FY 2018 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 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. 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 (the FD&C 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) 2018.

In FY 2018, a total of 76 entities registered as outsourcing facilities. Two facilities that were initially registered as outsourcing facilities in FY 2018 withdrew their registration before the end of the fiscal year. On the last day of FY 2018, 74 facilities were registered.

In FY 2018, FDA spending to support oversight of outsourcing facilities totaled $25,258,809. This included budget authority (BA) and outsourcing facility fees. These funds supported full-time equivalents (FTEs) across FDA. Outsourcing facility fees supported 12 FTEs in FY 2018 out of the total of 72 FTEs dedicated to oversight of outsourcing facilities. Oversight of outsourcing facilities includes activities conducted by the Center for Drug Evaluation and Research (CDER), the Office of Regulatory Affairs (ORA), and FDA Headquarters (HQ). This does not include the Center for Veterinary Medicine or the Center for Biologics Evaluation and Research, as CQA does not cover the compounding of animal drugs or biologics.

FDA had cash collections of $1,415,523 in outsourcing facility fees during FY 2018. In addition, FDA had a carryover balance of $678,186 from the prior fiscal year. Of the total amount of outsourcing facility fees available in FY 2018 ($2,094,538), FDA spent $1,883,011 to support oversight of outsourcing facilities in FY 2018 (7 percent of total spending for this purpose) and carried a balance of $211,527 forward to pay for the costs of 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 oversight of outsourcing facilities. FDA also will continue to ensure the fees supplement and do not supplant budget authority for oversight of outsourcing facilities.

In FY 2019, 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 contamination, 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 FDA's assessment and use of fees collected from human drug compounders registered with FDA as outsourcing facilities during the period of October 1, 2017, through September 30, 2018.

B. Report Requirements

In accordance with the FD&C Act, section 744K(h), FDA will submit an annual report to Congress on the assessment, collection, and the use of the fees collected for such 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). 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 public health by ensuring 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. FDA helps to speed innovations that make medical products more effective, safer, and more 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.

Program Organization

There are three major components that support the CQA program: CDER, ORA, 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 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 BA appropriations to support activities related to outsourcing facility oversight.

FDA spends CQA fee collections and BA appropriations to hire, support, and maintain personnel for drug compounding oversight activities to help ensure the quality of compounded drugs available to the American public. CQA's fee structure is outlined in **Exhibit 2**.

Exhibit 2: CQA Fee Structure

Fee Type		Definition
Annual Establishment	*Non-small business*	Assessed to entities that elect to register with FDA as outsourcing facilities. Each year, the registration period for outsourcing facilities begins on October 1st and ends on December 31st. The annual establishment fee is payable upon receipt of an invoice which will be sent after FDA has determined that the registration information submitted by the entity is complete.
	Small business	Assessed to entities that elect to register with FDA as outsourcing facilities and qualify for a small business reduction. Entities with gross annual sales totaling $1,000,000 or less in the 12 months ending on April 1st of the FY immediately preceding the FY 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 annual adjustments that must be made for inflation and small business. The fee amounts are to be published in the Federal Register each year, typically at the beginning of August (CQA Fee Rates Archive).

E. Legal Conditions

The FD&C Act, as amended by CQA, specifies that for fiscal year 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 2018 applicable to outsourcing facilities, as outlined in the Agency's 2018 Compounding Policy Priorities Plan, including a draft guidance on the evaluation of bulk drug substances nominated for use in compounding under section 503B, a Federal Register notice proposing that three bulk drug substances not be included on the 503B bulks list, a final guidance on compounded drug products that are essentially copies of approved drug products under

section 503B, a final guidance on the definition of "facility" under section 503B, and a revised draft guidance on insanitary conditions at compounding facilities.

As noted, in FY 2018, a total of 76 entities registered as outsourcing facilities. Of these 76 facilities, 68 paid the non-small business establishment fee, and 8 paid the small business establishment fee. Two facilities that were initially registered as outsourcing facilities in FY 2018 withdrew their registration before the end of the fiscal year. On the last day of FY 2018, 74 facilities were registered.

Table 1: Number of Firms Registered as Outsourcing Facilities during FY 2018 by Geographical Location

Geographical Location	States Included	Number of Registered Outsourcing Facilities
Northeast	Connecticut, Massachusetts, New Jersey, New York, Pennsylvania, and Vermont	19
Southeast	Alabama, Arkansas, Florida, Mississippi, North Carolina, South Carolina, and Tennessee	23
Midwest	Kansas, Missouri, and Ohio	7
Southwest	Arizona, Oklahoma, and Texas	14
West	California, Colorado, Idaho, Nevada, and Utah	13
Total		**76**

Table 1 shows the geographical locations of the firms registered as outsourcing facilities in FY 2018. Outsourcing facilities vary widely in terms of scope of distribution and the types of products compounded. Some distribute drugs primarily within the state in which they are located pursuant to prescriptions for identified individual patients. Others operate on a larger scale, distributing drug products without prescriptions to healthcare 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 5 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 to compound 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 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 2 most recent fiscal years. The total number of outsourcing facilities that remained registered increased from FY 2017 to FY 2018.

