FY 2016 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 inspecting outsourcing facilities; and the number of inspections and reinspections of such facilities performed each year. This report covers fiscal year (FY) 2016.

In FY 2016, a total of 68 entities registered as outsourcing facilities. Four facilities that were initially registered as outsourcing facilities in FY 2016 withdrew their registration before the end of the fiscal year. On the last day of FY 2016, 64 facilities were registered.

In FY 2016, FDA spending to support oversight of outsourcing facilities totaled $12,986,407. This included budget authority, outsourcing facility fees, and one-time no-year drug safety funds. These funds supported 55 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 2016 out of the total of 55 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 $1,161,546 in outsourcing facility fees during FY 2016. In addition, FDA had a carryover balance of $663,958 from the prior fiscal year. Of the total amount of outsourcing facility fees available in FY 2016 ($1,825,504), FDA spent $1,482,911 to support oversight of outsourcing facilities in FY 2016 (11 percent of total spending for this purpose) and carried a balance of $342,593 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 2017, FDA will continue to enhance oversight of outsourcing facilities, which includes promptly investigating reports of serious adverse events and product quality issues such as drug contamination, inspecting outsourcing facilities according to 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 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) 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." (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)). 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 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)). 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 inspecting 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 (section 744K(c)(4) of the FD&C Act).

The reinspection fee is designed to reimburse FDA when it must inspect a particular 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 2015 and 2016. For more information about how FDA calculated the fees please refer to the FY 2016 outsourcing facility fee rates published on August 3, 2015, 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
2015	$16,442	$5,103	$15,308
2016	$16,465	$5,203	$15,610

[2] FDA published FY 2016 outsourcing facility fee rates on August 3, 2015, in the *Federal Register* -- https://www.gpo.gov/fdsys/pkg/FR-2015-08-03/pdf/2015-18916.pdf

2.2 – DESCRIPTION OF FEES COLLECTED

In FY 2016, FDA collected 62 establishment fees for non-small businesses, six small business establishment fees, and four reinspection fees from outsourcing facilities.

At the end of FY 2016, FDA also had one open receivable which can be seen below in Table 2. The open receivable is for a reinspection fee invoiced in September 2016.

Four other reinspections occurred in FY 2016 and the invoices for the reinspection fees were issued in early FY 2017. Given the timing of the invoices, these reinspection fees are not currently included in the table below, although they will be reported in next year's report as FY 2016 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 2016 (registration or reinspection) is considered part of the FY 2016 cohort and even if the fee is paid in FY 2017, is attributed to FY 2016 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, 2016

FEES COLLECTED	FY 2015	FY 2016
Non-Small Business Establishment Fees	$1,035,846	$1,020,830
Small Business Establishment Fees	$10,206	$31,218
Reinspection Fees	$61,232	$62,440
TOTAL COLLECTIONS	**$1,107,284**	**$1,114,488**
FEES RECEIVABLE	**FY 2015**	**FY 2016**
Non-Small Business Establishment Fees	$0	$0
Small Business Establishment Fees	$0	$0
Reinspection Fees	$0	$15,610
TOTAL RECEIVABLES	**$0**	**$15,610**

Numbers have been rounded to the nearest dollar

2.3 – SUMMARY DESCRIPTION OF ENTITIES PAYING THE FEES

As noted, in FY 2016, a total of 68 entities registered as outsourcing facilities. Of these 68 facilities, 62 paid the non-small business establishment fee, and 6 paid the small business establishment fee. Four facilities that were initially registered as outsourcing facilities in FY 2016 withdrew their registration before the end of the fiscal year. On the last day of FY 2016, 64 facilities were registered.

Of the 68 firms that were registered as outsourcing facilities at some point during FY 2016, 12 were located in the northeast (Connecticut, Pennsylvania, New Jersey, New York, and Vermont); 22 in the southeast (Alabama, Arkansas, Florida, Mississippi, North Carolina, South Carolina, and Tennessee); 7 in the midwest (Indiana, Kansas, Missouri, and Ohio); 17 in the southwest (Arizona, Oklahoma, and Texas); and 10 in the west (California, Colorado, Idaho, Nevada, Utah, and Washington).

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), and 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 that, in FY 2016 (1) registered and remained registered during FY 2016, or (2) registered and then de-registered as an outsourcing facility. The total number of registered outsourcing facilities increased from FY 2015 to FY 2016.

