

### 3.5 – TOTAL BSUFA PROGRAM COSTS

#### Introduction

In FY 2016, FDA supported the BsUFA program with both user fees and non-user fee appropriations. There are four organizations that support the BsUFA program: the Center for Drug Evaluation and Research (CDER), the Center for Biologics Evaluation and Research (CBER), the Office of Regulatory Affairs (ORA), and FDA Headquarters (HQ).

In FY 2016, the total costs for the BsUFA program increased by approximately 31 percent from the cost for the program in FY 2015, because of increased workload associated with submissions and meetings. Please see the FY 2016 BsUFA Performance Report for more information.

#### Data

Table 5 shows the full cost of the BsUFA program (user fees and non-user fee appropriations) during the past 4 fiscal years by FDA organizational components (CDER, CBER, ORA, and HQ). The percentages spent in the various FDA components have remained essentially stable over time, with CDER at approximately 88 percent, CBER at approximately 1 percent, ORA at approximately 3 percent, and HQ at approximately 8 percent.

**TABLE 5: BSUFA PROGRAM – HISTORICAL TREND OF TOTAL COSTS BY ORGANIZATION AS OF SEPTEMBER 30 OF EACH FISCAL YEAR**

Fiscal Year	Total Spent	Spent by CDER	CDER %	Spent by CBER	CBER %	Spent by ORA	ORA %	Spent by HQ	HQ %
2013	\$28,040,547	\$24,759,346	88%	\$1,097,336	4%	\$0	0%	\$2,183,865	8%
2014	\$23,391,649	\$21,087,708	90%	\$490,174	2%	\$0	0%	\$1,813,767	8%
2015	\$34,817,217	\$30,604,475	88%	\$39,841	0%	\$1,136,046	3%	\$3,036,855	9%
2016	\$45,569,430	\$40,284,316	88%	\$203,767	1%	\$1,516,990	3%	\$3,564,356	8%

Numbers have been rounded to the nearest dollar.

Table 6 provides the total amount spent on the BsUFA program for the last 4 fiscal years as well as the dollar amount and percentage derived from fees and non-user fee appropriations. As expected, the percentage derived from user fees has risen over time.

**TABLE 6: BSUFA PROGRAM – HISTORICAL TREND OF TOTAL COSTS BY FUNDING SOURCE AS OF SEPTEMBER 30 OF EACH FISCAL YEAR**

Fiscal Year	Total Spent	Spent from Appropriations	Appropriations Percent	Spent from BsUFA Fees	BsUFA Fee Percent
2013	\$28,040,547	\$28,040,547	100%	\$0	0%
2014	\$23,391,649	\$21,074,247	90%	\$2,317,402	10%
2015	\$34,817,217	\$32,550,420	93%	\$2,266,797	7%
2016	\$45,569,430	\$32,353,416	71%	\$13,216,014	29%

Numbers have been rounded to the nearest dollar.

## References

An expense category breakout of the FY 2015 and FY 2016 dollar amounts spent from BsUFA fees is provided in Table 2 in section 3.2 – User Fee Obligations.

The development of the costs associated with the BsUFA program is described in more detail in section 4.4 – Appendix D.