FY 2016 BsUFA
FINANCIAL REPORT

REQUIRED BY THE

BIOSIMILAR USER FEE ACT OF 2012

FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

EXECUTIVE SUMMARY

The Biosimilar User Fee Act of 2012 (BsUFA) requires the Food and Drug Administration (FDA or the Agency) to report annually to Congress on the financial aspects of its implementation. This report covers fiscal year (FY) 2016 and is the fourth annual financial report submitted to Congress since the inception of BsUFA.

BsUFA specifies that the following two legal conditions must be satisfied each year for FDA to collect and spend biosimilar biological product user fees:

1. The fee amounts FDA may collect for each fiscal year must be specified in that year's appropriation acts.

2. FDA must allocate a minimum of $20,000,000 in non-user fee appropriations, multiplied by the adjustment factor applicable to that fiscal year, for the process for the review of biosimilar biological product applications.

FDA met the two legal conditions in FY 2016, and this report explains how they were satisfied. The statements and tables in the report also provide data on biosimilar biological product user fee collections, expenditures, and carryover balances.

In FY 2016, FDA had net collections of $26.9 million in BsUFA fees, spent $13.2 million in user fees for the BsUFA program, and carried a balance of $52.6 million forward to support the BsUFA program in future fiscal years. In FY 2016, FDA supported the BsUFA program with both BsUFA fees (29 percent) and non-user fee appropriations (71 percent).

BsUFA fees and non-user fee appropriations in FY 2016 supported 174 full-time equivalents, including salaries and operational expenses to support the staff responsible for the BsUFA program. Detailed program accomplishments can be found in the FY 2016 BsUFA Performance Report.

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1: BACKGROUND

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Biosimilar User Fee Act (BsUFA) (Title IV of the Food and Drug Administration Safety and Innovation Act), authorizes the Food and Drug Administration (FDA or the Agency) to collect user fees from the biosimilar biological product industry to supplement the non-user fee appropriations that the Agency spends on the process for the review of biosimilar biological product applications. FDA spends fee revenues and non-user fee appropriations to hire, support, and maintain personnel for the review of biosimilar biological product applications, and to help ensure that safe and effective biosimilar biological products reach the American public more quickly.

BsUFA establishes fees for certain activities in connection with biosimilar biological product development, for review of certain types of applications and supplements for biosimilar biological products, for approved biosimilar biological products, and for establishments where approved biosimilar biological products are made (sections 744H(a)(1)-(4), respectively, of the FD&C Act).

There are three types of fees for activities in connection with biosimilar biological product development: the initial biosimilar biological product development (BPD) fee, the annual BPD fee, and the reactivation fee. The initial BPD fee for a product is due when the sponsor submits an investigational new drug (IND) application that FDA determines is intended to support a biosimilar biological product application or within 5 calendar days after FDA grants the first BPD meeting for the product, whichever occurs first. The initial BPD fee rate for a fiscal year is equal to 10 percent of the fee rate established under the Prescription Drug User Fee Act (PDUFA) for a human drug application requiring clinical data for that fiscal year. A sponsor who has paid the initial BPD fee for a product is considered to be participating in FDA's BPD program for the product.

Once a sponsor has paid the initial BPD fee for a product, the annual BPD fee for the product is due on October 1 beginning in the next fiscal year. The annual BPD fee is assessed for the product each fiscal year until the sponsor either submits a marketing application for the product that is accepted for filing or discontinues participation in FDA's BPD program for the product not later than August 1 of the preceding fiscal year. The annual BPD fee rate for a fiscal year is also equal to 10 percent of the fee rate established under PDUFA for a human drug application requiring clinical data for that fiscal year.

The reactivation fee is assessed on a sponsor who previously discontinued participation in FDA's BPD program for a product, but wants to rejoin the BPD program for that same product. This fee is due when the sponsor submits an IND that FDA determines is intended to support a biosimilar biological product application or within 5 calendar days after FDA grants the sponsor's request for a BPD meeting for the product, whichever occurs first. The reactivation fee is equal to 20 percent of the fee rate established under PDUFA for a human drug application requiring clinical data for that fiscal year. Annual BPD fees will resume beginning in the fiscal year after the fiscal year in which the reactivation fee was paid.

