FY 2019 COMPOUNDING QUALITY ANNUAL REPORT

REQUIRED BY THE

COMPOUNDING QUALITY ACT

FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Executive Summary

In November 2013, the President signed into law the Drug Quality and Security Act (DQSA), Public Law 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 the 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 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) 2019.

In FY 2019, 80 entities registered as outsourcing facilities. Four facilities that were initially registered as outsourcing facilities in FY 2019 withdrew their registration before the end of the fiscal year. On the last day of FY 2019, 76 facilities were registered.

In FY 2019, FDA spending to support its oversight of outsourcing facilities totaled $28,182,345. This amount not only included budget authority and outsourcing facility fees but also supported full-time equivalents (FTEs) across FDA. In particular, the outsourcing facility fees supported nine FTEs in FY 2019 out of the 66 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 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 cash collections of $1,600,982 in outsourcing facility fees during FY 2019. In addition, FDA had a carryover balance of $211,527 and $2,839 in recoveries from the prior fiscal year. Of the total amount of outsourcing facility fees available in FY 2019 ($1,815,348), FDA spent $1,485,197 to support its oversight of outsourcing facilities in FY 2019 (which is 5 percent of its total spending for this purpose) and carried forward a balance of $330,150 to pay for the costs of its oversight of outsourcing facilities in future fiscal years. 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 2020, 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 the Agency's) assessment and use of fees collected from human drug compounders registered with FDA as outsourcing facilities during the period of October 1, 2018, through September 30, 2019.

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., by 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 (1) by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices and (2) 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. FDA helps to speed innovations that make medical products more effective, safe, and affordable and helps the public get 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 development of medical products to respond to deliberate and naturally emerging public health threats.

Program Organization

There are three major components that support the Compounding Quality Act (CQA) program: The Center for Drug Evaluation and Research (CDER), the Office of Regulatory Affairs (ORA), and FDA 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 the public's 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 the public's health by maximizing the compliance of FDA-regulated products and by 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 drug compounding oversight activities to help ensure the quality of compounded drugs available to the American public. The CQA fee structure is outlined in **Exhibit 2**.

Exhibit 2: CQA Fee Structure

Fee Type		Definition
Annual Establishment	*Non-small Business*	Assessed annually to entities that elect to register or re-register with FDA as outsourcing facilities. Each year, the registration period for outsourcing facilities begins on October 1 and ends on December 31. 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	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		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]

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."

F. Performance Summary

FDA issued several major policy documents in FY 2019 applicable to outsourcing facilities, as outlined in the Agency's 2019 Compounding Policy Priorities Plan, including a final guidance on the evaluation of bulk drug substances nominated for use in compounding under section 503B of the FD&C Act and a *Federal Register* notice identifying two bulk drug substances that FDA considered and did not include on the 503B Bulks List. FDA also issued a *Federal Register* notice proposing, for public comment, that nine bulk drug substances not be included on the 503B Bulks List. In addition, FDA issued a revised draft guidance concerning current good manufacturing practice requirements for outsourcing facilities, and FDA issued a final rule to amend the list of drug products that cannot be compounded under the exemptions provided by section 503A and section 503B of the FD&C Act because they have been withdrawn or removed from the market for a safety or effectiveness reason.[2]

In FY 2019, 80 entities registered as outsourcing facilities. Of these 80 facilities, 70 paid the non-small business establishment fee, and 10 paid the small business establishment fee. Four facilities that were initially registered as outsourcing facilities in FY 2019 withdrew their registration before the end of the fiscal year. On the last day of FY 2019, 76 facilities were registered.

Table 1: Number of Firms Registered as Outsourcing Facilities During FY 2019 by Geographical Location

Geographical Location	States Included	Number of Registered Outsourcing Facilities
Northeast	Connecticut, Massachusetts, New Jersey, New York, Pennsylvania, and Vermont	21
Southeast	Alabama, Arkansas, Florida, Mississippi, North Carolina, South Carolina, and Tennessee	23
Midwest	Kansas, Missouri, and Ohio	6
Southwest	Arizona, Oklahoma, and Texas	14
West	California, Colorado, Idaho, Nevada, and Utah	12
Total		**76**

Table 1 shows the geographical locations of the firms registered as outsourcing facilities in FY 2019. 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 pursuant to prescriptions for identified individual patients. Other outsourcing facilities operate

[1] CQA user fee rates for fiscal year (FY) 2019 and FY 2020 are available at https://www.fda.gov/industry/fda-user-fee-programs/human-drug-compounding-outsourcing-facility-fees.
[2] For more information on FDA's compounding policy documents, visit https://www.fda.gov/drugs/human-drug-compounding/regulatory-policy-information.

on a larger scale, distributing drug products without prescriptions to health care facilities nationwide, and some distribute drugs both with and without prescriptions. 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 2018 to FY 2019.

