

3.2 – USER FEE OBLIGATIONS

Introduction

BsUFA fees may be expended only for costs necessary to support the “process for the review of biosimilar biological product applications,” as defined in BsUFA. In FY 2016, FDA obligated \$13,216,014 in biosimilar biological product user fees to support the BsUFA program.

For ease of reading, the “process for the review of biosimilar biological product applications” is referred to as the “BsUFA program” in this report. For more information on the allowable and excluded costs, see section 4.3 - Appendix C

Fluctuations in object class obligations are due to variations in programmatic operations from year to year. As a result, increases or decreases in specific categories do not necessarily indicate growth or reductions in the overall BsUFA program.

Data

Table 2 provides a breakdown of user fee obligations by expense category during the past 2 fiscal years.

**TABLE 2: BIOSIMILAR BIOLOGICAL PRODUCT USER FEE OBLIGATIONS
BY OBJECT CLASS EXPENSE CATEGORY BREAKDOWN
AS OF SEPTEMBER 30, 2015, AND 2016**

Object Class Expense Category	FY 2015	FY 2016
Personnel Compensation Benefits		
Full-time permanent	\$420,571	\$5,713,736
Other than full-time permanent	\$124,120	\$466,521
Other personnel compensation	\$65,448	\$194,469
Military personnel	\$41,951	\$175,636
Special personnel services payments	\$0	\$688
Civilian personnel benefits	\$191,351	\$1,612,098
Military personnel benefits	\$23,155	\$105,609
Benefits former personnel	\$0	\$0
Total Personnel Compensation and Benefits	\$866,595	\$8,268,757
Non-Pay Costs		
Travel & transportation of persons	\$2,209	\$65,803
Transportation of things	\$0	\$0

Object Class Expense Category	FY 2015	FY 2016
Rent payments to GSA	\$117,414	\$0
Rent payments to others	\$0	\$360
Communications, utilities, & miscellaneous	\$0	\$0
Printing & reproduction	\$0	\$0
Other contractual services:		
Consulting services	\$178,134	\$195,859
Other services	\$54,616	\$1,750,880
Purchases of goods & services from Government accounts	\$192,896	\$1,567,653
Operations & maintenance of facilities	\$0	\$0
Research & development contracts	\$0	\$0
Operations & maintenance of equipment	\$215,253	\$83,616
Subsistence & support of persons	\$0	\$0
Supplies & materials	\$71,701	\$790,242
Equipment	\$567,979	\$492,846
Land & structure	\$0	\$0
Grants, subsidies, & contributions	\$0	\$0
Insurance claims & indemnities	\$0	\$0
Interest account	\$0	\$0
Receivables – collected	\$0	\$0
Total Non-Pay Costs	\$1,400,202	\$4,947,257
Total Obligations	\$2,266,797	\$13,216,014

Numbers have been rounded to the nearest dollar.

References

Allowable and excluded costs are described in section 4.3 - Appendix C.