FY 2019 BsUFA
FINANCIAL REPORT

REQUIRED BY THE

BIOSIMILAR USER FEE ACT

FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Executive Summary

The Biosimilar User Fee Act (BsUFA), as amended, requires the Food and Drug Administration (FDA) to report annually on the financial aspects of BsUFA implementation. This is the second report under the second authorization of BsUFA (namely, BsUFA II) and covers fiscal year (FY) 2019.

BsUFA specifies that the following two legal conditions must be satisfied each year for FDA to collect and spend BsUFA 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 million 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 2019, and this report explains how these legal conditions were satisfied. The statements and tables in the report provide data on biosimilar biological product user fee collections, expenditures, and carryover balances, as well as comparative data from prior years.

In FY 2019, FDA had net collections of $35 million in BsUFA fees, spent $42 million in user fees for the BsUFA program, and carried forward a cumulative balance of $32 million for future fiscal years.

BsUFA user fees and non-user fee appropriations in FY 2019 supported 184 full-time equivalents, including salaries and operational expenses, to support the process for the review of biosimilar biological product applications. Detailed program accomplishments can be found in the FY 2019 BsUFA Performance Report.

Report Overview

A. Scope

This financial report addresses the implementation of the Biosimilar User Fee Act (BsUFA) by the Food and Drug Administration (FDA or the Agency) and FDA's use of biosimilar biological product user fees during the period of October 1, 2018, through September 30, 2019. This report presents the legal conditions that must be satisfied for FDA to collect and spend biosimilar biological product user fees each year and documents how FDA has determined that those requirements were met. In addition, this report presents summary statements of FY 2019 fee collections, carryover balances, obligations of user fees, and total costs of the process for the review of biosimilar biological product applications from both BsUFA fees and non-user fee appropriations.

B. Report Requirements

In accordance with section 744I(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), FDA shall prepare and submit to Congress an annual financial report on FDA's implementation of its authority for biosimilar biological product user fees during each fiscal year and the use by FDA of the fees collected for such fiscal year. The purpose of this report is to meet these requirements.

FDA is required to submit the financial report to Congress no later than 120 days after the end of each fiscal year (September 30). Additional details on financial reporting requirements and commitments addressed by this report are included in **Appendix A**.

Management Discussion

C. Organization Background

FDA is responsible for protecting the public's health (1) by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices and (2) by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation. FDA also has responsibility for regulating the manufacturing, marketing, and distribution of tobacco products and for helping to speed innovations that make medical products more effective, safe, and affordable and by helping the public get accurate, science-based information needed to use medical products and consume foods to maintain and improve their health. FDA similarly plays a significant role in the nation's counterterrorism capability. FDA fulfills this responsibility by ensuring the security of the food supply and by fostering development of medical products to respond to deliberate and naturally emerging public health threats.

Program Organization

There are four major FDA components 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 Headquarters (HQ).

Exhibit 1 provides an overview of the mission for each of these components.

Exhibit 1: User Fee Program Components

Component	Mission
CDER	Protects and promotes the public's health by helping to ensure that human drugs are safe and effective, meet established quality standards, and are available to patients.
CBER	Protect and enhance the public's health through the regulation of biological and related products including blood, vaccines, allergenics, tissues, and cellular and gene therapies.
ORA	Protects consumers and enhances public health by maximizing the compliance of FDA-regulated products and by minimizing the risk associated with those products.
HQ	Provides FDA-wide program direction and administrative services to ensure FDA's consumer and patient safety programs are effectively and efficiently managed.

User Fee Governance

The Agency's expanding level of user fees, the reporting of Agency performance commitments associated with these fees, and the need for FDA to convey how these fees are executed calls for strong financial governance. This financial governance includes an understanding of the design of the user fee programs, clear financial plans, data-driven decisions on resource allocation, consistency and transparency about assumptions, reliable financial forecasting, and accountability for resources spent.

FDA's user fee governance process leverages the User Fee Financial Management Committee, which consists of senior financial, business operations, and program experts across the Agency that evaluate user fee resource needs, develop financial allocation plans, and forecast resource requirements – both programmatic and administrative – to support user fee financial decisions. The User Fee Financial Management Committee is responsible for providing oversight and support of appropriate standards and policies to ensure FDA compliance with sound financial management practices, as well as compliance with statutory provisions that authorize FDA to collect and spend user fees. The User Fee Financial Management Committee receives policy guidance and strategic direction directly from FDA's Executive Committee relative to how the Agency will forecast and react to industry trends, plan and manage its research agenda in support of the user fee programs, and forecast its user fee workload. The User Fee Financial Management Committee advises the Executive Committee and other Center- and Office-level bodies on a variety of financial and performance related topics.

D. User Fee Background and Structure

Under BsUFA, FDA collects fees from biosimilar biological product manufacturers to fund the biosimilar biological product review process. The FD&C Act, as amended by BsUFA, authorizes FDA to collect fees from industry to supplement non-user fee appropriations that the Agency spends on the process for the review of biosimilar biological product applications.

BsUFA II was authorized under the FDA Reauthorization Act of 2017 (FDARA) from October 1, 2017, through September 30, 2022. The 5-year reauthorization authorizes continued funding for FDA from FY 2018 through FY 2022 to support the efficiency and effectiveness of the biosimilar biological product review program. BsUFA II continues to enhance FDA's capacity to facilitate timely access to safe and effective biosimilar medicines for patients.

FDA spends BsUFA user fee collections and non-user fee appropriations to hire, support, and maintain personnel for the review of biosimilar biological product applications to help ensure that safe and effective biosimilar biological products are available to the American public.

BsUFA II establishes an efficient user fee structure comprised of initial and annual biosimilar biological product development (BPD) fees, reactivation fees, biosimilar biological product application fees, and biosimilar biological product program fees. This structure is intended to enhance FDA's predictability of funding, reduce administrative inefficiencies, and improve FDA's management of funding.

Exhibit 2 outlines the BsUFA II user fee structure.

Exhibit 2: BsUFA II Fee Structure

Fee Type		Definition
Biosimilar Biological Product Development (BPD)	*Initial*	Initial BPD fee is a one-time fee that is assessed to a sponsor to enter the BPD program.
	Annual	Beginning in the next fiscal year after a sponsor has paid the initial BPD fee, the sponsor must pay an annual fee for the product in each fiscal year.
	Reactivation	A sponsor that has discontinued participation in the BPD program for a product and wants to resume participation in the BPD program for that product must pay a reactivation fee.
Application	*With Clinical Data*	A biosimilar biological product application for which clinical data (other than comparative bioavailability studies) with respect to safety or effectiveness are required for approval is assessed **a full application fee** when the application is submitted.
	Without Clinical Data	A biosimilar biological product application for which clinical data (other than comparative bioavailability studies) with respect to safety or effectiveness are not required for approval is assessed **one-half of a full application fee**.
Program		Biosimilar biological product program fees are assessed annually for eligible products.

The statute specifies how the fees must be calculated each fiscal year, including annual adjustments that must be made for inflation. The fee amounts are to be published in the *Federal Register* each year;[1] this typically occurs at the beginning of August.

BsUFA user fees are not a fee-for-service. These user fees are pooled and may be used for the allowable activities, as set forth in the FD&C Act. Refer to **Appendix B** for a detailed list of allowable and excluded activities.

Appendix C provides more information on the history of the BsUFA user fee program.