Table 2: Number of Entities Registered and De-Registered as Outsourcing Facilities as of September 30, 2019

Fee Type	FY 2018	FY 2019
Registered and Remained Registered Through the End of the Fiscal Year	74	76
Registered but then De-Registered	2	4

Financial Information

This section provides an overview of the program financials for CQA for the two 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 as of September 30, 2019

Budgetary Resources	Notes	FY 2018	FY 2019
Total Carryover, Beginning of Year		$678,186	$211,527
Cash Collections		$1,415,523	$1,600,982
Recoveries	Note 1	$828	$2,839
Total Budgetary Resources		**$2,094,538**	**$1,815,348**

Obligations	Notes	FY 2018	FY 2019
Total Payroll and Operating	Note 2	$1,786,047	$1,451,134
Total Rent	Note 3	$33,727	$34,063
Total Shared Services	Note 4	$63,237	$0
Total Obligations		**$1,883,011**	**$1,485,197**

Carryover	Notes	FY 2018	FY 2019
Total Carryover, End of Year		**$211,527**	**$330,150**

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.

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 operating expenses by changes in the Consumer Price Index (CPI), and payroll-related expenses by changes in FDA's average personnel compensation and benefits amounts.

  The inflation adjustment utilized in FY 2019 was 1.092148 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 equaling the amount that FDA would have collected if no entity qualified for the small business reduction.

  The small business adjustment amount in FY 2019 was $1,993.

Table 4 provides the annual collections by fee type.

Table 4: CQA Fee Collections by Fee Type for FY 2018 and FY 2019 as of September 30, 2019

Fees Collected	FY 2018	FY 2019
Non-Small Business Establishment Fee	$1,180,752	$1,286,250
Small Business Establishment Fee	$42,912	$54,610
Reinspection Fees	$209,209	$163,820
Total Cash Collections	**$1,432,873**	**$1,504,680**

Fees Receivable	FY 2018	FY 2019
Non-Small Business Establishment Fee	$0	$0
Small Business Establishment Fee	$0	$0
Reinspection Fees	$0	$0
Total Fees Receivable	**$0**	**$0**

Numbers have been rounded to the nearest dollar.

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 2018 and FY 2019

Obligations	Notes	FY 2018	FY 2019
Payroll & Operating	Note 2		
CDER		$1,315,577	$1,060,391
ORA		$470,471	$390,743
HQ		$0	$0
Total Rent	Note 3	$33,727	$34,063
Total Shared Services	Note 4	$63,237	$0
Total Obligations		**$1,883,011**	**$1,485,197**

Numbers have been rounded to the nearest dollar.

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

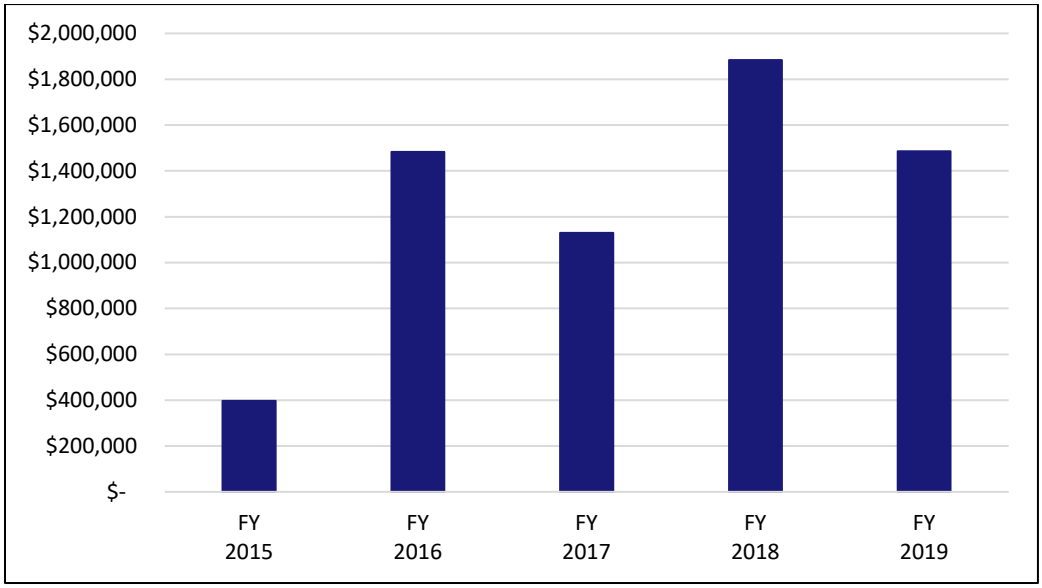
- **Payroll and Operating:** These obligations provide for all payroll and operating costs that support oversight of outsourcing facilities. Payroll and operating includes, for example, core regulatory review functions, inspections, guidance and policy development activities, scientific activities, and management and administrative functions that support the CQA program.
- **Rent:** This is paid to the General Services Administration (GSA) 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.