In addition to the fees for biosimilar biological product development, sponsors must pay fees for certain marketing applications and supplements, and on approved biosimilar biological products and the establishments where they are manufactured in final dosage form. Application and supplement fees are due upon submission of the application or supplement. Establishment and product fees are due annually on October 1. The BsUFA application fee is equal to the human drug application fee under PDUFA, minus the cumulative amount of BPD and reactivation fees

already paid for the product that is the subject of the application. The BsUFA supplement fee is half the amount of the BsUFA application fee. Establishment and product fee rates under BsUFA are equal to the human drug establishment and product fee rates under PDUFA.

BsUFA requires FDA to submit a financial report to Congress no later than 120 days after the end of each fiscal year. This financial report addresses the implementation and use of biosimilar biological product user fees by FDA during the period October 1, 2015, through September 30, 2016. This report discusses the legal conditions that must be satisfied for FDA to collect and spend biosimilar biological product user fees each year and describes how FDA met those requirements. Additionally, this report presents summary statements of FY 2016 fee collections, carryover balances, obligations of user fees, and the total costs associated with the BsUFA program supported by both user fees and non-user fee appropriations.

2: LEGAL CONDITIONS

BsUFA imposes two legal conditions that must be satisfied for FDA to collect and spend biosimilar biological product user fees. A summary of how each of these legal conditions was satisfied in FY 2016 is shown below.

Legal Condition 1 – The amount of user fees collected for each fiscal year must be specified in that year's appropriation acts. The Consolidated Appropriations Act, 2016 (Public Law 114-113), which the President signed on December 18, 2015, made appropriations through September 30, 2016, for the salaries and expenses account of FDA. It specified that $21,540,000 shall be derived from BsUFA fees, and that BsUFA fees collected in excess of this amount are also appropriated for FDA. Thus, in FY 2016, the first legal condition was satisfied.

Legal Condition 2 – FDA may not spend BsUFA fees in a fiscal year unless it allocates a minimum of $20,000,000 in appropriated funds (excluding user fees), multiplied by the adjustment factor applicable to that fiscal year, for the BsUFA program. The specified minimum level for FY 2016 is $21,167,560. In FY 2016, FDA allocated and obligated $32,353,416 in appropriated funds (excluding user fees) for the BsUFA program, as defined in section 744G(13). Since FDA allocated and obligated more than the specified minimum amount in FY 2016, the second legal condition was satisfied.

References

Detailed explanations and calculations of how each of these legal conditions was satisfied in FY 2016 are described in section 4.1 - Appendix A.

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

Fees Collected	FY 2015	FY 2016
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
Total Collections	**$23,866,970**	**$26,123,040**

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.

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.

3.3 – CARRYOVER BALANCES

Introduction

BsUFA user fees collected, appropriated, and not obligated at the end of a fiscal year remain available to FDA in future fiscal years. These funds are referred to as carryover balances. The operations in FY 2016 resulted in a net increase of the carryover balance of $13,697,038—from $38,864,573 to $52,561,611.

Table 3 reflects the amount of fees collected net of any refunds or other adjustments that occurred during each fiscal year for all cohort years combined, and the amount obligated during the fiscal year. The numbers do not include any accounts receivable. Therefore the numbers for FY 2015 and FY 2016 may differ from the numbers which reflect the total net collections for the cohort years only, as shown in Table 1, section 3.1 – User Fee Collections.

Obligations in Table 3 include any recoveries and deobligations from prior years, which may cause differences from Tables 2 and 6. In FY 2016, FDA did not recover any prior-year BsUFA deobligations.

Data

Table 3 captures FDA's carryover balances at the beginning of each fiscal year from the first year of BsUFA implementation.

TABLE 3: BIOSIMILAR BIOLOGICAL PRODUCT USER FEE COLLECTIONS, OBLIGATIONS, AND CARRYOVER BALANCES BY FISCAL YEAR

Program	Fiscal Years	Beginning Carryover	Net Collection	Obligations	Year-End Carryover
BsUFA	2013	$0	$6,464,085	$0	$6,464,085
	2014	$6,464,085	$14,141,179	$2,317,402	$18,287,862
	2015	$18,287,862	$22,843,508	$2,266,797	$38,864,573
	2016	$38,864,573	$26,913,052	$13,216,014	$52,561,611

Numbers have been rounded to the nearest dollar.