E. Legal Conditions

The FD&C Act, as amended by BsUFA, specifies that two legal conditions must be satisfied each year for FDA to collect and spend biosimilar biological product user fees. **Exhibit 3** describes those legal conditions and provides a brief explanation as to how those legal conditions were met for FY 2019.

[1] See the BsUFA user fee rates archive at https://www.fda.gov/industry/biosimilar-user-fee-amendments/bsufa-user-fee-history.

Exhibit 3: BsUFA II Legal Conditions

Legal Condition #	Details	
1	Description	The amount of user fees collected for each fiscal year must be specified in that year's appropriation acts.
	Met By	The Consolidated Appropriations Act, 2019 (Public Law 116-6), which the President signed on February 15, 2019, made appropriations through September 30, 2019, for the salaries and expenses account of FDA. This act specified that $38,847,000 shall be derived from BsUFA fees and that BsUFA fees collected in excess of this amount shall be appropriated for FDA. Thus, in FY 2019, the first legal condition was satisfied.
2	Description	FDA may not spend BsUFA fees in a fiscal year unless it allocates a minimum of $20 million in appropriated funds (excluding user fees), multiplied by the adjustment factor applicable to that fiscal year, for the BsUFA program. The statute provides that FDA will be considered to have met this requirement in a fiscal year if at least an amount that is 15 percent below the minimum level is spent.
	Met By	The specified minimum level for FY 2019 is $22,038,420. In FY 2019, FDA allocated and obligated $23,152,080 in appropriated funds (excluding user fees) for the BsUFA program. Because FDA allocated and obligated more than the specified minimum amount in FY 2019, the second legal condition was satisfied.

The legal conditions as stated in FD&C Act and details on the adjustment factor are included in **Appendix D.**

F. Strategic Plan

As part of BsUFA II, FDA will continue to facilitate the development of biosimilar biological products (including interchangeable biosimilars) through the strategic development of FDA's biosimilar biological product review program and through an ongoing clarification of the approval pathway for these products. In 2018, FDA developed the Biosimilars Action Plan (BAP), which advances policies to facilitate the efficient development and review of biosimilar biological products. FDA continues to effectively allocate its fiscal and human resources to support these priorities and address challenges and opportunities for the continued development of FDA's biosimilar biological product review program. The deliverables described in the BAP are in various stages of progress, and many of the deliverables have been accomplished. This plan aligns with FDA's strategic priorities and reflects FDA's commitments in the BsUFA II goals letter,[2] innovations in regulatory science, and expanded opportunities for collaboration.

To better support these objectives, FDA transitioned the Therapeutic Biologics and Biosimilars Staff (TBBS) to the Office of Therapeutic Biologics and Biosimilars (OTBB) in March 2019. The establishment of OTBB is intended to improve coordination and support of all activities under the BsUFA program, accelerate responses to stakeholders, and support efficient operations and policy development. The Agency intends to utilize user fee resources, including the carryover balance, to fulfill these priorities, build staff capacity for OTBB, launch the new scientific staffing capability to enhance hiring and retention, and implement relevant portions of the 21st Century Cures Act. Other OTBB ongoing activities

[2] The BsUFA II goals letter, Biosimilar Biological Product Reauthorization Performance Goals and Procedures Fiscal Years 2018 Through 2022, is available at www.fda.gov/downloads/ForIndustry/UserFees/BiosimilarUserFeeActBsUFA/UCM521121.pdf.

include the development and implementation of new FDA review tools, including standardized review templates; the publication of timely guidance for sponsors to provide scientific and regulatory predictability; and the modernization of the Purple Book[3] to include more information about licensed biological products.

FDA will continue to play a critical role in facilitating increased access to biosimilars. FDA is committed to transparent, science-based regulation of biosimilar biological products that maintains the dynamic balance between innovation and timely access, as Congress intended.

G. Performance Summary

FDA agreed to certain performance goals and other commitments as part of the BsUFA II goals letter. For FY 2019, there were 25 performance goal categories for the BsUFA user fee program. The workload associated with maintaining these performance goals varies from year to year and has a substantial effect on finances. Preliminary data indicate that FDA has the potential to meet or exceed 15 of the 25 goals that apply to the FY 2019 cohort once these actions are completed. In FY 2019, FDA did not meet the review goal for resubmitted original biosimilar applications and did not meet certain meeting management goals for BsUFA meetings. The resubmitted original biosimilar applications cohort was small; a single missed goal resulted in a drop below the performance goal. Several factors affected the ability to meet the meeting management goals, including a small number of meeting requests for certain meeting types, and a single missed goal resulted in a large percentage impact on performance. Other factors that affected the ability to meet the meeting management goals included an increasing resource-intensive meeting workload, common across all user fee programs, which created a strain on the same set of key staff within relevant offices/divisions.

Details on the program performance can be found in the FY 2019 BsUFA Performance Report, which is available at www.fda.gov.

Financial Information

This section provides an overview of the program financials for BsUFA for FYs 2018 and 2019. These financials include user fee revenues, obligations, carryover, non-user fee appropriations, and full-time equivalents (FTEs).

H. User Fee Program Financials

Table 1 represents a summary of the BsUFA financial position for FY 2018 and FY 2019. The financial notes can be found in **Appendix E**

[3] https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/purple-book-lists-licensed-biological-products-reference-product-exclusivity-and-biosimilarity-or

Table 1: Biosimilar Biological Product User Fee Collections, Obligations, and Carryover for Fiscal Years 2018 and 2019

Budgetary Resources	Notes	FY 2018	FY 2019
Target Revenue	Note 1	**$40,214,000**	**$38,847,000**
Total Carryover, Beginning of Year		$48,723,308	$38,757,343
Net Collections		$29,238,601	$34,685,713
Recoveries	Note 2	$1,074,997	$456,236
Total Budgetary Resources		**$79,036,907**	**$73,899,291**

Obligations	Notes	FY 2018	FY 2019
Total Payroll & Operating	Note 3	$34,535,211	$35,210,375
Total Rent	Note 4	$1,104,785	$1,382,811
Total Shared Services	Note 5	$4,639,568	$5,465,202
Total Obligations		**$40,279,564**	**$42,058,388**

Carryover	Notes	FY 2018	FY 2019
Total Carryover, End of Year		**$38,757,343**	**$31,840,903**

The Target Revenue has been rounded to the nearest thousand dollars.
All other numbers have been rounded to the nearest dollar.

Budgetary Resources: The "Budgetary Resources" component of **Table 1** illustrates the sum of available user fee funding (i.e., the existing available carryover balance and additional user fee collections) that was used to fund obligations. The "Target Revenue" component is the annual revenue amount established when fees for the fiscal year are set. The "Net Collections" component is the amount collected during the fiscal year.

BsUFA II specifies how the fees must be calculated for each fiscal year, including annual adjustments for inflation and changes in the capacity needs of the program. FDA applies those adjustments, as appropriate, in the target revenue for annual fee setting – see **Table 2**.

Obligations: The "Obligations" component of **Table 1** shows the annual expenditure of BsUFA fee funds broken out into major expense categories. BsUFA fees may be expended only for costs to support the "process for the review of biosimilar biological product applications," as defined in BsUFA II. For more information on the allowable and excluded costs, see **Appendix B.**

Carryover: BsUFA fees are available until expended. This means that the fees that are collected, appropriated, and not obligated at the end of a fiscal year remain available to FDA for use in future fiscal years. The unobligated BsUFA funds at the end of each fiscal year are referred to as the "total carryover," as shown in **Table 1**. Maintaining an appropriate level of carryover enables FDA to mitigate financial risks to the program, including, for example, the risk of under collecting fees and the risk of a lapse in appropriations, so that FDA can continue program operations under such financial constraints.