In FY 2019, FDA used available fee revenue to implement the regulatory framework, conduct stakeholder outreach with currently registered outsourcing facilities and compounders interested in registering as outsourcing facilities, perform inspections, and conduct regulatory oversight, including taking enforcement actions when appropriate.

Exhibit 3 displays FDA's level of spending to support the staff who and the activities that oversee the Agency's 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."

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 5 most recent fiscal years. The financial notes can be found in **Appendix B**.

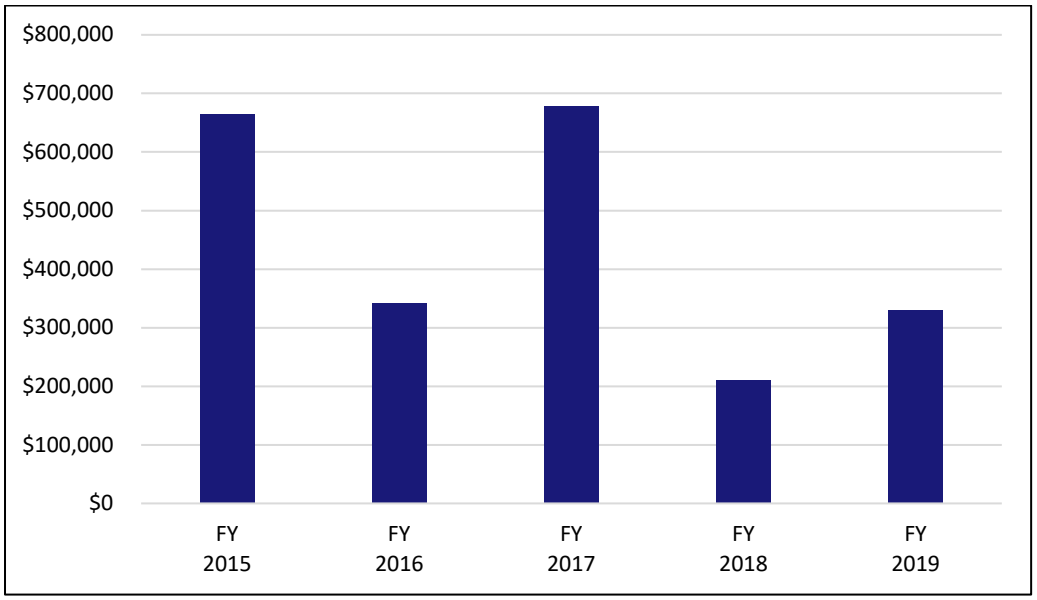
Table 6: Historical CQA Fee Collections, Obligations, and Carryover Balances by Fiscal Year

Carryover	Notes	FY 2015	FY 2016	FY 2017	FY 2018	FY 2019
Total Carryover, Beginning of Year		**$0**	**$663,958**	**$342,593**	**$678,186**	**$211,527**
Cash Collections		$1,060,226	$1,161,546	$1,465,529	$1,415,523	$1,600,982
Recoveries	Note 1	$0	$0	$392	$828	$2,839
Total Obligations		($396,268)	($1,482,911)	($1,130,328)	($1,883,011)	($1,485,197)
Total Carryover, End of Year		**$663,958**	**$342,593**	**$678,186**	**$211,527**	**$330,150**

Numbers have been rounded to the nearest dollar.