3.4 – RESERVES AND BALANCE AVAILABLE FOR ALLOCATION

Introduction

BsUFA's carryover balance in FY 2016 is $52,561,611. There are anticipated claims on this balance that are described below. After subtracting these claims, FDA's total remaining carryover balance is $52,061,611.

Data

Table 4 provides a summary of carryover balances as of September 30, 2016, and anticipated claims on those balances.

TABLE 4: SUMMARY STATEMENT OF BIOSIMILAR BIOLOGICAL PRODUCT USER FEE CARRYOVER BALANCE AS OF SEPTEMBER 30, 2016

Status of Carryover Funds	Amount	Notes
Total Carryover Balance	$52,561,611	
Reserve for Refunds	($500,000)	A
Remaining Carryover Balance	**$52,061,611**	

Numbers have been rounded to the nearest dollar.

Notes

A. Prudent operations require that a reserve be kept aside for potential refunds. For that purpose, a total of $500,000 is being set aside.

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.

3.6 – FULL-TIME EQUIVALENT

Introduction

Full-Time Equivalent (FTE) is a measure of a paid staff year devoted to the BsUFA program. In this table, an FTE does not represent an accounting of individual people, but rather an estimate of labor hours expended on BsUFA activities on an FTE basis.

Data

Table 7 presents total FTE levels that support the BsUFA program by FDA organizational components (CDER, CBER, ORA, and HQ) for the last 4 fiscal years, paid from both user fees and non-user fee appropriations. Staff in the consolidated shared services organization (facilities, procurement, information technology (IT) services, etc.) are included in the FTE levels for the various components.

Due to a system upgrade that was in progress at the end of FY 2015, the typical data for that year's FTE calculations was unavailable. FDA had to estimate the breakdown for FY 2015 using an alternative methodology based on high-level FTEs. In FY 2016, after the system upgrade was complete, FDA was able to return to the normal methodology. This change in methodology has caused an overstatement of process FTEs for FY 2015. In addition, beginning in FY 2015, the calculation to determine the allocation of shared services FTEs among programs was amended to more accurately estimate labor hours expended on BsUFA activities. This recalculation includes the addition of the Office of Human Resources and a restructuring of the activities related to the Office of Information Management.

TABLE 7: HISTORICAL TREND OF TOTAL FTES UTILIZED BY ORGANIZATION AS OF SEPTEMBER 30 OF EACH FISCAL YEAR

Fiscal Year	CDER	CBER	ORA	HQ	Total
2013	87	4	0	7	98
2014	70	1	0	7	78
2015	137	0	5	11	153
2016	155	1	5	13	174

Numbers have been rounded to the nearest full FTE.

References

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

4: APPENDICES

4.1 – APPENDIX A: CONDITIONS FOR ASSESSMENT AND USE OF FEES

Introduction

The FD&C Act, as amended by BsUFA, specifies two legal conditions that must be met each fiscal year for FDA to collect and spend biosimilar biological product user fees. This appendix provides detailed descriptions of these conditions and explanations of how FDA met these conditions in FY 2016. A summary of the legal conditions is provided in section 2 – Legal Conditions.

Adjustment Factor

The "adjustment factor applicable to a fiscal year" referred to in section 744H(e)(2)(B) is defined in section 744G(1) of the FD&C Act. It provides that the adjustment factor applicable to a fiscal year is the Consumer Price Index (CPI) for all urban consumers (Washington-Baltimore, DC-MD-VA-WV; Not Seasonally Adjusted; All items) of the preceding fiscal year divided by the CPI for September 2011.

For FY 2016, the applicable adjustment factor, rounded to six decimal places, is 1.058378. It is calculated via the following: the numerator is the CPI for September 2015, 156.278; the denominator is the CPI for September 2011, 147.658. After applying the adjustment factor of 1.058378, the minimum appropriation spending level for the BsUFA program for FY 2016 is $21,167,560.

