

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