Exhibit 4 provides a historical perspective of FDA's CQA carryover for the last 5 fiscal years. FDA implemented mitigation strategies to manage the carryover balance and further support oversight of outsourcing facilities. The delayed FY 2019 appropriation deferred FDA's access to FY 2019 CQA fees and contributed to the increased carryover amount for the fiscal year. 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," as defined by Office of Management and Budget (OMB) Circular A-11, section 85, 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 2019, FDA's outsourcing facility fees supported six CDER FTEs and three ORA FTEs. This is a small fraction of the full level of effort required to support FDA's oversight of outsourcing facilities during FY 2019.

Table 7 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, ORA, and HQ.

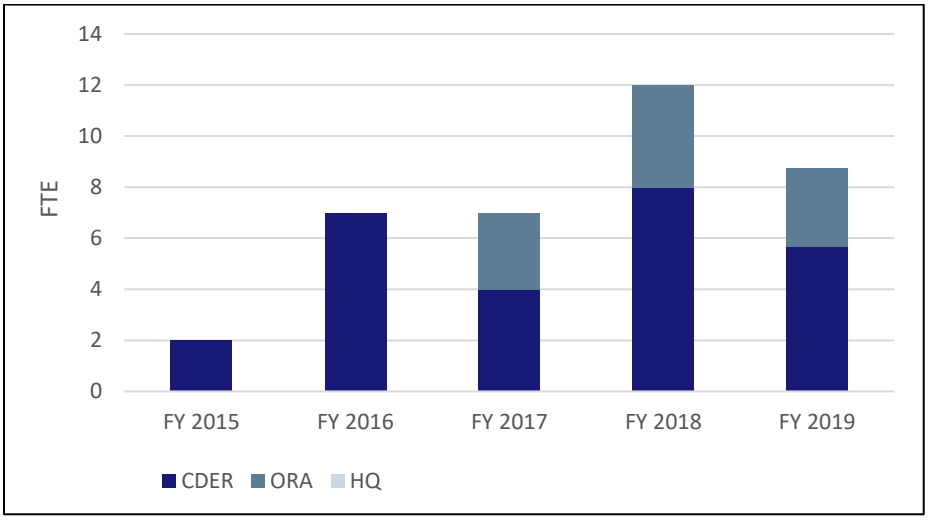
Table 7: Historical Trend of FTEs Supported by CQA Fees as of September 30 of Each Fiscal Year

Organization	FY 2015	FY 2016	FY 2017	FY 2018	FY 2019
CDER	2	7	4	8	6
ORA	0	0	3	4	3
HQ	0	0	0	0	0
Total FTEs	**2**	**7**	**7**	**12**	**9**

Numbers have been rounded to the nearest FTE.

Exhibit 5 provides the historical trend of fee-paid FTE distribution and levels across FDA organizations for the past 5 years. There has been an upward trend in FTE levels because of the need for staff to support FDA's oversight of outsourcing facilities.

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

> (O)ne 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 2019, FDA conducted 29 inspections of outsourcing facilities. Of these 29 inspections, 11 were "reinspections" as defined in CQA. As of September 30, 2019, FDA collected 10 reinspection fees and is pending the collection of one reinspection fee.

Table 8 provides a summary of outsourcing facility inspections and reinspections for the 2 most recent fiscal years.

Table 8: Outsourcing Facility Inspection Summary by Type as of September 30, 2019

Inspection Type	FY 2018	FY 2019
503B Inspections	25	18
503B Reinspections	15	11
Total Inspections	**40**	**29**

The number of inspections and reinspections decreased from FY 2018 to FY 2019, as FDA sought to increase engagement through regulatory meetings and enforcement actions. Outsourcing facility inspections were funded by outsourcing facility fees and BA.

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 Internal Control and Enterprise Risk Management (OMB A-123), implements the requirements of the FMFIA. The FMFIA requires that management establish and maintain effective internal control to achieve the following objectives:

1. Effective and efficient operations,
2. Reliable financial 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 a cost-effective internal control and compliance program that includes programmatic and operational controls, as well as controls over financial reporting, and supports sound financial management. The Government Accountability Office 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 A-123 requires an annual internal control assessment, and FMFIA requires the head of each executive agency to report annually to the President and Congress on the effectiveness of the internal controls and any identified material weaknesses in those controls. FDA's FY 2019 Assurance Statement, already submitted to HHS, found no material weaknesses or financial system nonconformances.