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

Entities	FY 2015	FY 2016
Registered and remained registered through the end of the fiscal year	55	64
Registered but then de-registered	9	4

2.4 – DESCRIPTION OF THE HIRING AND PLACEMENT OF NEW STAFF

In FY 2016, 7 full-time equivalents (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 2016 (55 FTEs).

Table 4 presents total fee-paid FTE levels that supported outsourcing facility oversight by FDA organizational components for FY 2015 and 2016. The table displays data for CDER, the Office of Regulatory Affairs (ORA), and FDA Headquarters (HQ).

Due to a system upgrade that was in progress at the end of FY 2015, the typical data for that year's FTE calculations was unavailable. FDA had to estimate the breakdown for FY 2015 using an alternative methodology based on high-level FTEs. In FY 2016, after the system upgrade was complete, FDA was able to return to the normal methodology. In addition, beginning in FY 2015, the calculation to determine the allocation of shared services FTEs among programs was amended to more accurately estimate labor hours expended on CQA activities. This recalculation includes the addition of the Office of Human Resources and a restructuring of the activities related to the Office of Information Management.

TABLE 4: FTES DEVOTED TO THE OVERSIGHT OF OUTSOURCING FACILITIES PAID FOR BY FEES AS OF SEPTEMBER 30, 2016 OF EACH FISCAL YEAR

Fiscal Year	CDER	ORA	HQ	Total
2015	2	0	0	2
2016	7	0	0	7

Numbers have been rounded to the nearest FTE

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 the inspection assignments; conducting inspections; handling issues that arise during the inspections such as the need to take environmental samples; assessing the 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 2016, FDA obligated $1,482,911 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 ($342,593) are referred to as carryover balances.

The outsourcing facility fees represent a small portion of the overall outsourcing facility oversight program – in FY 2016, FDA spent a total $12,986,407 to support oversight of outsourcing facilities including $1,482,911 (11 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 two fiscal years.

TABLE 5: OUTSOURCING FACILITY FEE OBLIGATIONS BY OBJECT CLASS EXPENSE CATEGORY BREAKDOWN AS OF SEPTEMBER 30, 2015 AND 2016

Object Class Expense Category	FY 2015	FY 2016
Personnel Compensation Benefits		
Full-time permanent	$325,000	$780,203
Other than full-time permanent	$0	$11,533
Other personnel compensation	$0	$2,739
Military personnel	$0	$10,897
Special personnel services payments	$0	$0

Object Class Expense Category	FY 2015	FY 2016
Civilian personnel benefits	$38,000	$255,366
Military personnel benefits	$0	$6,474
Benefits former personnel	$0	$0
Total Personnel Compensation and Benefits	**$363,000**	**$1,067,213**
Non-Pay Costs		
Travel & transportation of persons	$0	$368,619
Transportation of things	$0	$0
Rent payments to GSA	$0	$0
Rent payments to others	$0	$0
Communications, utilities & miscellaneous	$0	$0
Printing & reproduction	$0	$0
Other Contractual Services:		
Consulting services	$0	$46,931
Other services	$33,268	$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 and support of persons	$0	$0
Supplies & materials	$0	$148
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	**$33,268**	**$415,698**
Total Obligations	**$396,268**	**$1,482,911**

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 2015 and FY 2016 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 2016, FDA did not recover any prior year 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
CQA	2015	N/A	$1,060,226	$396,268	$663,958
	2016	$663,958	$1,161,546	$1,482,911	$342,593

Numbers have been rounded to the nearest dollar

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 2016, FDA conducted 26 inspections of outsourcing facilities. Nine of these inspections were reinspections as defined in CQA. As of September 30, 2016, FDA collected four reinspection fees and is pending collection of one fee. The remaining four reinspection fees were invoiced in early FY 2017.

Table 7 provides a summary of outsourcing facility inspections and reinspections in FY 2016 and FY 2015. In FY 2016, the number of inspections decreased from FY 2015 as FDA assessed the inspection results and took action, as appropriate, with respect to inspections that occurred in prior years. There was also an increase in the number of reinspections in FY 2016 as compared to FY 2015 because FDA only began inspecting outsourcing facilities in the middle of FY 2014. Outsourcing facility inspections were funded by outsourcing facility fees and budget authority.

Table 7: Outsourcing Facility Inspection Summary by Type as of September 30, 2016

INSPECTION TYPE	FY 2015	FY 2016
503B Inspections	27	17
503B Reinspections	4	9
TOTAL INSPECTIONS	**31**	**26**