FY 2017 CQA
ANNUAL REPORT

REQUIRED BY THE

COMPOUNDING QUALITY ACT

FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

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) 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 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 that includes: a description of fees assessed and collected for such year; a summary description of entities paying the fees; a description of the hiring and placement of new staff; a description of the use of fee resources to support the inspection of outsourcing facilities; and the number of inspections and reinspections of such facilities performed each year. This report covers fiscal year (FY) 2017.

In FY 2017, a total of 77 entities registered as outsourcing facilities. Six facilities that were initially registered as outsourcing facilities in FY 2017 withdrew their registration before the end of the fiscal year. On the last day of FY 2017, 71 facilities were registered.

In FY 2017, FDA spending to support oversight of outsourcing facilities totaled $16,404,785. This included budget authority, outsourcing facility fees, and one-time no-year drug safety funds. These funds supported full-time equivalents (FTEs) across FDA. (In this report, the time worked by one full-time person for 1 year is referred to as an FTE). Outsourcing facility fees supported 7 FTEs in FY 2017 out of the total of 64 FTEs dedicated to oversight of outsourcing facilities. Oversight of outsourcing facilities includes activities conducted by the Center for Drug Evaluation and Research, the Office of Regulatory Affairs, and FDA Headquarters. 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 net collections of $1,465,529 in outsourcing facility fees during FY 2017. In addition, FDA had a carryover balance of $342,593 from the prior fiscal year. Of the total amount of outsourcing facility fees available in FY 2017 ($1,808,122), FDA spent $1,130,328 to support oversight of outsourcing facilities in FY 2017 (7 percent of total spending for this purpose) and carried a balance of $678,186 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. Going forward, 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 2018, 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.

TABLE OF CONTENTS

1: BACKGROUND

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Compounding Quality Act (CQA) (Title I of the Drug Quality and Security Act (DQSA), Public Law 113-54), created a new category of regulated entity, human drug compounding outsourcing facilities. Under section 503B of the FD&C Act, a human drug compounder can elect to register with the Food and Drug Administration (FDA or the Agency) as an outsourcing facility. An outsourcing facility is defined as "a facility at one geographic location or address that (i) is engaged in the compounding of sterile drugs; (ii) has elected to register as an outsourcing facility; (iii) and complies with all of the requirements of this section." (See section 503B(d)(4) of the FD&C Act.) CQA authorizes FDA to assess and collect fees from entities that register with FDA as outsourcing facilities. FDA spends fee revenues to hire, support, and maintain personnel for the oversight of these outsourcing facilities.

Outsourcing facilities are subject to current good manufacturing practice (CGMP) requirements under section 501(a)(2)(B) of the FD&C Act and will be inspected by FDA on a risk-based schedule (see sections 503B(a) and 503B(b)(4) of the FD&C Act). Drug products compounded by or under the direct supervision of a licensed pharmacist at an outsourcing facility may be able to qualify for exemptions from the following three sections of the FD&C Act: (1) section 505 (concerning FDA approval of drugs); (2) section 502(f)(1) (concerning the labeling of drug products with adequate directions for use); and section 582 (concerning the drug supply chain security requirements). An outsourcing facility is not required to be a licensed pharmacy and may or may not obtain patient-specific prescriptions.

To qualify for the exemptions, certain conditions must be met. For example, outsourcing facilities must report the drugs that they compound, as well as certain adverse events, to FDA. They must not compound drugs that are essentially copies of one or more approved drugs, and the compounded drugs must not be sold or transferred by an entity other than the outsourcing facility that compounded them. CQA lists the conditions under which drugs compounded by outsourcing facilities can qualify for the exemptions in section 503B of the FD&C Act and is available on FDA's website.[1]

Under CQA, outsourcing facility fees shall be used to supplement and not supplant any other federal funds available to carry out the activities relating to outsourcing facility oversight (section 744K(d) and section 744K(e) of the FD&C Act). Therefore, the fees are used to augment appropriations that FDA uses for oversight of outsourcing facilities.

CQA requires FDA to submit an annual report to Congress no later than 120 days after each fiscal year (section 744K(h) of the FD&C Act). As required by statute, this report presents: 1) a description of fees assessed; 2) a description of fees collected; 3) a summary description of entities paying the fees; 4) a description of the hiring and placement of new staff; 5) a description of the use of fee resources to support inspections of outsourcing facilities; and 6) the number of inspections and reinspections of facilities performed each year.

