FY 2018 BsUFA
FINANCIAL REPORT

REQUIRED BY THE

BIOSIMILAR USER FEE ACT

FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Table of Contents

Executive Summary

The Biosimilar User Fee Act (BsUFA), as amended, requires the Food and Drug Administration (FDA or the Agency) to report annually on the financial aspects of BsUFA implementation. This is the first report under the second authorization of BsUFA (BsUFA II) and covers fiscal year (FY) 2018.

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 $20,000,000 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 2018, 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 2018, FDA had net collections of $29.24 million in BsUFA fees, spent $40.28 million in user fees for the BsUFA program, and carried a cumulative balance of $38.76 million forward for future fiscal years.

BsUFA user fees and non-user fee appropriations in FY 2018 supported 209 full-time equivalents (FTEs), 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 2018 BsUFA Performance Report.

Report Overview

A. Scope

This financial report addresses the implementation of BsUFA and use of biosimilar biological product user fees by FDA during the period of October 1, 2017, through September 30, 2018. It 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 determined that those requirements were met. In addition, this report presents summary statements of FY 2018 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 will publish an annual financial report on the implementation of the authority for biosimilar biological product user fees during such 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 public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices and 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 advancing the public's health by helping to speed innovations that make medical products more effective, safer, and more 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.

Program Organization

There are four major 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 public health by helping to ensure that human drugs are safe and effective, meet established quality standards, and are available to patients.
CBER	Helps to ensure the safety, purity, and potency of biological products, including vaccines, blood and blood products, and gene therapies for the prevention, treatment, or cure of human diseases or conditions.
ORA	Protects consumers and enhances public health by maximizing compliance of FDA regulated products and minimizing 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 includes an understanding of the design of these programs, clear financial plans, data-driven decisions on resource allocation, consistency and transparency about assumptions, reliable financial forecasting, and accountability for resources spent.

For most of FY 2018, FDA's user fee governance process leveraged the User Fee Council. FDA has since transitioned from that governance structure to a new model that leverages a new committee, which is referred to as the User Fee Financial Management Committee. The User Fee Financial Management Committee 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 will receive 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 will advise 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, application fees, and biosimilar biological product program fees. The structure is intended to enhance predictability of funding, reduce administrative inefficiency, and improve 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 the 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 and 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; this typically occurs at the beginning of August (BsUFA User Fee Rates Archive).

BsUFA user fees are not a fee-for-service. 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 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 2018.

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, 2018 (Public Law 115-141), which the President signed on March 23, 2018, made appropriations through September 30, 2018, for the salaries and expenses account of FDA. It specified that $40,214,000 shall be derived from BsUFA fees, and that BsUFA fees collected in excess of this amount are also appropriated for FDA. Thus, in FY 2018, the first legal condition was satisfied.
2	Description	FDA may not spend BsUFA fees in a fiscal year unless it allocates a minimum of $20,000,000 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 2018 is $21,711,380. In FY 2018, FDA allocated and obligated $22,324,558 in appropriated funds (excluding user fees) for the BsUFA program. Since FDA allocated and obligated more than the specified minimum amount in FY 2018, 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 ongoing clarification of approval pathway for these products. FDA has developed the Biosimilars Action Plan (BAP), which advances policies to facilitate the efficient development and approval of biosimilar biological products. FDA will 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. This plan aligns with FDA's strategic priorities and reflects FDA's commitments in the BsUFA II goals letter,[1] innovations in regulatory science, and expanded opportunities for collaboration.

To better support these objectives, FDA is currently in the process of transitioning the Therapeutic Biologics and Biosimilars Staff (TBBS) to the Office of Therapeutic Biologics and Biosimilars (OTBB). 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 ongoing activities include the development and implementation of new FDA review tools, including standardized review templates, publishing timely guidance for sponsors to provide scientific and regulatory predictability, and modernizing the Purple Book to include more information about licensed biological products.

[1] Biosimilar Biological Product Reauthorization Performance Goals and Procedures Fiscal Years 2018 Through 2022 available at www.fda.gov/downloads/ForIndustry/UserFees/BiosimilarUserFeeActBsUFA/UCM521121.pdf.

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 2018, there were 25 performance goal categories for the BsUFA user fee program. Workload associated with maintaining these performance goals varies from year to year and has a substantial effect on finances. Preliminary data indicates that FDA has the potential to meet or exceed 22 of the 25 goals that apply to the FY 2018 cohort once these actions are completed. In FY 2018, FDA did not meet certain meeting management goals for BsUFA meetings. Several factors affected the ability to meet these meeting management goals including a small number of meeting requests for certain meeting types, with the result that a single missed scheduling goal resulted in a large percentage impact on performance. Other factors included FDA understaffing and increasingly resource-intensive performance goals, common across all user fee programs, which created a strain on limited resources within relevant offices/divisions. Refer to the FY 2018 BsUFA Performance Report for additional details.