Table 2: Number of Entities Registered and De-Registered as Outsourcing Facilities as of September 30, 2018

Fee Type	FY 2017	FY 2018
Registered and remained registered through the end of the fiscal year	71	74
Registered but then de-registered	6	2

Financial Information

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

G. Fee Program Financials

Table 3 represents a summary of the CQA financial position, as it relates to fee resources (collections and carryover). This table also provides an overview of 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, 2018

Budgetary Resources	Notes	FY 2017	FY 2018
Total Carryover, Beginning of Year		$342,593	$678,186
Cash Collections		$1,465,529	$1,415,523
Recoveries	Note 1	$392	$828
Total Budgetary Resources		**$1,808,514**	**$2,094,538**

Obligations	Notes	FY 2017	FY 2018
Total Payroll and Operating	Note 2	$1,068,547	$1,786,047
Total Rent	Note 3	$0	$33,727
Total Shared Services	Note 4	$61,781	$63,237
Total Obligations		**$1,130,328**	**$1,883,011**

Carryover	Notes	FY 2017	FY 2018
Total Carryover, End of Year		**$678,186**	**$211,527**

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. "Cash collections" is the actual amount collected during the fiscal year.

CQA specifies how the fees must be calculated each fiscal year, including 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 FD&C Act section 744K, 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 statute. Fees are to be adjusted for the following factors:

- **Inflation Adjustment Factor:** The 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 2018 was 1.072835 percent.

- **Small Business Adjustment Factor:** The 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 FDA would have collected if no entity qualified for the small business reduction.

  The small business adjustment amount in FY 2018 was $1,271.

Table 4 provides the annual collections by fee type.

Table 4: CQA Fee Collections by Fee Type for FY 2017 and FY 2018

Fees Collected	FY 2017	FY 2018
Non-Small Business Establishment Fee	$1,196,492	$1,180,752
Small Business Establishment Fee	$31,674	$42,912
Reinspection Fees	$237,555	$128,744
Total Cash Collections	**$1,465,721**	**$1,352,408**

Fees Receivable	FY 2017	FY 2018
Non-Small Business Establishment Fee	$0	$0
Small Business Establishment Fee	$0	$0
Reinspection Fees	$15,837	$16,093
Total Fees Receivable	**$15,837**	**$16,093**

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 2017 and FY 2018

Obligations	Notes	FY 2017	FY 2018
Payroll & Operating	Note 2		
CDER		$702,497	$1,315,577
ORA		$366,050	$470,471
HQ		$0	$0
Total Rent	Note 3	$0	$33,727
Total Shared Services	Note 4	$61,781	$63,237
Total Obligations		**$1,130,328**	**$1,883,011**

Numbers have been rounded to the nearest dollar.

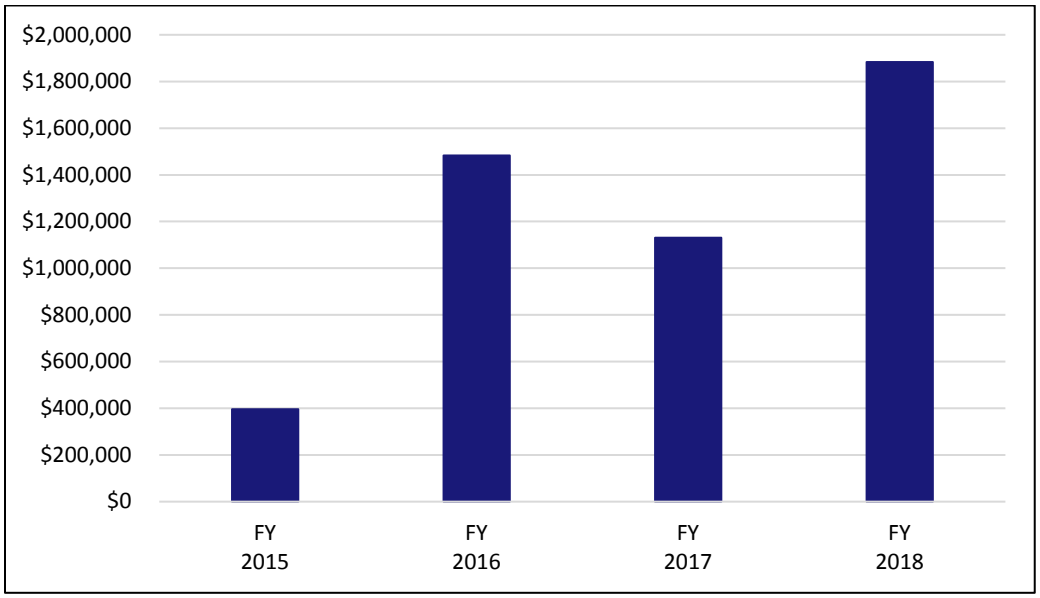
Total obligations include payroll and operating, rent, and shared services costs. The details of each component are as follows:

- **Payroll and Operating:** These obligations provide for all payroll and operating costs that support oversight of outsourcing facilities. This 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 IT.