I. User Fee Revenue

Table 2 outlines the estimated annual target revenue amounts for FY 2019. The financial notes referenced in this table can be found in **Appendix E.**

Table 2: Biosimilar Biological Product Revenue and Collections Statement for FY 2019

Target Revenue	Notes	FY 2019
Base Amount		$40,214,000
Inflation Adjustment	Note 6	$733,463
Capacity Planning Adjustment	Note 7	N/A
Operating Reserve Adjustment	Note 8	($2,100,000)
Target Revenue Total	Note 1	**$38,847,000**

Base Amount/Target Revenue numbers have been rounded to the nearest thousand dollars. All other numbers have been rounded to the nearest dollar.

The process for setting the annual target revenue is defined in the statute. The base amount for FY 2019 is defined in the statute and is adjusted for the following factors, if applicable: inflation adjustment, capacity planning adjustment, and operating reserve adjustment. Please refer to the respective notes for more details and a definition of each adjustment.

Under BsUFA II, user fees include BPD fees (initial BPD fees, annual BPD fees, and reactivation fees), biosimilar biological product application fees, and biosimilar biological product program fees. User fee collections are recognized and reported in the year the fee was originally due (referred to as the "cohort year"). 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 annually updates the prior years' numbers.

Cohort Year

The year in which user fee collections are originally due and reported. For example, a fee originally due in FY 2019 but received in FY 2020 is attributed to FY 2019 collections.

FDA issues invoices for BPD and program fees twice a year: in August for fees due on October 1, and in December after the close of the fiscal year for the new BPD and program fees not previously assessed.

Under BsUFA, by the end of the fiscal year, fees collected and appropriated (but not obligated) continue to remain available to FDA in future years. The balance carried over from year to year is described in **Section K – User Fee Carryover**.

Table 3 outlines BsUFA collections by fee source and cohort year. Refer to **Section D** for more background and information on the BsUFA II fee structure.

Table 3: Biosimilar Biological Product User Fee Collections by Fee Source for Cohort Years 2018 and 2019

Fees Collected	Cohort Year 2018			Cohort Year 2019		
	Estimated†	Actual	% Dif.	Estimated†	Actual	% Dif.
BPD Fees	$14,768,857	$17,040,975	15%	$16,130,569	$16,130,583	0%
Application Fees	$22,707,685	$9,170,411	-60%	$15,720,705	$12,227,215	-22%
Program Fees	$2,737,458	$2,433,296	-11%	$6,995,726	$6,995,726	0%
Total Collections	**$40,214,000**	**$28,644,682**	**-29%**	**$38,847,000**	**$35,353,524**	**-9%**

Fees Receivable	Actual	Actual
BPD Fees	$227,213	$185,409
Application Fees	$0	$0
Program Fees	$0	$0
Total Receivables	**$227,213**	**$185,409**

Numbers have been rounded to the nearest dollar.
†Estimated values were taken from the BsUFA user fee rates for FY 2018 and FY 2019.

J. User Fee Obligations

BsUFA fees may be expended only for costs of the "process for the review of biosimilar biological product applications," as defined in BsUFA II. For more information on the allowable and excluded costs, see **Appendix B.**

Table 4 provides a comparison of user fee obligations by expense category during the past 2 fiscal years. The financial notes can be found in **Appendix E**.

Table 4: Biosimilar Biological Product User Fee Obligations by Expense Category for FYs 2018 and 2019

User Fee Obligations	Notes	FY 2018	FY 2019
Payroll & Operating	Note 3		
CBER		$0	$0
CDER		$31,113,433	$33,004,440
ORA		$1,128,256	$676,738
HQ		$2,293,521	$1,529,197
Total Rent	Note 4	$1,104,785	$1,382,811
Total Shared Services	Note 5	$4,639,586	$5,465,202
Total Obligations		**$40,279,564**	**$42,058,388**

Numbers have been rounded to the nearest dollar.

Total obligations include payroll and operating, rent, and shared services costs. The details of each component of total obligations is as follows:

- **Payroll and Operating:** These obligations provide for all payroll and operating costs that support the allowable activities for which BsUFA fees may be expended, as set forth in the

statute. Payroll and operating includes, for example, core regulatory review functions, pre-approval inspections, guidance and policy development activities, scientific activities, and management and administrative functions that support the BsUFA program.

- **Rent:** This is paid to the General Services Administration (GSA) for the federal buildings that FDA occupies, as well as to non-federal sources for direct leases and services. Rental rates vary based on the type and location of the space provided.
- **Shared Services:** FDA has several shared service organizations that provide support across the user fee programs, such as human resources and information technology (IT).

In FY 2019, FDA obligated roughly $1.8 million, or 4 percent, more in BsUFA funding than it did in FY 2018. This increase is commensurate with the growth in the overall size of the BsUFA program.

For historical context, **Table 5** provides the total amount spent, inclusive of user fee funds and non-user fee funds, by FDA and by each relevant FDA organization on the BsUFA program for the past 5 years.

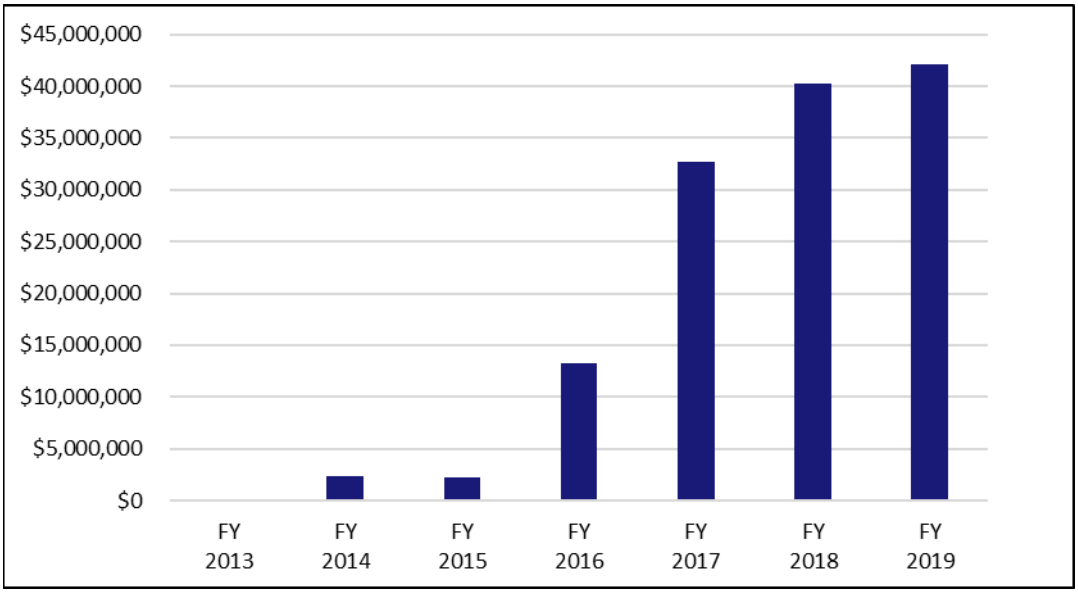
Table 5: BsUFA Program – Historical Trend of Total Costs by Organization as of September 30 of Each Fiscal Year

Costs		FY 2015	FY 2016	FY 2017	FY 2018	FY 2019
Total Spent		$34,817,217	$45,569,429	$55,814,043	$62,604,122	$65,210,467
CBER	Spent	$39,841	$203,767	$155,952	$465,335	$963,752
	Percent	0%	0%	0%	1%	2%
CDER	Spent	$30,604,475	$40,284,316	$48,863,293	$55,471,096	$58,878,375
	Percent	88%	88%	88%	89%	90%
ORA	Spent	$1,136,046	$1,516,990	$2,629,013	$1,909,924	$1,226,634
	Percent	3%	3%	5%	3%	2%
HQ	Spent	$3,036,855	$3,564,356	$4,165,785	$4,757,767	$4,141,706
	Percent	9%	8%	7%	8%	6%

Numbers have been rounded to the nearest dollar.

