

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