Additionally, FDA has established a Senior Assessment Team (SAT) as the governance body responsible for providing oversight and accountability for FDA's internal control over financial reporting, including overseeing the FMFIA and OMB A-123 assessments, and for fostering an environment that promotes strong internal control. The SAT is chaired by the FDA Chief Financial Officer (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 appointed by the CFO. The SAT members are representatives from each FDA Center and Office.

In accordance with FMFIA, OMB A-123, the Green Book, and HHS guidelines, FDA has a robust internal control program, including integrated controls throughout processes. The Agency also conducts an annual assessment of its internal control activities as well as operational risk reviews. In addition, FDA has an Enterprise Risk Management (ERM) Program, which began in earnest in FY 2016 and is integrated with FDA's FMFIA efforts. Under the ERM Program, FDA has refreshed the enterprise risk profile and facilitated risk response planning for five priority enterprise risks. To accomplish this, Centers and Offices have engaged through senior leadership interviews, as well as working groups and problem-solving sessions. Further, FDA has established an ERM Community of Practice and continues to align and integrate core ERM methodologies with those of internal controls. FDA's ERM Program has facilitated cross-Center and Office collaboration to identify and manage risks. This program is governed by the ERM Council, which is chaired by the Chief Operating Officer and the CDER Deputy Director for Operations.

FDA's internal control program includes an evaluation of controls over reporting, charge card compliance, improper payments, and financial systems compliance. One of the cycle memos included in the assessment scope includes internal controls over reporting for the reimbursable activity process, specifically focused on the Accounts Receivable and Payment process associated with the user fee programs. This includes controls over reconciliation performance, aging, write-offs, and the interface between the User Fee System and the Unified Financial Management System. As an FDA-owned system, FDA's User Fee System is compliant with HHS requirements and requirements of the Federal Financial Management Improvement Act (FFMIA) of 1996. In addition, FDA's Integrated Budget and Acquisition Planning System (IBAPS) meets FDA and HHS system requirements.

FDA is also a participant in the annual audit of the consolidated financial statements of HHS, including the consolidated balance sheet, the related consolidated statement of net costs and changes in net position, the combined statement of budgetary resources, and the related notes to the financial statements. The FY 2019 audit found that the financial statements fairly present, in all material respects, the consolidated financial position of HHS as of September 30, 2019, and 2018, and its consolidated net cost, changes in net position, budgetary resources, and related notes are in accordance with generally accepted accounting principles in the United States.

FDA has also implemented other internal control procedures, including a continuous monitoring program to oversee the timely implementation of corrective action plans for deficiencies identified through any of its control assessments. This continuous monitoring program allows for management oversight of targeted remediation efforts and strengthening of internal controls. In addition, FDA offers annual internal control training sessions, which cover the importance of internal controls, timely deficiency remediation, and roles and responsibilities.

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 listing 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

GSA 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, and 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 number of employees that must be housed.

Note 4. Shared Service Costs

FDA contains several shared service organizations that provide support to FDA's oversight of outsourcing facilities. The shared service organizations 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.

- **Employee Safety & Environmental Management**: Provides safety, health, and environmental compliance for all FDA employees.
- **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 Human Resources**: Supports workforce relations, client services, executive resources, accountability programs, policy and program development, and systems data and management.
- **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 the public health.
- **Alternative Dispute Resolution:** Provides an alternative resource to existing administrative processes and assists in addressing work-related issues.
- **Division of Budget Execution and Control:** Initiates, monitors and analyzes FDA budget resources. The Agency 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.
- **Division 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.
- **Management Analysis Services Staff:** Provides organizational expertise and policy advice, as well as consultation and support to ensure an efficient Agency structure that delivers on the FDA mission.
- **Office of External Affairs – History:** Provides research, documentation, and preservation of significant FDA historical resources, as well as serving as historian for the Agency.
- **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 the public health by enhancing the safety and security of all personnel, facilities, and information.
- **Paperwork Reduction Act:** FDA's PRA staff acts as the liaison between FDA Centers, HHS, and OMB on all information collection matters.