Exhibit 4 below provides an illustration of the historical BsUFA obligations.

Exhibit 4: Historical User Fee Obligations by Fiscal Year



As demonstrated by this graph, there was a significant increase in BsUFA user fee obligations from the end of BsUFA I into BsUFA II. This increase reflects the transition from a brand-new program to a maturing program. This increase was less pronounced in FY 2019, with a modest four percent increase in BsUFA fee expenditures.

K. User Fee Carryover

BsUFA fees collected, appropriated, and not obligated at the end of the fiscal year remain available to FDA in future fiscal years. This balance is referred to as the BsUFA "carryover."

Maintaining an appropriate level of carryover enables FDA to mitigate financial risks to the program, including, for example, the risk of under collecting fees and the risk of a lapse in appropriations. FDA considers a reasonable range of carryover for the BsUFA program to maintain in anticipation of these risks to be about 21 weeks. Please see additional discussion in **Section O**. FDA notes that this reasonable range is higher for BsUFA than for the Prescription Drug User Fee Act or the Generic Drug User Fee Amendments. This is because BsUFA is a much smaller program, as measured by workload or planned expenditures, and small shifts in submissions could have a significant impact on workload and the requisite funding needed to maintain operations.

Carryover can be broken out into the following two categories:

- **Carryover Unavailable for Use** – This value represents carryover funds subject to claims or restrictions that preclude FDA from obligating the carryover funds.
- **Carryover Available for Use** – This value represents carryover funds that are not subject to any claims or restrictions and are therefore available for obligation.

The net change in carryover balance each year is equal to net collections minus net obligations. This value is demonstrated best in **Table 1** above.

Table 6 provides the BsUFA carryover balances, recoveries, claims, and restrictions for FY 2018 and FY 2019.

Table 6: BsUFA Carryover Balances for FYs 2018 and 2019

Carryover	Notes	FY 2018	FY 2019
Total Carryover, End of Year		**$38,757,343**	**$31,840,903**
Refunds	Note 9	($500,000)	($500,000)
Carryover Unavailable for Use, End of Year		**($500,000)**	**($500,000)**
Carryover Available for Use, End of Year		**$38,257,343**	**$31,340,903**

Numbers have been rounded to the nearest dollar.

To determine how much carryover is available for obligation at the end of a fiscal year, the following factors must be considered:

- **Total Carryover, End of Year** – This is the total amount of unobligated fee funds at the end of the fiscal year.
- **Carryover Unavailable for Use, End of Year** – As noted above, this value includes unobligated fee funds subject to any claims or restrictions on fees collected. This includes:
    - **Refunds** – FDA maintains a small amount to provide for any refunds, as a matter of prudent operations. For that purpose, a total of $500,000 is being set aside. See **Note 9** for additional details.
- **Carryover Available for Use, End of Year** – As noted above, this is the total carryover less any carryover unavailable for use. These funds become the carryover available for use at the beginning of the next fiscal year.

The operations in FY 2019 resulted in a net decrease of the total carryover balance of $6,916,440, from $38,757,343 at the end of FY 2018 to $31,840,903 at the end of FY 2019. The primary drivers of this reduction in the available carryover balance was an increase in obligations, as noted in **Exhibit 4**, and net collections in FY 2019 were approximately 9 percent less ($4M) than expected (i.e., the target revenue).

Table 7 reflects the historical amount of fees collected and obligated during the previous and current reauthorization periods.

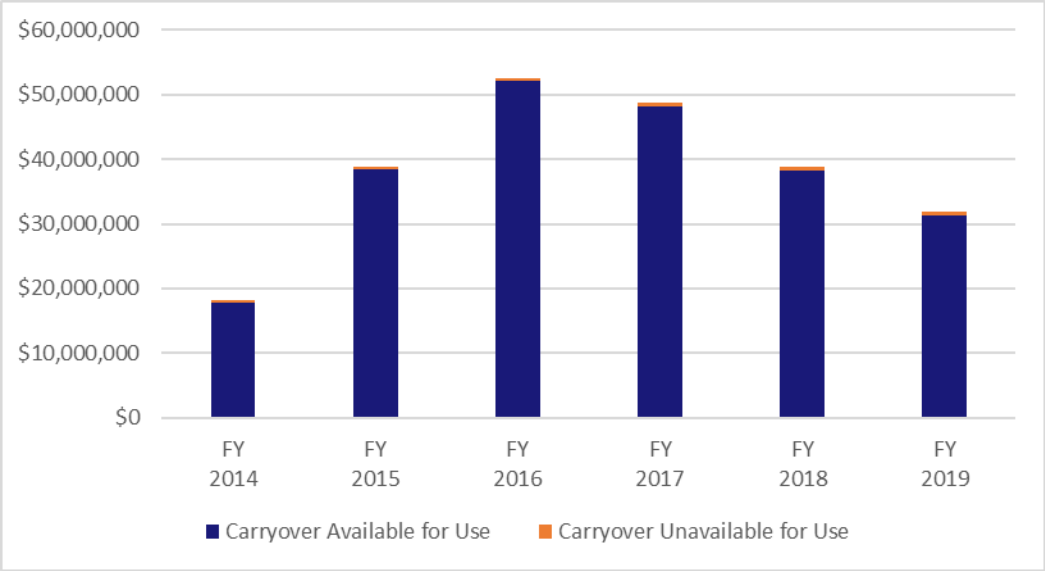
Table 7: Historical Biosimilar Biological Product User Fee Collections, Obligations, and Carryover Balances by Reauthorization Period

Carryover	Notes	BsUFA I	BsUFA II	
		FY 2013 – 2017	FY 2018	FY 2019
Total Carryover, Beginning of Year		**$0**	**$48,723,308**	**$38,757,343**
Net Collections		$99,201,695	$29,238,601	$34,685,713
Recoveries	Note 2	$39,497	$1,074,997	$456,236
Total Obligations		($50,478,387)	($40,279,564)	($42,058,388)
Total Carryover, End of Year		**$48,723,308**	**$38,757,343**	**$31,840,903**

Numbers have been rounded to the nearest dollar.

Exhibit 5 provides a historical perspective of carryover for the last 5 fiscal years. As exhibited by the graph, carryover had trended upward until recently. This is because FDA implemented mitigation strategies to manage the carryover balance. This is illustrated by the decrease in the carryover amount for the past 3 fiscal years.

Exhibit 5: Historical Carryover by Fiscal Year



L. Non-User Fee Appropriations

For FDA to obligate user fees collected under BsUFA, a certain amount of non-user fee appropriations must be spent on the process for the review of biosimilar biological product applications during a fiscal year. This is often referred to as a "non-user fee spending trigger."[4] The spending trigger was $21,711,380 for FY 2018 and $22,038,420 for FY 2019.

