FY 2015 CQA
ANNUAL REPORT

REQUIRED BY THE

COMPOUNDING QUALITY ACT

FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

EXECUTIVE SUMMARY

In November 2013, President Obama 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), authorizes the Food and Drug Administration (FDA) to assess and collect fees from human drug compounders that register with FDA as outsourcing facilities.

The 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) 2015.

In this report, the time worked by one full-time person for one year is referred to as a full-time equivalent (FTE). In FY 2015, FDA spending to support oversight of outsourcing facilities totaled $14.4 million including Budget Authority (BA), outsourcing facility fees, and one-time no-year drug safety funds. These funds supported 61 FTEs across the Agency. Oversight of outsourcing facilities includes activities conducted by the Center for Drug Evaluation and Research (CDER), the Office of Regulatory Affairs (ORA), and the Office of the Commissioner. This does not include the Center for Veterinary Medicine (CVM) or Center for Biologics Evaluation and Research (CBER) as the CQA does not cover the compounding of animal drugs or biologics.

FDA collected $1.1 million in outsourcing facility fees during FY 2015. Outsourcing facility fees supported two FTEs in FY 2015, out of a total of 61 FTEs dedicated to oversight of outsourcing facilities. Of the $1.1 million collected, FDA spent $396,268 to support oversight of outsourcing facilities in FY 2015 and carried a balance of $663,958 forward to pay for the costs of oversight of outsourcing facilities in future fiscal years. Going forward, FDA intends to fully 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 BA for oversight of outsourcing facilities.

In FY 2016, 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 that will assist outsourcing facilities with complying with the law.

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1: BACKGROUND

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Compounding Quality Act (CQA) (Title I of the 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. The 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.

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.)

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 that outsourcing facility that compounded them. The 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 the 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 compounding outsourcing facilities.

The 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 is required to pay only one-third 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. For more information about how FDA calculated the fees please refer to the FY 2015 outsourcing facility fee rates published on August 1, 2014, in the Federal Register.[2]

Table 1: Outsourcing Facility Fee Categories and Fee Rates in FY 2015

	Standard Establishment Fee	Small Business Establishment Fee	Reinspection Fee
FY 2015	$16,442	$5,103	$15,308

[2] FDA published FY 2015 outsourcing facility fee rates on August 1, 2014, in the Federal Register -- http://www.gpo.gov/fdsys/pkg/FR-2014-08-01/pdf/2014-18111.pdf

2.2 – DESCRIPTION OF FEES COLLECTED

In FY 2015, FDA collected establishment fees for non-small businesses from 62 outsourcing facilities and small business establishment fees from two facilities. FDA also collected reinspection fees from two facilities.

In addition to what was collected, at the end of FY 2015, FDA also had two open receivables for the CQA program, which can be seen below in Table 2. The first open receivable is for a standard establishment fee for a firm that submitted registration information to FDA in September 2015, and the second open receivable is for a reinspection fee for a reinspection invoiced in September 2015.

Also, one reinspection occurred in FY 2015, and the invoice for the reinspection fee was issued in early FY 2016. Given the timing of the invoice, this reinspection fee is not currently included in the table below, although it will be reported in next year's report as an FY 2015 fee.

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 2015 (registration or reinspection) is considered part of the FY 2015 cohort and even if the fee is paid in FY 2016, is attributed to FY 2015 collections. To ensure the quality of the information provided in this financial report, FDA intends to update prior years' numbers in the next year's report.

Table 2 provides totals of fees collected during and receivable from the past fiscal year.

TABLE 2: OUTSOURCING FACILITY FEE COLLECTIONS BY FEE TYPE SOURCE AS OF SEPTEMBER 30, 2015

FEES COLLECTED	FY 2015
Non-Small Business Establishment Fees	$1,019,404
Small Business Establishment Fees	$10,206
Reinspection Fees	$30,616
TOTAL COLLECTIONS	**$1,060,226**
FEES RECEIVABLE	
Non-Small Business Establishment Fees	$16,442
Small Business Establishment Fees	$0
Reinspection Fees	$15,308
TOTAL RECEIVABLES	**$31,750**

Numbers have been rounded to the nearest dollar

2.3 – SUMMARY DESCRIPTION OF ENTITIES PAYING THE FEES

As noted, in FY 2015, a total of 64 entities registered as outsourcing facilities. Of these 64 entities, 62 paid the non-small business establishment fee, and 2 paid the small business establishment fee. 9 firms that initially registered as outsourcing facilities in FY 2015 withdrew their registration before the end of the fiscal year. On the last day of FY 2015, 55 firms were registered.

In addition, 2 entities paid a reinspection fee.