CQA fees are used to support the costs of oversight of outsourcing facilities and represent a small portion of the 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 2018, 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 take enforcement actions. **Exhibit 3** displays FDA's increased level of spending, in FY 2018, to support the staff and activities to oversee outsourcing facilities.

Exhibit 3: Historic CQA Fee Obligations by Fiscal Year



J. Fee Carryover

CQA fees collected, appropriated, and not obligated at the end of the 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 4 most recent fiscal years. The financial notes can be found in **Appendix B**.

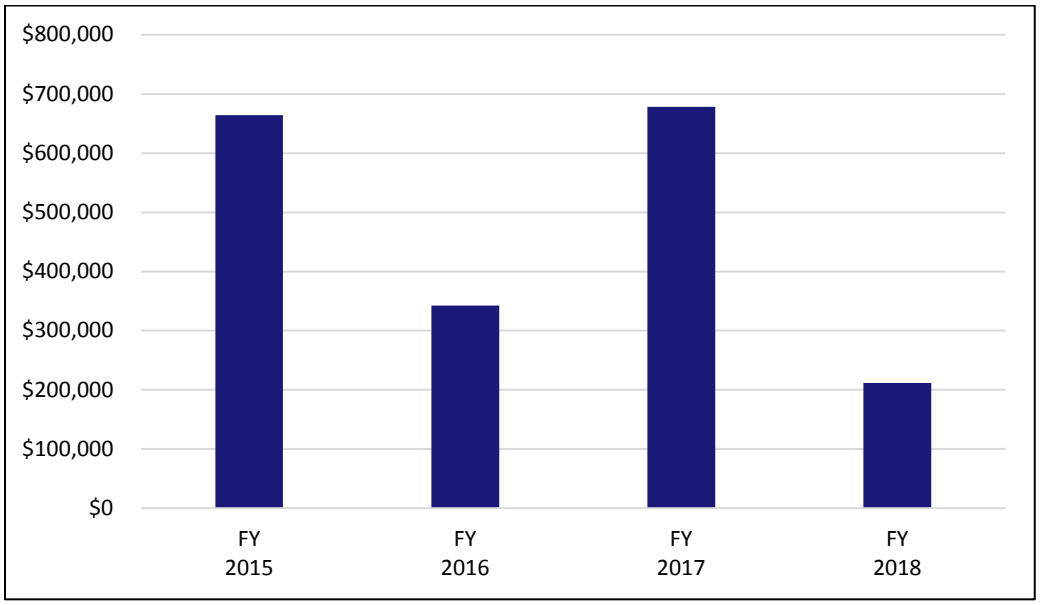
Table 6: Historic CQA Fee Collections, Obligations, and Carryover Balances by Fiscal Year

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

Numbers have been rounded to the nearest dollar.

Exhibit 4 provides a historical perspective of carryover for the last 4 fiscal years. In FY 2018, FDA implemented mitigation strategies to further support oversight of outsourcing facilities and manage the carryover balance. This resulted in a decrease in the carryover amount for this past fiscal year.

Exhibit 4: Historic CQA Fee Carryover by Fiscal Year



K. Full-Time Equivalents (FTEs)

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 2018, outsourcing facility fees supported eight CDER FTEs and four ORA FTEs. This is a small fraction of the full level of effort required to support oversight of outsourcing facilities during FY 2018.

Table 7 presents total fee-paid FTE levels that supported outsourcing facility oversight by FDA organizational components for the past 4 fiscal years. The table displays data for CDER, ORA, and HQ.