The non-user fee spending trigger amount is determined by multiplying the base amount of non-user fee appropriations spent on the biosimilar biological product review process ($20 million) times the adjustment factor for the fiscal year. See **Note 10** for more details on the adjustment factor.

Table 8 provides the total amount spent on the BsUFA program for the past 5 years and the dollar amount and percentages derived from user fees and non-user fee appropriations. The percentages attributable to BsUFA fees have increased over time.

[4] The statute provides that this requirement is met if at least an amount that is 15 percent below the minimum level is spent (see section 744H(f)(2)(C) of the FD&C Act).

Table 8: Historical Biosimilar Biological Product User Fee Obligations by Funding Source as of September 30 of Each Fiscal Year

Obligations		FY 2015	FY 2016	FY 2017	FY 2018	FY 2019
Total Obligated		$34,817,217	$45,569,430	$55,814,043	$62,604,122	$65,210,467
Non-User Fee Appropriations	Total	$32,550,420	$32,353,416	$23,096,373	$22,324,558	$23,152,080
	Percent	93%	71%	41%	36%	36%
User Fee Revenue	Total	$2,266,797	$13,216,014	$32,717,670	$40,279,564	$42,058,388
	Percent	7%	29%	59%	64%	64%

Numbers have been rounded to the nearest dollar.

M. FTEs

"FTE employment" (often referred to as "staff year"), as defined by the Office of Management and Budget (OMB) Circular A-11, section 85, means the total number of regular straight-time hours—not including overtime or holiday hours—worked by employees, divided by the number of compensable hours applicable to each fiscal year. Annual leave, sick leave, compensatory time off, and other approved leave categories are considered "hours worked" for purposes of defining FTE employment.

As it specifically relates to BsUFA, FTEs are referred to as "Process FTEs," which is how FDA measures a paid staff year devoted to the BsUFA program. In the table below, an FTE does not represent an accounting of individual people but rather an estimate of labor hours expended on BsUFA activities. Funding is distributed to FDA Centers based on the workload to support payroll to accomplish the program goals.

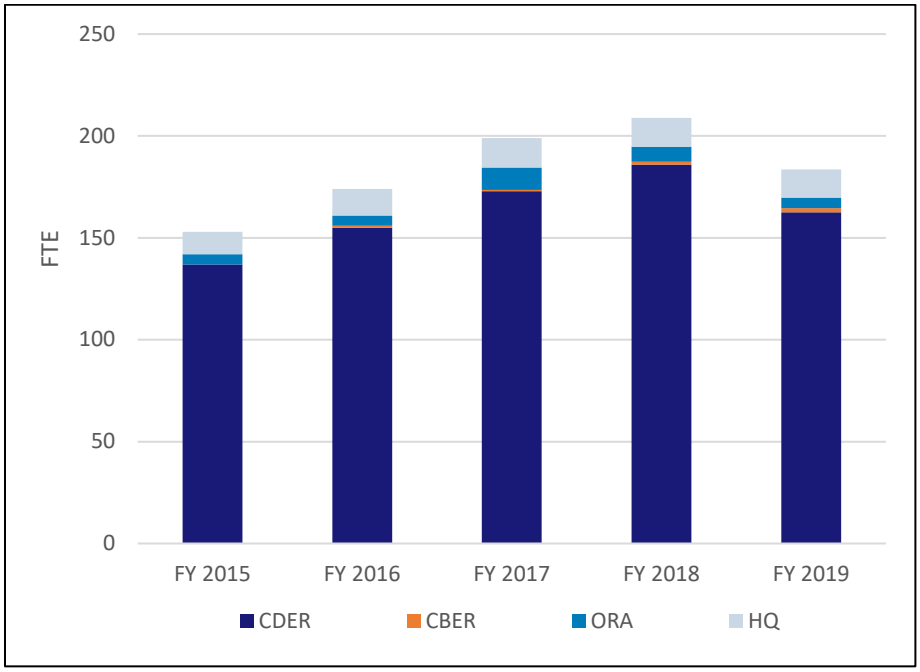
Table 9 presents total Process FTE levels, paid from user fee and non-user fee appropriations, that support the BsUFA program. The data cover the past 5 years and are arranged by FDA organizational components (CDER, CBER, ORA, and HQ). Staff in the consolidated shared services organizations (facilities, procurement, IT services, etc.) are included in the FTE levels for various components.

Table 9: Historical Trend of Total Process FTEs Utilized by Organization as of September 30 of Each Fiscal Year

Fiscal Year	FY 2015	FY 2016	FY 2017	FY 2018	FY 2019
CBER	0	1	1	2	2
CDER	137	155	173	186	163
ORA	5	5	11	7	5
HQ	11	13	14	14	14
Total	**153**	**174**	**199**	**209**	**184**

Exhibit 6 provides the historical trend of FTE distribution and levels across FDA organizations for the past 5 years.

Exhibit 6: Historical Total Process FTE Levels by FDA Organization



Planned Hiring

In the BsUFA II goals letter, FDA committed to hiring 15 new FTEs in FY 2018 to enhance FDA's capacity for biosimilar guidance development, reviewer training, and timely communication. FDA hired 8 FTEs in FY 2018 and 5 FTEs in FY 2019, resulting in 13 of the 15 targeted hires. FDA acknowledges that there are systemic issues with the Agency's hiring process, as noted in the report, *Initial Assessment of FDA Hiring and Retention – A Path Forward*,[5] that impact BsUFA hiring. Addressing these systemic issues will take time, and FDA does not expect to see significant improvements in hiring early in BsUFA II.

FDA also notes that FY 2019 was interrupted by the longest federal government shutdown in history (35 days). The shutdown slowed down FDA's business operations, including the hiring process. At the same time, FDA continued to compete in a very strong job market for medical and pharmaceutical fields. Government compensation lags behind private sector benefits for many of the occupations needed to support the BsUFA program. These factors, in addition to hiring system issues, contributed to FDA missing the targeted 15 new hires.

FDA will continue to strive to meet hiring goals and increase staff to address the increasing workload. In addition, FDA will review the financial status and workload demands of the program on a regular basis to ensure that funds are utilized to meet program commitments.

[5] This report is available at https://www.fda.gov/media/108866/download.

Management Assurance

N. Internal Controls

The Federal Managers' Financial Integrity Act of 1982 (FMFIA) is intended to strengthen internal controls and accounting systems. OMB Circular No. A-123, *Management's Responsibility for Enterprise Risk Management and Internal Control* (OMB A-123), implements the requirements of the FMFIA. The FMFIA requires that management establish and maintain effective internal control to achieve the following objectives:

1. Effective and efficient operations,
2. Reliable financial reporting, and
3. Compliance with applicable laws and regulations.

The Department of Health and Human Services (HHS) provides guidance to its operating divisions (OpDivs) to implement FMFIA through its FMFIA Guidelines. OpDivs, including FDA, are responsible for developing and maintaining a cost-effective internal control and compliance program that includes programmatic and operational controls, as well as controls over financial reporting, and supports sound financial management. The Government Accountability Office *Standards for Internal Control in the Federal Government* (Green Book) states, "Management is responsible for an effective internal control system. As part of this responsibility, management sets the entity's objectives, implements controls, and evaluates the internal control system." OMB A-123 requires an annual internal control assessment, and FMFIA requires the head of each executive agency to report annually to the President and Congress on the effectiveness of the internal controls and any identified material weaknesses in those controls. FDA's FY 2019 Assurance Statement, already submitted to HHS, found no material weaknesses or financial system nonconformances.

