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