

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>