Additionally, FDA has established a Senior Assessment Team (SAT) as the governance body responsible for providing oversight and accountability for FDA's internal control over financial reporting, including overseeing the FMFIA and OMB A-123 assessments, and for fostering an environment that promotes strong internal control. The SAT is chaired by the FDA Chief Financial Officer (CFO) and co-chaired by the Deputy CFO and Director of the Office of Financial Management, as well as a Program Co-Chair who is a Center Deputy Executive appointed by the CFO. The SAT members are representatives from each FDA Center and Office.

In accordance with FMFIA, OMB A-123, the Green Book, and HHS guidelines, FDA has a robust internal control program, including integrated controls throughout processes. The Agency also conducts an annual assessment of its internal control activities as well as operational risk reviews. In addition, FDA has an Enterprise Risk Management (ERM) Program, which began in earnest in FY 2016 and is integrated with FDA's FMFIA efforts. Under the ERM Program, FDA has refreshed its enterprise risk profile and has facilitated its risk response planning for five priority enterprise risks. To accomplish this, Centers and Offices are engaged through senior leadership interviews, as well as through working groups and problem-solving sessions. Further, FDA has established an ERM Community of Practice and continues to align and integrate core ERM methodologies with those of internal controls. FDA's ERM program has facilitated cross-Center and Office collaboration to identify and manage risks. It is governed by the ERM Council, which is chaired by the Chief Operating Officer and the CDER Deputy Director for Operations.

FDA's internal control program includes an evaluation of controls over reporting, charge card compliance, improper payments, and financial systems compliance. One of the cycle memos included in the assessment scope includes internal controls over reporting for the reimbursable activity process, specifically focused on the Accounts Receivable and Payment process associated with the user fee programs. This process includes controls over reconciliation performance, aging, write-offs, and the interface between the User Fee System and the Unified Financial Management System. As an FDA-owned system, FDA's User Fee System is compliant with HHS's requirements and the requirements of the Federal Financial Management Improvement Act of 1996. In addition, FDA's Integrated Budget and Acquisition Planning System (IBAPS) meets FDA's and HHS's system requirements.

FDA is also a participant in the annual audit of the consolidated financial statements of HHS, including the consolidated balance sheet, the related consolidated statement of net costs and changes in net position, the combined statement of budgetary resources, and the related notes to the financial statements. The FY 2019 audit found that the financial statements present fairly, in all material respects, the consolidated financial position of HHS as of September 30, 2019, and 2018, and the consolidated net costs, changes in net position, budgetary resources, and related notes of these financial statements are in accordance with generally accepted accounting principles in the United States.

FDA has also implemented other internal control procedures, including a continuous monitoring program to oversee the timely implementation of corrective action plans for deficiencies identified through any of the Agency's control assessments. This continuous monitoring program allows for management oversight of targeted remediation efforts and a strengthening of internal controls. In addition, FDA offers annual internal control training sessions, which cover the importance of internal controls, timely deficiency remediation, and roles and responsibilities.

O. Risks and Challenges

Financial Risks and Mitigation

As is the case with all financial programs, there are certain financial risks and challenges that exist with FDA's user fee programs. These risks and challenges can vary from program to program, with some being in FDA's control and some out of FDA's control. An example of a shared financial risk across all user fee programs is that FDA cannot obligate funds in advance of receiving the funds, either through appropriated user fee collections or non-user fee appropriations. FDA can only assume what the Agency's total appropriation will be in any given year. As a result, FDA has some risk of missing important performance goals or failing to meet the non-user fee spending trigger for the fiscal year if the total appropriation comes in considerably lower than anticipated. To move forward in the best interests of the user fee program, below is a list of foreseeable risks associated with the collections and obligations of funds for which FDA has identified contingency plans.

- **Uncertainty of User Fees and Non-User Fee Appropriations Levels:** It is difficult to predict the amount of non-user fee appropriations that will be approved by Congress, which creates financial planning challenges for the program because non-user fee fund levels are often uncertain for a good portion of the fiscal year. With Continuing Resolutions (CRs) becoming more prevalent, FDA has been spending at or slightly below levels from the prior authorized fiscal year during the CR period, thus limiting its ability to spend the non-user fee appropriations from the onset. Fluctuations in submissions from year to year can change the total program

cost. This creates a situation where, because of extended CR periods, FDA is uncertain of its non-user fee appropriations for a significant portion of the year, yet it must still meet the non-user fee spending trigger. BsUFA I utilized a conservative approach in spending user fee revenues because of the uncertain revenue levels, which contributed to a relatively large carryover balance. BsUFA II provides for a 15 percent range in which FDA can comply with its non-user fee spending trigger requirements.[6]

- **Lapse in Non-User Fee Appropriations:** FDA is mitigating this risk to the program by maintaining a certain level of carryover so that it can continue program operations in the event of a lapse of appropriations. FDA has committed to reducing the BsUFA carryover balance to no greater than 21 weeks. See **Note 8** for additional details.

- **Under-Executing Planned Spend:** BsUFA budgetary resources have been under-spent because of the uncertainty around the timing of revenue (user fee and non-user fee) availability, non-user fee spending trigger requirements, and difficulties with hiring. To minimize this risk, FDA has continued to enhance its planning and execution around the hiring of new staff and contract actions in the second year of the authorization. By putting more emphasis on the initial planning of initiatives in the early years of the 5-year cycle, FDA predicts that there will be less variance while comparing planned allocations to actual expenditures than FDA has experienced in the past.

- **Under Collecting and Over Collecting Fees:** Because the BsUFA program experiences variations in workload, it is difficult to forecast the required revenue and set fees at appropriate levels. If FDA does not receive the estimated number of industry submissions, there may be an excess or deficit in its targeted revenue. When FDA under collects user fees, it leverages its carryover balance to maintain continuity in operations. When FDA over collects, the carryover may increase without additional planned expenditures being identified to obligate those funds. The changes in the fee structure, minimization of clean-up billing, and the operating reserve are meant to mitigate these risks in BsUFA II. Resource capacity planning will help improve fee setting and allow FDA to adjust for sustained increases in workload. In addition, FDA monitors collections throughout the fiscal year, and the User Fee Financial Management Committee and other FDA senior leaders determine how to mitigate any instances when user fee revenue deviates from forecasted estimates.

In addition to these mitigation strategies, FDA implemented IBAPS to enable greater and more timely insight into budget activity across the Agency. IBAPS improves the accuracy and availability of budget and acquisition information that enables FDA to better plan, forecast, track, and analyze the data to make better informed decisions about the best use of its resources.

Strategic Challenges

FDA has committed to improving its hiring and retention of scientific staff as described in the BsUFA II goals letter. As initiatives associated with these commitments span the course of BsUFA II, the benefits expected from these initiatives will not be immediate, and, thus, FDA may experience delays in hiring staff for the BsUFA program.

[6] 21 U.S.C. 379j-52(f)(2)(C).

Appendices

A. Reporting Requirements

The following table provides details regarding the financial reporting requirements and commitments for BsUFA II that are addressed by this report.

Reference	Details
Section 744I(b) of the FD&C Act	FDA must submit a fiscal report, beginning with fiscal year 2018, no later than 120 days after the end of each fiscal year for which fees are collected. This report must include information on the implementation of the authority for biosimilar biological product user fees and the use of fees collected for such fiscal year.
Section IV.A.4 of the BsUFA II goals letter	FDA will include, in the annual BsUFA Financial Report, information on "how the capacity adjustment fee revenues are being utilized."