[1] http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm376732.htm

2: Program Information

2.1 – DESCRIPTION OF FEES ASSESSED

There are two types of outsourcing facility fees assessed: the annual establishment fee and the reinspection fee.

Under section 744K(g) of the FD&C Act, to be considered registered as an outsourcing facility in a fiscal year, a facility must, among other things, pay the establishment fee due in the fiscal year.

An outsourcing facility that qualifies as a small business under section 744K(c)(4) of the FD&C Act can qualify for a reduction of the establishment fee.

The reinspection fee is designed to reimburse FDA when it must inspect an outsourcing facility more than one time because of noncompliance identified in a previous inspection. A reinspection fee will be incurred for each reinspection that occurs until FDA finds that the non-compliant conditions have been adequately addressed. There is no small business reduction for the reinspection fee.

Table 1 shows the fee rates that FDA published for FY 2016 and FY 2017. For more information about how FDA calculated the fees, please refer to the FY 2017 outsourcing facility fee rates published on August 1, 2016, in the *Federal Register*.[2]

TABLE 1: OUTSOURCING FACILITY FEE CATEGORIES AND FEE RATES

Fiscal Year	Non Small Business Establishment Fee	Small Business Establishment Fee	Reinspection Fee
2016	$16,465	$5,203	$15,610
2017	$16,852	$5,279	$15,837

[2] FDA published FY 2017 outsourcing facility fee rates on August 1, 2016, in the *Federal Register* -- https://www.gpo.gov/fdsys/pkg/FR-2016-08-01/pdf/2016-18093.pdf

2.2 – DESCRIPTION OF FEES COLLECTED

In FY 2017, FDA collected 71 establishment fees for non-small businesses, 6 small business establishment fees, and 12 reinspection fees from outsourcing facilities.

At the end of FY 2017, FDA also had one receivable for FY 2016 and one for FY 2017 from uncollected reinspection fees. After 90 days of attempting to collect the delinquent debt, FDA turns these receivables over to the Program Support Center (PSC), Department of Health and Human Services, for further attempts at collection. After 120 days of the debt being outstanding, PSC turns the debt over to the United States Treasury for further collection efforts.

Three other reinspections occurred in FY 2017, and the invoices for the reinspection fees will be issued in early FY 2018. Given the timing of the invoices, these reinspection fees are not included in the table below, although they will be reported in next year's report as FY 2017 collections. Fee collections are reported in the year the fee was originally incurred—referred to as the cohort year. For example, a fee for an event that occurred in FY 2017 (registration or reinspection) is considered part of the FY 2017 cohort and, even if the fee is paid in FY 2018, it is attributed to FY 2017 collections. To ensure the quality of the information provided in this financial report, FDA updates prior years' numbers in each report.

Table 2 provides totals of fees collected during the past 2 fiscal years and reflects the amount of open receivables.

TABLE 2: OUTSOURCING FACILITY FEE COLLECTIONS BY FEE TYPE SOURCE AS OF SEPTEMBER 30, 2017

FEES COLLECTED	FY 2016	FY 2017
Non-Small Business Establishment Fees	$1,020,830	$1,196,492
Small Business Establishment Fees	$31,218	$31,674
Reinspection Fees[3]	$124,880	$190,044
TOTAL COLLECTIONS	**$1,176,928**	**$1,418,210**
FEES RECEIVABLE		
Non-Small Business Establishment Fees	$0	$0
Small Business Establishment Fees	$0	$0
Reinspection Fees	$15,610	$15,837
TOTAL RECEIVABLES	**$15,610**	**$15,837**

Numbers have been rounded to the nearest dollar

[3] Adjustments were made after the close of FY 2017 to reflect the revised cohort year collections.

2.3 – SUMMARY DESCRIPTION OF ENTITIES PAYING THE FEES

As noted, in FY 2017, a total of 77 entities registered as outsourcing facilities. Of these 77 facilities, 71 paid the non-small business establishment fee, and 6 paid the small business establishment fee. Six facilities that were initially registered as outsourcing facilities in FY 2017 withdrew their registration before the end of the fiscal year. On the last day of FY 2017, 71 facilities were registered.