Legal Condition 1

The first legal condition, provided in section 744H(e)(2)(A) of the FD&C Act, states:

> Subject to subparagraphs (C) and (D), the fees authorized by this section shall be collected and available in each fiscal year in an amount not to exceed the amount specified in appropriation acts.

The Consolidated Appropriations Act, 2016 (Public Law 114-113), which the President signed on December 18, 2015, made appropriations through September 30, 2016, for the salaries and expenses account of FDA. It specified that $21,540,000 shall be derived from BsUFA fees, and that BsUFA fees collected in excess of this amount are also appropriated for FDA. Therefore, the first legal condition was satisfied for FY 2016.

Legal Condition 2

The second legal condition, provided in section 744H(e)(2)(B) of the FD&C Act, states:

> The fees authorized by this section shall be available for a fiscal year beginning after fiscal year 2012 to defray the costs of the process for the review of biosimilar biological product applications (including such costs for an additional number of full-time equivalent positions in the Department of Health and Human Services to be engaged in such process), only if the Secretary allocates for such purpose an amount for such fiscal year (excluding amounts from fees collected under this section) no less than $20,000,000 multiplied by the adjustment factor applicable to the fiscal year involved.

In other words, the second legal condition requires FDA to allocate a minimum of $20,000,000 in non-user fee appropriations, multiplied by the adjustment factor applicable to that fiscal year, 1.058378, for the costs of the BsUFA program.

In FY 2016, FDA obligations from appropriations (excluding user fees) for the BsUFA program were $32,353,416, which exceeded the required minimum of $21,167,560 by $11,185,856. Therefore, the second legal condition was satisfied, and the full amount of fees collected for FY 2016 will be retained for FDA to spend in subsequent fiscal years on the BsUFA program.

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).

4.3 – APPENDIX C: ALLOWABLE AND EXCLUDED COSTS FOR THE BSUFA PROGRAM

Introduction

Section 744G of the FD&C Act, as amended, defines the term "process for the review of biosimilar biological product applications" and the costs that may be included in that process. Fees may only be spent for activities that are included in this definition, although fee-generating activities are only a small subset of the activities that are included in this definition. FDA identifies those activities that are applicable to the BsUFA program in this appendix. In Appendix D, FDA describes how the costs for the BsUFA program are developed, based on the allowable activities identified below.

BsUFA Program Costs

Included Activities

Section 744G(13) of the FD&C Act defines the term "process for the review of biosimilar biological product applications" to mean the following activities of FDA with respect to the review of submissions in connection with biosimilar biological product development, biosimilar biological product applications, and supplements:

A. The activities necessary for the review of submissions in connection with biosimilar biological product development, biosimilar biological product applications, and supplements.

B. Actions related to submissions in connection with biosimilar biological product development, the issuance of action letters which approve biosimilar biological product applications or which set forth in detail the specific deficiencies in such applications, and where appropriate, the actions necessary to place such applications in condition for approval.

C. The inspection of biosimilar biological product establishments and other facilities undertaken as part of FDA's review of pending biosimilar biological product applications and supplements.

D. Activities necessary for the release of lots of biosimilar biological products under section 351(k) of the Public Health Service Act.

E. Monitoring of research conducted in connection with the review of biosimilar biological product applications.

F. Postmarket safety activities with respect to biologics approved under biosimilar biological product applications or supplements, including the following activities:

    i. Collecting, developing, and reviewing safety information on biosimilar biological products, including adverse-event reports.

    ii. Developing and using improved adverse-event data-collection systems, including IT systems.

iii. Developing and using improved analytical tools to assess potential safety problems, including access to external databases.

iv. Implementing and enforcing section 505(o) of the FD&C Act (relating to post-approval studies and clinical trials and labeling changes) and section 505(p) of the FD&C Act (relating to risk evaluation and mitigation strategies).

v. Carrying out section 505(k)(5) of the FD&C Act (relating to adverse-event reports and postmarket safety activities).

All costs represented by the above activities are collectively referred to in this report as costs for "the process for the review of biosimilar biological product applications."