Of the 64 firms that were registered as outsourcing facilities at some point during FY 2015, 13 were located in the northeast (e.g., Connecticut, Pennsylvania, New Jersey, New York, and Vermont); 25 in the southeast (e.g., Alabama, Arkansas, Florida, Mississippi, North Carolina, South Carolina, Tennessee, and West Virginia); 6 in the midwest (e.g., Indiana, Kansas, Missouri, and Ohio); 11 in the southwest (e.g., Arizona, Oklahoma, and Texas); 8 in the west (e.g., California, Colorado, Nevada, Utah, and Washington); and 1 foreign firm located in Europe.

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 five 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 2015 (1) registered and remained registered during the FY15, or (2) registered and then de-registered as an outsourcing facility.

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

Entities	FY 2015
Registered and remained registered through FY 2015	55
Registered for FY 2015 but then de-registered	9

2.4 – DESCRIPTION OF THE HIRING AND PLACEMENT OF NEW STAFF

In FY 2015, two FTEs in 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 2015 (61 FTEs). Due to administrative challenges, FDA did not obligate all of the outsourcing facility fee collections during FY 2015 and the carryover balance is expected to be used in FY 2016 to support oversight of outsourcing facilities.

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

TABLE 4: FTES DEVOTED TO THE OVERSIGHT OF OUTSOURCING FACILITIES PAID FOR BY FEES AS OF SEPTEMBER 30, 2015

Fiscal Year	CDER	ORA	OC	Total
2015	2	0	0	2

Numbers have been rounded to the nearest FTE

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

Under the 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, and state collaboration and coordination. Activities related to inspections and enforcement include not only conducting inspections, but also include writing the inspection assignments; 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 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 2015, FDA obligated $396,268 out of $1,060,226 from outsourcing facility fees. Under the CQA, fees collected, appropriated, and not obligated at the end of a fiscal year remain available to FDA in future fiscal years. These funds ($663,958) are referred to as carryover balances.

The outsourcing facility fees represent a small portion of the overall outsourcing facility oversight program – in FY 2015, FDA spent a total $14.4 million to support oversight of outsourcing facilities including $396,268 from outsourcing facility fees. Going forward, FDA intends to fully 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 fiscal year.

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

Object Class Expense Category	FY 2015
Personnel Compensation Benefits	
Full-time Permanent	$325,000
Other than full-time permanent	$0
Other personnel compensation	$0
Military personnel	$0
Special Personnel Services Payments	$0
Civilian personnel benefits	$38,000
Military personnel benefits	$0

Benefits former personnel	$0
Total Personnel Compensation and Benefits	**$363,000**
Non-Pay Costs	$0
Travel & transportation of persons	$0
Transportation of things	$0
Rent payments to GSA	$0
Rent payments to others	$0
Communications, utilities & miscellaneous	$0
Printing & reproduction	$0
Other Contractual Services:	$0
Consulting services	$0
Other services	$33,268
Purchases of Goods & services from Government accounts	$0
Operations & maintenance of facilities	$0
Research & development contracts	$0
Operations & maintenance of equipment	$0
Subsistence and support of persons	$0
Supplies & materials	$0
Equipment	$0
Land & structure	$0
Grants, subsidies, & contributions	$0
Insurance claims & indemnities	$0
Interest Account	$0
Total Non-Pay Costs	**$33,268**
Total Obligations	**$396,268**

Numbers have been rounded to the nearest dollar

Table 6 reflects the carryover balance from the beginning to the end of the fiscal year, the net amount collected, and any refunds or other adjustments that occurred.

TABLE 6: OUTSOURCING FACILITY FEE COLLECTIONS, OBLIGATIONS, AND CARRYOVER BALANCE AS OF SEPTEMBER 30, 2015

	FISCAL YEAR	BEGINNING CARRYOVER	NET COLLECTIONS	OBLIGATIONS	YEAR-END CARRYOVER
CQA	2015	N/A	$1,060,226	$396,268	$663,958

Numbers have been rounded to the nearest dollar

2.6 – NUMBER OF INSPECTIONS AND REINSPECTIONS OF FACILITIES PERFORMED

The 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 2015, FDA conducted 31 inspections of outsourcing facilities. Four of these inspections were reinspections of four different facilities as defined in the CQA. Reinspection fees were collected for two of the four reinspections conducted during FY 2015; one fee was assessed in FY 2015 but collection was pending as of September 30, 2015, and one fee for a reinspection that occurred late in FY 2015 was assessed in FY 2016.

Table 7 provides a summary of outsourcing facility inspections and reinspections in FY 2015. Outsourcing facility inspections were funded by outsourcing facility fees, budget authority, and one-time, no-year drug safety funds.

TABLE 7: OUTSOURCING FACILITY INSPECTION SUMMARY BY TYPE AS OF SEPTEMBER 30, 2015

INSPECTION TYPE	FY 2015
503B Inspections	27
503B Reinspections	4
TOTAL INSPECTIONS	31