Of the 77 firms that were registered as outsourcing facilities at some point during FY 2017, 19 were in the northeast (Connecticut, Massachusetts, New Jersey, New York, Pennsylvania, and Vermont); 22 in the southeast (Alabama, Arkansas, Florida, Mississippi, North Carolina, South Carolina, and Tennessee); 8 in the midwest (Illinois, Kansas, Missouri, and Ohio); 14 in the southwest (Arizona, Oklahoma, and Texas); and 14 in the west (California, Colorado, Idaho, Nevada, and Utah).

Outsourcing facilities vary widely in terms of scope of distribution and the types of products they compound. 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 (e.g., vials or syringes) of a single drug product. Many outsourcing facilities are state-licensed pharmacies, but some are not. In addition, although all outsourcing facilities compound sterile drugs (e.g., injectables for various routes of administration), many also compound non-sterile drugs (e.g., solid oral dosage forms); most, but not all, outsourcing facilities compound drug products from bulk drug substances. The types of drug products compounded by outsourcing facilities include, for example, ophthalmics, anesthetics, antibiotics, hormones, steroids, dermatologic products, and vitamin injections.

Table 3 lists the number of entities in FY 2017 that (1) registered and remained registered during FY 2017 or (2) registered and then de-registered as an outsourcing facility. The total number of registered outsourcing facilities increased from FY 2016 to FY 2017.

TABLE 3: NUMBER OF ENTITIES REGISTERED AND DE-REGISTERED AS OUTSOURCING FACILITIES

Entities	FY 2016	FY 2017
Registered and remained registered through the end of the fiscal year	64	71
Registered but then de-registered	4	6

2.4 – DESCRIPTION OF THE HIRING AND PLACEMENT OF NEW STAFF

FTE is a measure of a paid staff year devoted to outsourcing facility oversight. In this table, FTE does not represent an accounting of individual people, but rather an estimate of labor hours expended on outsourcing facility oversight activities.

In FY 2017, four FTEs in the Center for Drug Evaluation and Research (CDER) were supported by outsourcing facility fees. This is a small fraction of the full level of effort required to support oversight of outsourcing facilities during FY 2017.

Table 4 presents total fee-paid FTE levels that supported outsourcing facility oversight by FDA organizational components for the past 3 years. The table displays data for CDER, the Office of Regulatory Affairs (ORA), and FDA Headquarters (HQ).

TABLE 4: FTES DEVOTED TO THE OVERSIGHT OF OUTSOURCING FACILITIES PAID FOR BY FEES AS OF SEPTEMBER 30, 2017 OF EACH FISCAL YEAR

Fiscal Year	CDER	ORA	HQ	Total	Notes
2015	2	0	0	2	
2016	7	0	0	7	
2017	4	3	0	7	A

Numbers have been rounded to the nearest FTE

Notes

A. Unrounded figures: CDER – 4.38, ORA – 3.27, HQ – 0, Total – 7.65.

2.5 – DESCRIPTION OF THE USE OF FEE RESOURCES TO SUPPORT INSPECTING OUTSOURCING FACILITIES

Under CQA, outsourcing facility fees may be expended solely to pay for the costs of oversight of outsourcing facilities. Oversight of outsourcing facilities includes activities related to inspections and enforcement, policy development and implementation, stakeholder outreach, and state collaboration and coordination. Activities related to inspections and enforcement include training investigators on how to conduct inspections of outsourcing facilities; writing inspection assignments; conducting inspections; handling issues that arise during inspections such as the need to take environmental samples; assessing inspection results; taking administrative, regulatory, or judicial action, such as issuing a warning letter or initiating an injunction, as appropriate; and taking any other action necessary to protect the public health, such as recommending that a firm recall potentially dangerous compounded drugs. FDA is also working on establishing CGMP regulations for outsourcing facilities and developing other policies necessary for oversight. Outsourcing facilities are also required to report certain adverse events associated with their products, and FDA reviews these reports and investigates the adverse events as appropriate.

In FY 2017, FDA obligated $1,130,328 from outsourcing facility fees. Under CQA, fees collected, appropriated, and not obligated at the end of a fiscal year remain available to FDA in future fiscal years. These funds ($678,186) are referred to as carryover balances.

The outsourcing facility fees represent a small portion of the overall outsourcing facility oversight program—in FY 2017, FDA spent a total of $16,404,785 to support oversight of outsourcing facilities, including $1,130,328 (7 percent) from outsourcing facility fees. Going forward, FDA intends to utilize the carryover funds as well as new fees collected to support oversight of outsourcing facilities. The fees are critical to help sustain the level of effort required to effectively oversee outsourcing facilities. Because the fees represent a small fraction of the resources necessary to provide the needed oversight, FDA will not be able to rely solely on projected fees to sustain the increased pace of inspections and other oversight of this category of compounding facilities.

