4.2 – APPENDIX B: FEES AND WAIVERS

BsUFA Fee History

BsUFA established the following fee types and directs FDA to set the BsUFA fee rates for each fiscal year – (1) the initial and annual BPD fee rates for a fiscal year are equal to 10 percent of the fee rate established under PDUFA for an application requiring clinical data for that fiscal year; (2) the BPD reactivation fee is equal to 20 percent of the fee rate established under PDUFA for an application requiring clinical data for that fiscal year; and (3) the application, establishment, and product fee rates under BsUFA are equal to the application, establishment, and product fee rates under PDUFA, respectively.

Table 8 shows the user fee rates that FDA published for the past 4 fiscal years.

TABLE 8: TRENDS IN BPD, APPLICATION, ESTABLISHMENTS, AND PRODUCT FEES[1]

Fiscal Year	Initial and Annual BPD Fees	Reactivation BPD Fees	Establishment Fees	Product Fees	Application - Requiring Clinical Data - Fees	Supplement - Requiring Clinical Data - Fees
2013	$195,880	$391,760	$526,500	$98,380	$1,958,800	$979,400
2014	$216,910	$433,820	$554,600	$104,060	$2,169,100	$1,084,550
2015	$233,520	$467,040	$569,200	$110,370	$2,335,200	$1,167,600
2016	$237,420	$474,840	$585,200	$114,450	$2,374,200	$1,187,100

Application fees can differ in each instance due to previously paid BPD fees subtracted from the application fee rate.

BsUFA Program Waivers

BsUFA provides for a waiver of the application fee for the first biosimilar biological product application submitted by a small business or its affiliate. For purposes of this waiver provision, the term "small business" means an entity that has fewer than 500 employees, including employees of affiliates, and does not have a drug product that has been approved under a human drug application (as defined in section 735 of the FD&C Act) or a biosimilar biological product application (as defined in section 744G(4)) and introduced or delivered for introduction into interstate commerce. See section 744H(c) of the FD&C Act.

In FY 2016, FDA did not grant any small business waivers for BsUFA fees.

[1] FDA published FY 2016 biosimilar biological product user fee rates on August 3, 2015, in the *Federal Register* (https://www.gpo.gov/fdsys/pkg/FR-2015-08-03/pdf/2015-18908.pdf).