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**