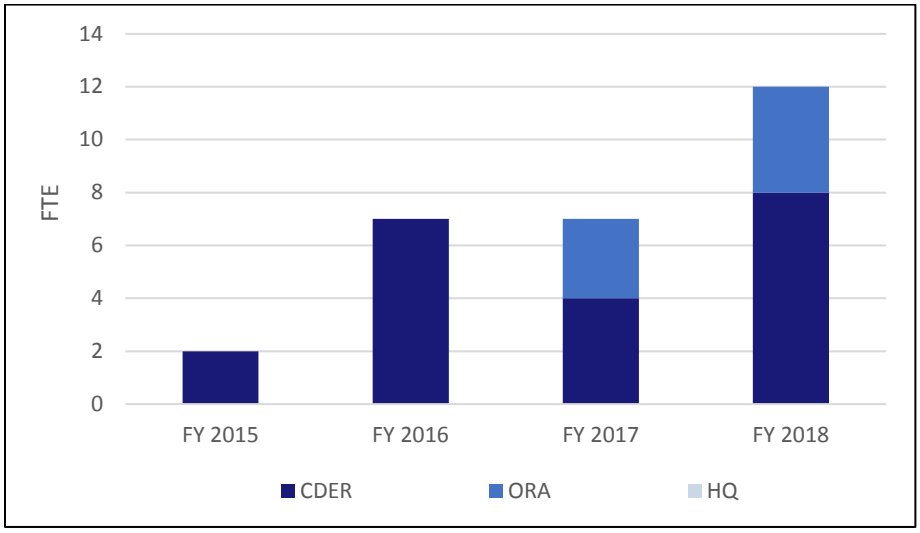
Table 7: Historic Trend of FTEs Supported by CQA Fees as of September 30 of Each Fiscal Year

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

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 4 years. There has been a steady, upward trend in terms of FTE levels due to the need for additional staff to support the oversight of outsourcing facilities.

Exhibit 5: Historic 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 law 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 2018, FDA conducted 40 inspections of outsourcing facilities. Of these inspections, 15 were reinspections as defined in CQA. As of September 30, 2018, FDA collected 8 reinspection fees and is pending collection of 1 reinspection fee. The remaining 6 reinspection fees will be invoiced in early FY 2019.

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, 2018

Inspection Type	FY 2017	FY 2018
503B Inspections	23	25
503B Reinspections	16	15
Total Inspections	**39**	**40**

The number of inspections increased from FY 2017 to FY 2018, as FDA sought to inspect a steadily increasing number of outsourcing facilities. The number of reinspections stayed relatively the same. Outsourcing facility inspections were funded by outsourcing facility fees and BA.

Management Assurance

M. Internal Controls

The Federal Managers' Financial Integrity Act (FMFIA) of 1982 is intended to strengthen internal controls and accounting systems. The Office of Management and Budget's Circular No. A-123, *Management's Responsibility for Internal Control and Enterprise Risk Management* (OMB A-123), implements the requirements of FMFIA. FMFIA requires that management establish and maintain effective internal control to achieve the objectives of:

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'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 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 2018 Assurance Statement already submitted to HHS, found no material weaknesses or financial system nonconformances.

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 to foster 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 Officer 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 the HHS Guidelines, FDA has a robust internal control program, including integrated controls throughout processes, and conducts an annual assessment of its internal control activities. 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 5 priority enterprise risks. To accomplish this, Centers and Offices are 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. It is governed by the ERM Council that 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 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 FFMIA. 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 sheets, the related consolidated statement of net cost and changes in net position, the combined statement of budgetary resources, and the related notes to the financial statements. The FY 2018 audit found that the financial statements present fairly, in all material respects, the consolidated financial position of HHS as of September 30, 2018 and 2017, and its consolidated balance sheets, statements of net cost, changes in net position, combined statement of budgetary resources, and related notes are in accordance with U.S. generally accepted accounting principles.

FDA has also implemented other internal control procedures including a continuous monitoring program to oversee the timely implementation of any 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 FDAs 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 Spend:** Historically, CQA budgetary resources have been under-spent due to 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 while comparing planned allocations to 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 fund 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 the BA appropriations from the onset.

- **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. Description of fees assessed and collected for such year
2. Summary description of entities paying the fees
3. Description of the hiring and placement of new staff
4. Description of the use of fee resources to support the inspection of outsourcing facilities
5. The number of inspections and reinspections of such facilities performed 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. Pay 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 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. Since 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 (ERIC)**: Provides support to all FDA users requesting administrative, IT, facilities, human resources, and other employee services.

- **Employee Safety & Environmental Management (ESEM)**: Provides safety, health, and environmental compliance for all FDA employees.
- **Office of Acquisitions and Grants Services (OAGS)**: Manages contracts, grants, and other agreements.
- **Office of External Affairs (OEA) – History**: Provides the development, coordination, and dissemination of FDA communications and outreach to the news media and various stakeholders.
- **Office of Equal Employment Opportunity (OEEO)**: 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 (OFEMS)**: Provides FDA employees with office and laboratory facilities.
- **Office of Financial Management (OFM):** Provides financial managerial services and policy guidance.
- **Office of Human Resources (OHR)**: Supports workforce relations, client services, executive resources, accountability programs, policy and program development, and systems data and management.
- **Office of Information Management and Technology (OIMT)**: 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.