Table 5 provides a breakout of fee obligations by expense category during the past 2 fiscal years.

TABLE 5: OUTSOURCING FACILITY FEE OBLIGATIONS BY OBJECT CLASS EXPENSE CATEGORY BREAKDOWN AS OF SEPTEMBER 30, 2016 AND 2017

Object Class Expense Category	FY 2016	FY 2017
Personnel Compensation Benefits		
Full-time permanent	$780,203	$632,926
Other than full-time permanent	$11,533	$25,179
Other personnel compensation	$2,739	$19,498
Military personnel	$10,897	$119,852
Special personnel services payments	$0	$0
Civilian personnel benefits	$255,366	$211,744
Military personnel benefits	$6,474	$59,348
Benefits former personnel	$0	$0
Total Personnel Compensation and Benefits	**$1,067,213**	**$1,068,547**
Non-Pay Costs		
Travel & transportation of persons	$368,619	$0
Transportation of things	$0	$0
Rent payments to General Services Administration (GSA)	$0	$0
Rent payments to others	$0	$0
Communications, utilities, & miscellaneous	$0	$0
Printing & reproduction	$0	$0
Other contractual services:		
Consulting services	$46,931	$61,781
Other services	$0	$0
Purchases of goods & services from government accounts	$0	$0
Operations & maintenance of facilities	$0	$0
Research & development contracts	$0	$0
Operations & maintenance of equipment	$0	$0
Subsistence & support of persons	$0	$0
Supplies & materials	$148	$0
Equipment	$0	$0
Land & structure	$0	$0

Grants, subsidies, & contributions	$0	$0
Insurance claims & indemnities	$0	$0
Interest account	$0	$0
Receivables – collected	$0	$0
Total Non-Pay Costs	**$415,698**	**$61,781**
Total Obligations	**$1,482,911**	**$1,130,328**

Numbers have been rounded to the nearest dollar

Table 6 reflects the amount of fees collected net of any refunds or other adjustments that occurred during each fiscal year, for all cohort years combined, and the amount obligated during the fiscal year. The numbers do not include any accounts receivable. Therefore, the numbers for FY 2016 and FY 2017 are different from the numbers in Table 2 in section 2.2 – Description of Fees Collected, which reflect the total net collections for the cohort years only.

Obligations in Table 6 include any recoveries and deobligations from prior years, which may cause differences from Table 5. In FY 2017, FDA recovered $392 in CQA deobligations.

TABLE 6: OUTSOURCING FACILITY FEE COLLECTIONS, OBLIGATIONS, AND CARRYOVER BALANCES BY FISCAL YEAR

FISCAL YEAR	BEGINNING CARRYOVER	NET COLLECTIONS	OBLIGATIONS	YEAR END CARRYOVER
2015	N/A	$1,060,226	$396,268	$663,958
2016	$663,958	$1,161,546	$1,482,911	$342,593
2017	$342,593	$1,465,529	$1,129,936	$678,186

2.6 – NUMBER OF OUTSOURCING FACILITY INSPECTIONS AND REINSPECTIONS PERFORMED

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 2017, FDA conducted 39 inspections of outsourcing facilities. Of these inspections, 16 were reinspections as defined in CQA. As of September 30, 2017, FDA collected 12 reinspection fees and is pending collection of 1 fee. The remaining three reinspection fees will be invoiced in early FY 2018.

Table 7 provides a summary of outsourcing facility inspections and reinspections in FY 2017 and FY 2016. In FY 2017, the number of inspections increased from FY 2016 as FDA assessed the inspection results and acted, as appropriate, with respect to inspections that occurred in prior years. There was also an increase in the number of reinspections in FY 2017 as compared to FY 2016 because FDA began inspecting outsourcing facilities in the middle of FY 2014, and the Agency is now going back to firms to reinspect and follow-up on the initial inspections. Outsourcing facility inspections were funded by outsourcing facility fees and budget authority.

TABLE 7: OUTSOURCING FACILITY INSPECTION SUMMARY BY TYPE AS OF SEPTEMBER 30, 2017

INSPECTION TYPE	FY 2016	FY 2017
503B Inspections	17	23
503B Reinspections	9	16
TOTAL INSPECTIONS	**26**	**39**