B. Allowable and Excluded Costs for the BsUFA Program

Section 744G(13) of the FD&C Act defines the phrase "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:

Included Activities	
1. The activities necessary for the review of submissions in connection with biosimilar biological product development, biosimilar biological product applications, and supplements. 2. 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 when appropriate, the actions necessary to place such applications in condition for approval. 3. 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. 4. Activities necessary for the release of lots of biosimilar biological products under section 351(k) of the Public Health Service Act. 5. Monitoring of research conducted in connection with the review of biosimilar biological product applications.	6. Post-market safety activities with respect to biologics approved under biosimilar biological product applications or supplements, including the following activities: a. Collecting, developing, and reviewing safety information on biosimilar biological products, including adverse-event reports. b. Developing and using improved adverse-event data-collection systems, including IT systems. c. Developing and using improved analytical tools to assess potential safety problems, including access to external databases. d. 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). e. Carrying out section 505(k)(5) of the FD&C Act (relating to adverse-event reports and post-market safety activities).

Section 744G(9) of the FD&C Act defines the phrase "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 the following:

Included Expenses
1. Officers and employees of FDA, contractors of FDA, advisory committees, and the costs related to such officers, employees, and committees, and to contracts with such contractors; 2. Management of information and the acquisition, maintenance, and repair of computer resources; 3. Leasing, maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, scientific equipment, and other necessary materials and supplies; and 4. Collecting fees under section 744H of the FD&C Act and accounting for resources allocated for the review of submissions in connection with biosimilar biological product development, biosimilar biological product applications, and supplements.

The BsUFA program excludes costs related to the following:

Excluded Products	Excluded Activities
1. 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; 2. Allergenic extract products; 3. Whole blood or a blood component for transfusion; 4. In vitro diagnostic biological products; and 5. A biological product for further manufacturing use only.	1. Enforcement policy development not related to section 505(o) and (p) of the FD&C Act; 2. Post-approval compliance activities not related to the enforcement of section 505(o) and (p) of the FD&C Act; 3. Advertising review activities once marketing of the product has begun; 4. Inspections unrelated to the review of covered applications, unless undertaken for the enforcement of section 505(o) and (p) of the FD&C Act; and 5. Research unrelated to the BsUFA program.

C. User Fee Program History

The FD&C Act, as amended by BsUFA, authorizes FDA 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.

Originally authorized in 2012, BsUFA was reauthorized by FDARA in 2017 (BsUFA II) with the support of the biopharmaceutical industry, public stakeholders, Congress, and the Administration.

D. 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 describes these conditions and the applicable adjustment factor, as set forth in the FD&C Act.

Adjustment Factor

To determine whether the legal conditions are satisfied, FDA must calculate and incorporate an adjustment factor in its assessment of the second condition. The term "adjustment factor" is defined for purposes of BsUFA II as follows:[7]

> The term "adjustment factor" applicable to a fiscal year is the Consumer Price Index for urban consumers (Washington-Baltimore, DC-MD-VA-WV; Not Seasonally Adjusted; All items) for October of the preceding fiscal year divided by such Index for October 2011.

As a result of a geographical revision made by the Bureau of Labor and Statistics in January 2018, the "Washington, DC-Baltimore" index was discontinued and replaced with two separate indices (i.e., the "Washington-Arlington-Alexandria" and "Baltimore-Columbia-Towson" indices). To continue applying a Consumer Price Index (CPI) that best reflects the geographic region in which FDA is located and that provides the most current data available, the "Washington-Arlington-Alexandria" index will be used in calculating the adjustment factor for FY 2019 and subsequent years. Additionally, because the data in this index for October are unavailable, FDA utilizes the most recent data, which is from September.

The CPI for September 2018, the September of the fiscal year preceding FY 2019, was 263.056. The CPI for September 2011 was 238.725. Dividing the CPI of September 2018 by the CPI of September 2011 yields an adjustment factor of 1.101921 (rounded to the sixth decimal place) for FY 2019.

Legal Conditions

Exhibit 7, below, provides the details regarding each legal condition contained in the FD&C Act.

Exhibit 7: Legal Conditions

Legal Condition #	FD&C Act Section	Details
1	744H(f)(2)(A)	"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, or otherwise made available for obligation for such fiscal year."
2	744H(f)(2)(B)(i)	"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."

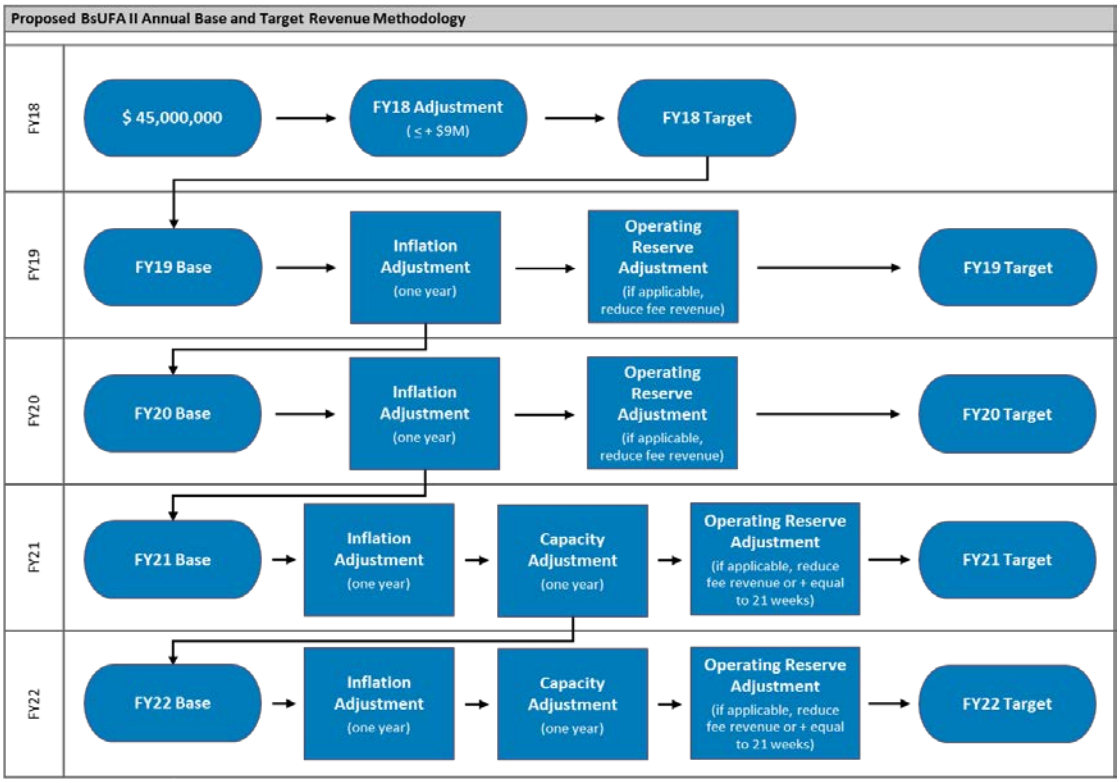
[7] See section 744G(1) of the FD&C Act.

E. Financial Notes

Note 1. Annual Target Revenue Methodology

Exhibit 8, outlines the BsUFA II Annualized Base and Target Revenue Methodology.

Exhibit 8: BsUFA II Annualized Base and Target Revenue Methodology



Note 2. Recoveries

Recoveries account for funds returned to the Agency in the form of deobligations of prior year obligations. For example, recoveries could include funding from a contract that ended in a prior year and was not expended.