Section 744G(9) of the FD&C Act defines the term "costs of resources allocated for the process for the review of biosimilar biological product applications" as the expenses in connection with the BsUFA program for:

A. Officers and employees of the FDA, contractors of FDA, advisory committees, and the costs related to such officers, employees, and committees, and to contracts with such contractors;

B. Management of information and the acquisition, maintenance, and repair of computer resources;

C. Leasing, maintenance, renovation, and repair of facilities and acquisition, maintenance and repair of fixtures, furniture, scientific equipment, and other necessary materials and supplies; and

D. Collecting fees under section 744H and accounting for resources allocated for the review of submissions in connection with biosimilar biological product development, biosimilar biological product applications, and supplements.

Excluded Activities

The following types of products are not subject to BsUFA fees, and FDA excludes from the BsUFA program activities in connection with the following types of applications for licensure under section 351(k) of the Public Health Service Act:

- Applications that cite as the reference product a product approved before September 1, 1992, that is either a bovine blood product for topical application or a large-volume parenteral drug;

- Allergenic extract products;

- Whole blood or a blood component for transfusion;

- In vitro diagnostic biologic products; and

- A biological product for further manufacturing use only.

Excluded Process Activities

BsUFA fees may not be spent on the following types of activities:

- Enforcement policy development not related to sections 505(o) and (p) of the FD&C Act;
- Post-approval compliance activities not related to the enforcement of sections 505(o) and (p) of the FD&C Act;
- Advertising review activities once marketing of the product has begun;
- Inspections unrelated to the review of covered applications, unless undertaken for the enforcement of sections 505(o) and (p) of the FD&C Act; and
- Research unrelated to the BsUFA program.

4.4 – APPENDIX D: DEVELOPMENT OF COSTS FOR THE BSUFA PROGRAM

General Methodology

The costs associated with the BsUFA program are based on obligations attributed to CDER, CBER, ORA, and HQ. These organizations correspond to the cost categories presented as follows:

Cost Category	FDA Organization
Costs for the review of biosimilar biological product applications and supplements (including costs in connection with FDA's BPD program)	CDER and CBER
Field Inspection and Investigation Costs	ORA
Agency General and Administrative Costs	HQ

The costs for each component are shown in Table 5. They were derived using time-reporting systems in CDER, CBER, and ORA, and were calculated for HQ as described in more detail in this appendix. Using the definitions of costs and activities included in the BsUFA program, as explained in Appendix C, the cost categories within each organization listed above were identified as parts of the biosimilar biological product application review process.

Center Costs

Costs of the BsUFA program are tracked for each organizational component in CDER and CBER, usually at the division level. Most FDA components involved in the BsUFA program perform a mixture of activities – some within the scope of the BsUFA program, and some not. FDA groups its organizational components into three categories:

- direct review and laboratory,
- indirect review and support, and
- center-wide costs.

The allocation of costs for each category is discussed below.

Direct Review and Laboratory

Employees in all components of CDER and CBER, other than those noted below as Center indirect review and support components, are required to report their time for a total of 8 weeks (2 weeks per quarter) each fiscal year in activity-based time reporting systems. The activities in the systems allow identification of the nature of the activity, so that time reported can be separated into allowable and excluded activities as defined by BsUFA. The average percentage of time reported on the BsUFA program in CDER and CBER is applied to all costs incurred for the entire fiscal year in those Centers. This method provides an estimate of each Center's costs incurred while conducting the BsUFA program in FY 2016.

Indirect Review and Support

Indirect review and support components provide the infrastructure for the review process. In CDER, these components include portions of the Office of the Center Director, the Office of Strategic Programs, the Office of Management, the Office of Communications, and the Office of Executive Programs. In CBER, these components include portions of the Office of the Center Director, Office of Management, and the Office of Communications, Outreach, and Development. Most employees of these components do not report their time.

FDA assumes the time of management and administrative personnel supporting the BsUFA program is equivalent to the proportion of time Center employees in direct review and laboratory components spend on the BsUFA program. Thus, the average percentage of time expended on BsUFA program activities for all direct review and laboratory components in FY 2016 was applied to all costs incurred for the entire fiscal year by the indirect review and support components.

