

### 3: FINANCIAL INFORMATION

#### 3.1 – USER FEE COLLECTIONS

##### Introduction

BsUFA authorizes FDA to assess and collect user fees for certain activities in connection with biosimilar biological product development, for submission of specified applications and supplements, for approved biosimilar biological products, and for establishments that produce approved biosimilar biological products.

User fee collections are reported in the year the fee was originally due—referred to as the “cohort year.” For example, a fee originally due in FY 2015, even if it is received in FY 2016, is attributed to FY 2015 collections. Totals reported for each fiscal year are net of any refunds for the cohort year. To ensure the quality of the information provided in this financial report, FDA will annually update prior year numbers. There were no outstanding BsUFA fees remaining at the end of either fiscal year.

FDA issues invoices for annual BPD fees in August for fees due on October 1 and in November of the same year for BPD fees that became due after the initial invoices were issued. FDA issues invoices for product and establishment fees twice a year. For fees due on October 1, the invoices are issued in August; for product and establishment fees due that were not previously billed and paid, the invoices are issued in November after the close of the fiscal year. BPD fees increased 13 percent between FY 2015 and FY 2016.

##### Data

Table 1 provides the total user fees collected during the past 2 fiscal years.

**TABLE 1: BIOSIMILAR BIOLOGICAL PRODUCT USER FEE COLLECTIONS BY FEE SOURCE  
AS OF SEPTEMBER 30, 2016**

<b>Fees Collected</b>	<b>FY 2015</b>	<b>FY 2016</b>
BPD Fees	\$14,478,240	\$16,381,980
Application Fees	\$8,598,790	\$8,926,960
Establishment Fees	\$569,200	\$585,200
Product Fees	\$220,740	\$228,900
<b>Total Collections</b>	<b>\$23,866,970</b>	<b>\$26,123,040</b>

Numbers have been rounded to the nearest dollar.

##### References

Balances carried over from year to year are described in section 3.3 - Carryover Balances.

A table of BsUFA fee rates is provided in section 4.2 - Appendix B.