Note 3. Pay and Operating Costs

Pay and operating costs associated with the BSUFA program are based on obligations attributed to CBER, CDER, ORA, and HQ. These costs relate to how much of the BSUFA revenue is going toward payroll and operating expenses.

For payroll, employees are required to report their time in an activity-based reporting system, which allows FDA to identify activities that user fees can be used to support. See **Appendix B** for a listing of those activities. For operating activities (e.g., contracting services), funds are allocated based on the proportion to which those activities support the BsUFA program. If an operating activity solely supports BsUFA, it will be fully funded by the program. If the operating activity is shared, BsUFA will fund the activity in proportion to how it is used by the program as compared to other programs.

Note 4. Rent Costs

GSA charges rent to FDA for the federal buildings that FDA occupies. This rent is charged at different rates depending on the type and location of the space provided. Because rent is an essential support cost for the process for the review of biosimilar biological product applications, a portion of those charges is paid from non-user fee appropriations and a portion is paid from BsUFA fees. Also included in this account are recurring costs that FDA pays directly to non-federal sources under the delegation of direct lease and service authority. These services include rental of space and all recurring services for building operations such as overtime utilities, janitorial services, guards, and ground maintenance. The amount of rent and rent-related costs each Center pays is directly related to the number of employees that must be housed for that Center.

Note 5. Shared Service Costs

FDA contains several shared service organizations that provide support across the user fee programs. The shared service organizations include:

- **FDA Central**: Provides for Center-wide and Agency-wide services such as telecommunications, training, printing, mail and document management, IT systems, employee health units, and other support and miscellaneous services.
- **Employee Resource & Information Center**: Provides support to all FDA employees requesting administrative, IT, facilities, human resources, and other employee services.
- **Employee Safety & Environmental Management**: Provides safety, health, and environmental compliance for all FDA employees.
- **Office of Acquisitions and Grants Services**: Manages contracts, grants, and other agreements.
- **Office of Equal Employment Opportunity**: Promotes an inclusive work environment that ensures equal employment opportunity and fosters a culture that values diversity and empowers individuals.
- **Office of Facilities, Engineering, and Mission Support Services:** Provides FDA employees with office and laboratory facilities.
- **Office of Financial Management:** Provides financial managerial services and policy guidance.
- **Office of Human Resources**: Supports workforce relations, client services, executive resources, accountability programs, policy and program development, and systems data and management.
- **Office of Information Management and Technology**: Provides the information, communication, and knowledge infrastructure and services that enhance, transform, and sustain the ability of FDA to protect and promote the public health.
- **Alternative Dispute Resolution:** Provides an alternative resource to existing administrative processes and assists in addressing work-related issues.
- **Division of Budget Execution and Control:** Initiates, monitors, and analyzes FDA budget resources. The Agency budget is comprised of several appropriation accounts, including: Salaries and Expenses, Revolving Fund for Color Certification and other Services, Cooperative Research and Development Agreement, Contingency Fund, Building and Facilities, and Royalties.
- **Division of Ethics and Integrity:** Protects the integrity of FDA's programs and operations by promoting an ethical culture and ensuring compliance with applicable federal ethics laws.
- **Management Analysis Services Staff:** Provides organizational expertise and policy advice, as well as consultation and support to ensure an efficient Agency structure that delivers on the FDA mission.

- **Office of External Affairs – History:** Provides research, documentation, and preservation of significant FDA historical resources, as well as serving as historian for the Agency.
- **Office of Security Operations:** Develops and implements the Agency-wide security policies and programs by providing leadership and guidance to managers and staff on all aspects of security. Administers vital security functions that contribute to the Agency's mission of protecting the public health by enhancing the safety and security of all personnel, facilities, and information.
- **Paperwork Reduction Act Staff:** Acts as the liaison between FDA Centers, HHS, and OMB on all information collection matters.

Note 6. Inflation Adjustment

The inflation adjustment adjusts the base amount to maintain the purchasing power of fee funds in consideration of inflation. The adjustment is a composite measure that weights operating expenses by changes in the CPI and payroll-related expenses by changes in FDA's average personnel compensation and benefits amounts.

The inflation adjustment utilized in FY 2019 was 1.8239 percent.

Note 7. Capacity Planning Adjustment *(Interim method)*

The statute does not currently provide a method to adjust the BsUFA target revenue amount based on workload or the capacity needs of the program. The statute does, however, provide a procedure to develop a methodology to accurately assess changes in the resource capacity needs of the biosimilar biological product review program. This procedure includes a third-party assessment of methodological options, resulting in a report published for public comment not later than September 30, 2020. Following a review of the report and public comments, FDA will adopt a capacity planning methodology that will be effective beginning the first fiscal year for which fees are set after the methodology is established.

Note 8. Operating Reserve Adjustment

The operating reserve adjustment was established in the statute to provide a mechanism to support the management of a reasonable amount of fee funds carried over from year to year.

FDA is committed to reducing the BsUFA carryover balance to an amount that is no greater than 21 weeks of operating reserves by the end of FY 2022. The operating reserve adjustment provides a tool to help manage this amount. Beginning in FY 2019, FDA may use the operating reserve adjustment to lower the annual target revenue to help manage the committed carryover balance level.

Once the capacity planning adjustment is implemented, which FDA expects to occur in FY 2021, FDA may also utilize the operating reserve adjustment to increase the annual target revenue amount. This upward adjustment may not be made to provide for an increase that would result in a carryover balance of more than 21 weeks. FDA does not foresee the need to utilize this upward adjustment in BsUFA II; however, this is an option FDA expects will be available in FY 2021 and FY 2022 should the financial outlook change.

Should FDA make an operating reserve adjustment, either up or down, FDA must explain its rationale in the annual fee-setting *Federal Register* notices.

Note 9. Refunds

If an applicant submits a biosimilar biological product application before October 1 of the fiscal year and that application is accepted for filing on or after October 1 of that fiscal year, the applicant may request a refund of the annual BPD fee paid by the applicant for such fiscal year. If an application is refused for filing or is withdrawn without a waiver before filing, FDA will refund 75 percent of the application fee paid.

Refunds impact net fee collections for each fiscal year. Net collections reflect the amount of fees collected net any refunds or adjustments that occurred during that fiscal year.

Note 10. Minimum Non-User Fee Appropriations Adjustment Factor

FDA must calculate and incorporate an adjustment factor to determine the "non-user fee spending trigger" amount (see section 744H(f)(2)(B)(i) of the FD&C Act). For purposes of BsUFA II, the following definition of "adjustment factor" is applied:

> The term "adjustment factor" applicable to a fiscal year is the Consumer Price Index for urban consumers (Washington-Baltimore, DC-MD-VA-WV; Not Seasonally Adjusted; All items) for October of the preceding fiscal year divided by such Index for October 2011.

(Section 744G(1) of the FD&C Act). As a result of a geographical revision made by the Bureau of Labor and Statistics in January 2018, the "Washington, DC-Baltimore" index was discontinued and replaced with two separate indices (i.e., the "Washington-Arlington-Alexandria" and "Baltimore-Columbia-Towson" indices). To continue applying a CPI that best reflects the geographic region in which FDA is located and that provides the most current data available, the "Washington-Arlington-Alexandria" index will be used in calculating the adjustment factor for FY 2019 and subsequent years. Additionally, because the data in this index for October are unavailable, FDA utilizes the most recent data, which are from September.