Center-Wide Costs

A number of Center-wide and Agency-wide expenses are paid from the central accounts of the Center or of FDA rather than from funds allocated to a specific Center, division, or office within the Center. These costs include rent, telecommunications and utility costs, some computer equipment and support costs, and costs of the Office of Shared Services, which supports all FDA programs and activities. A percentage of these Center and FDA-wide costs are chargeable to the BsUFA program. That percentage is either a specific amount that is supported by independent documentation or is the amount of time reported for allowable activities (direct and indirect) in the Center, as a percentage of total time reported for all Center direct and indirect activities.

As in prior years, resources expended in FY 2016 by the Office of Shared Services to support the BsUFA program are reported as if they were incurred in CDER, CBER, ORA, or HQ.

Field Inspection and Investigation Costs

ORA incurs all field inspection, investigation, and laboratory analyses costs. ORA costs are incurred in both district offices (the “field”) and headquarters offices, which are tracked in the Field Accomplishment and Compliance Tracking System (FACTS). FACTS is a time and activity tracking system that captures time spent in a variety of categories, including inspections of manufacturing facilities, investigations of clinical studies, and analytical testing of samples, which are all part of the BsUFA program.

Table 9 summarizes the calculation of ORA costs for the BsUFA program for FY 2015 and FY 2016.

Total direct hours reported in FACTS are used to calculate the total number of FTEs required by ORA to perform these activities. In addition to the direct time, an allocation of support time is also included to represent the work done by ORA administrative and management personnel.

The Agency multiplies the total number of FTEs used in the BsUFA program by the average salary and benefits cost in ORA to arrive at ORA salary and benefits costs for work that is within the scope of the BsUFA program.

The Agency then allocates ORA obligations for operations and other costs to the human drug review activities based upon the ratio of user fees related FTEs to total ORA FTEs.

ORA costs for the BsUFA program described below include costs paid from non-user fee appropriations and costs paid from fee revenues.

TABLE 9: ORA COSTS OF THE BSUFA PROGRAM AS OF SEPTEMBER 30, 2015 AND 2016

Cost Component	FY 2015	FY 2016
FTE Utilized	5	5
ORA Average Salary and Benefits	$124,714	$124,404
Total Salary and Benefits	$623,570	$622,020
Operating and Other Costs[2]	$512,476	$894,970
Total	**$1,136,046**	**$1,516,990**

Numbers have been rounded to the nearest dollar.

[2] Other costs are central, GSA, rent, rent-related and shared services costs that are applicable to the BsUFA program.

Agency General and Administrative Costs

The Agency general and administrative costs include all costs incurred in FDA's HQ that are attributable to the Office of the Commissioner and all other FDA headquarters components that are not Centers or ORA. For the purpose of these calculations, HQ is considered to comprise the following offices:

- Immediate Office of the Commissioner
- Office of the Counselor to the Commissioner
- Office of Policy, Planning, Legislation, and Analysis
- Office of External Affairs
- Office of the Executive Secretariat
- Office of the Chief Counsel
- Office of Minority Health
- Office of Women's Health
- Office of the Chief Scientist (excluding the National Center for Toxicological Research)
- Office of Operations
- Office of Foods and Veterinary Medicine (excluding the Center for Food Safety and Applied Nutrition and the Center for Veterinary Medicine)
- Office of Medical Products and Tobacco (excluding CDER, CBER, the Center for Devices and Radiological Health, and the Center for Tobacco Products)
- Office of Global Regulatory Operations and Policy (excluding ORA)

In summary, the HQ costs include all of FDA except for the six product-oriented Centers, ORA, and the National Center for Toxicological Research.

The HQ costs applicable to the BsUFA program were calculated using a method prescribed by the Division of Cost Determination Management, Office of Finance, Office of the Secretary, Department of Health and Human Services. The method uses the percentage derived by dividing total HQ costs by the total FDA salary expenses (excluding benefits) after subtracting the salary expense (excluding benefits) from HQ. That percentage is then multiplied by the total salaries (excluding benefits) applicable to the BsUFA program in CDER, CBER, and ORA to derive the applicable Agency general and administrative costs.

Using this methodology, FDA dedicated $3,564,356 in general and administrative costs to the BsUFA program in FY 2016. The costs are total costs obligated from user fees and non-user fee appropriations and are approximately 8 percent of the FY 2016 BsUFA program costs.