial Management Improvement Act of 1996 (Appendix D).

FDA has also implemented other internal control procedures, including the performance of Organizational Risk Reviews, which are reviews of targeted financial and non-financial management processes to identify potential recommendations to enhance internal controls. Also, FDA maintains a Continuous Monitoring Program to oversee the timely implementation of corrective action plans for any deficiencies identified through any of its control assessments.

As a component of HHS, FDA's financial data is presented in HHS's consolidated financial statements. The FY 2022 HHS audit found that FDA's financial statements fairly present, in all material respects, the consolidated financial position of HHS as of September 30, 2021, and September 30, 2022, and related notes are in accordance with generally accepted accounting principles in the United States. Further, FDA's FY 2022 Assurance Statement found no material weaknesses or financial system nonconformances.

N. Financial Risks and Mitigation

As is the case with all financial programs, there are certain financial risks and challenges that exist with FDA's fee programs. These risks and challenges can vary from program to program, with some being in FDA's control and some out of FDA's control. Below is a list of foreseeable risks associated with the collections and obligations of funds for which FDA has identified contingency plans in order to move forward in the best interest of the program.

- **Under-Executing Planned Spending:** Historically, CQA budgetary resources have been under-spent because of the uncertainty of collections and difficulties with hiring. To minimize this risk, FDA is enhancing its planning and execution around the hiring of new staff and contract actions. By putting more emphasis on the initial planning of initiatives, FDA predicts that there will be less variance between planned allocations and actual expenditures than FDA has experienced in the past.

- **Uncertainty of Budget Authority Appropriations Levels:** It is difficult to predict the amount of BA appropriations that will be approved by Congress, which creates planning challenges because BA funding levels are often uncertain much of the fiscal year. With Continuing Resolutions (CR) becoming more prevalent, FDA has been required to spend at or slightly below levels from the prior authorized fiscal year during the CR period, thus limiting its ability to spend, at the outset, the BA appropriations.

- **Lapse in Budget Authority Appropriations:** FDA is maintaining a certain level of carryover, which can be used to preserve program operations for a limited time in the event of a government shutdown.

In addition to these mitigation strategies, FDA implemented IBAPS to enable greater and more timely insight into budget activity across the Agency. IBAPS improves the accuracy and availability of budget and acquisition information that enables FDA to better plan, forecast, track, and analyze the data to make better informed decisions about the best use of its resources.

Appendices

A. Reporting Requirements

CQA requires FDA to submit an annual report to Congress that includes:

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

B. Financial Notes

Note 1. Recoveries

Recoveries account for funds returned to the Agency in the form of deobligations of prior year obligations. For example, recoveries could include funding from a contract that ended in a prior year and was not expended.

Note 2. Payroll and Operating Costs

For payroll, employees are required to report their time in an activity-based reporting system, which allows FDA to identify activities that fees can be used to support. For operating activities (e.g., contracting services), funds are allocated based on the proportion to which those activities support the CQA program. If an operating activity solely supports CQA, it will be fully funded by the program. If the operating activity is shared, CQA will fund the activity in proportion to how it is used by the program as compared to other programs.

Note 3. 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. Because rent is an essential support cost for the oversight of outsourcing facilities, a portion of those charges is paid from BA appropriations and a portion is paid from CQA fees. Also included in this account are recurring costs that FDA pays directly to non-federal sources under the delegation of direct lease and service authority. These services include rental of space, as well as all recurring services for building operations such as overtime utilities, janitorial services, guards, and ground maintenance. The amount of rent and rent-related costs each Center pays is directly related to the square footage occupied by that Center.

Note 4. Shared Service Costs

FDA has several shared service organizations, located with the Working Capital Fund, that provide support across the user fee programs. The shared service organizations in FY 2022 include:

- **FDA Central**: Provides for Center-wide and Agency-wide services such as telecommunications, training, printing, mail and document management, IT systems, employee health units, and other support and miscellaneous services.
- **Employee Resource & Information Center**: Provides support to all FDA employees requesting administrative, IT, facilities, human resources, and other employee services.
- **Office of Acquisitions and Grants Services**: Manages contracts, grants, and other agreements.
- **Office of Equal Employment Opportunity**: Promotes an inclusive work environment that ensures equal employment opportunity and fosters a culture that values diversity and empowers individuals.
- **Office of Facilities, Engineering, and Mission Support Services**: Provides FDA employees with office and laboratory facilities.
- **Office of Financial Management:** Provides financial managerial services and policy guidance.
- **Office of Information Management and Technology**: Provides the information, communication, and knowledge infrastructure and services that enhance, transform, and sustain the ability of FDA to protect and promote public health.
- **Division of Budget Execution and Control:** Initiates, monitors, and analyzes FDA's budget resources. The Agency's budget is comprised of several appropriation accounts, including Salaries and Expenses, Revolving Fund for Color Certification and other Services, Cooperative Research and Development Agreement, Contingency Fund, Building and Facilities, and Royalties.
- **Office of Finance, Budget, Acquisitions, and Planning:** Leads FDA's budget, acquisitions, and financial management functions while ensuring the financial integrity of FDA's resources.
- **Office of Security 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. 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 Laboratory Safety:** Reinforces FDA's expectations for safety and laboratory security, enhances communications among FDA's safety staff, and provides program support.
- **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 Enterprise Management Services:** Provides strategic and tactical enterprise-wide services through the development and implementation of administrative policies, programs, and initiatives.

- **Office of Human Capital Management:** Provides human resource services that promote collaboration and a work environment that is characterized by diversity, fairness, open communication, personal accountability, trust, and mutual respect.
- **Office of Talent Solutions:** Provides high-quality and efficient human resource solutions that enable FDA to hire a talented and qualified workforce.
- **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.

This report was prepared by FDA's Office of Financial Management.
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