Financial Information

This section provides an overview of the program financials for BsUFA for fiscal years 2017 and 2018. These financials include user fee revenue, obligations, carryover, non-user fee appropriations, and full-time equivalents.

H. User Fee Program Financials

Table 1 represents a summary of the BsUFA financial position for FY 2017 and FY 2018. The financial notes can be found in **Appendix E**.

Table 1: Biosimilar Biological Product User Fee Collections, Obligations, and Carryover for Fiscal Years 2017 and 2018

Budgetary Resources	Notes	FY 2017	FY 2018
Target Revenue	Note 1	**N/A**	**$40,214,000**
Total Carryover, Beginning of Year		$52,561,611	$48,723,308
Net Collections		$28,839,871	$29,238,601
Recoveries	Note 2	$39,497	$1,074,997
Total Budgetary Resources		**$81,440,979**	**$79,036,907**

Obligations	Notes	FY 2017	FY 2018
Total Payroll & Operating	Note 3	$27,762,638	$34,535,211
Total Rent	Note 4	$1,094,000	$1,104,785
Total Shared Services	Note 5	$3,861,032	$4,639,568
Total Obligations		**$32,717,670**	**$40,279,564**

Carryover	Notes	FY 2017	FY 2018
Total Carryover, End of Year		**$48,723,308**	**$38,757,343**

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 is the annual revenue amount established when fees for the fiscal year are set. Net collections 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 "carryover balance," 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 FDA can continue program operations under such financial constraints.

I. User Fee Revenue

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

Table 2: Biosimilar Biological Product Revenue and Collections Statement for Fiscal Year 2018

Target Revenue	Notes	FY 2018
Base Amount		$45,000,000
Inflation Adjustment	Note 6	N/A
Capacity Planning Adjustment	Note 7	N/A
Operating Reserve Adjustment	Note 8	N/A
FY 2018 Adjustment	Note 9	($4,786,000)
Target Revenue Total	Note 1	**$40,214,000**

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 statute. The base amount for FY 2018 is defined in statute and is adjusted by the FY 2018 adjustment. In subsequent fiscal years, the base amount 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 definition of each adjustment.

Under BsUFA II, user fees include BDP fees (including initial biosimilar biological product development fees, annual biosimilar biological product development 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 2017, but received in FY 2018, is attributed to FY 2017 collections.

Decrease in Collections

The primary factor in the decrease in collections was the less than expected number of BsUFA applications submitted to the Agency.

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. Fee types changed from FY 2017 to FY 2018, so some fees are no longer applicable. Refer to **Section D** for more background and information regarding this change.

Table 3: Biosimilar Biological Product User Fee Collections by Fee Source for Cohort Years 2017 and 2018

Fees Collected	Cohort Year 2017			Cohort Year 2018		
	Estimated†	Actual	% Dif.	Estimated†	Actual	% Dif.
BPD Fees	N/A	$16,215,561	N/A	$14,768,857	$16,924,665	15%
Application Fees	N/A	$14,416,810	N/A	$22,707,685	$10,043,784	-56%
Product Fees	N/A	$782,000	N/A	N/A	N/A	N/A
Establishment Fees	N/A	$1,536,600	N/A	N/A	N/A	N/A
Program Fees	N/A	N/A	N/A	$2,737,458	$2,433,296	-11%
Total Collections	**N/A**	**$32,950,971**	**N/A**	**$40,214,000**	**$29,401,745**	**-27%**

Fees Receivable	Actual	Actual
BPD Fees	$293,049	$343,523
Application Fees	$0	$0
Product Fees	$0	N/A
Establishment Fees	$0	N/A
Program Fees	N/A	$0
Total Receivables	**$293,049**	**$343,523**

Numbers have been rounded to the nearest dollar.
†Estimated values were taken from the Biosimilar User Fee Rates for FY 2018.

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 breakout 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 Fiscal Years 2017 and 2018

User Fee Obligations	Notes	FY 2017	FY 2018
Payroll & Operating	Note 3		
CBER		$0	$0
CDER		$25,939,757	$31,113,433
ORA		$213,442	$1,128,256
HQ		$1,609,439	$2,293,521
Total Rent	Note 4	$1,094,000	$1,104,785
Total Shared Services	Note 5	$3,861,032	$4,639,586
Total Obligations		**$32,717,670**	**$40,279,564**

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 statute. This 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 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 IT.

In FY 2018, FDA made significant investments towards business management, general maintenance, IT, and regulatory science activities for BsUFA. In addition, FDA allocated resources to support the continued development of FDA's biosimilar biological product review program by establishing OTBB, to improve coordination and support of all activities under the BsUFA program, accelerate responses to stakeholders, and support efficient operations and policy development.

For historical context, **Table 5** provides the total amount spent by FDA and by each FDA organization on the BsUFA program for the past 5 years.

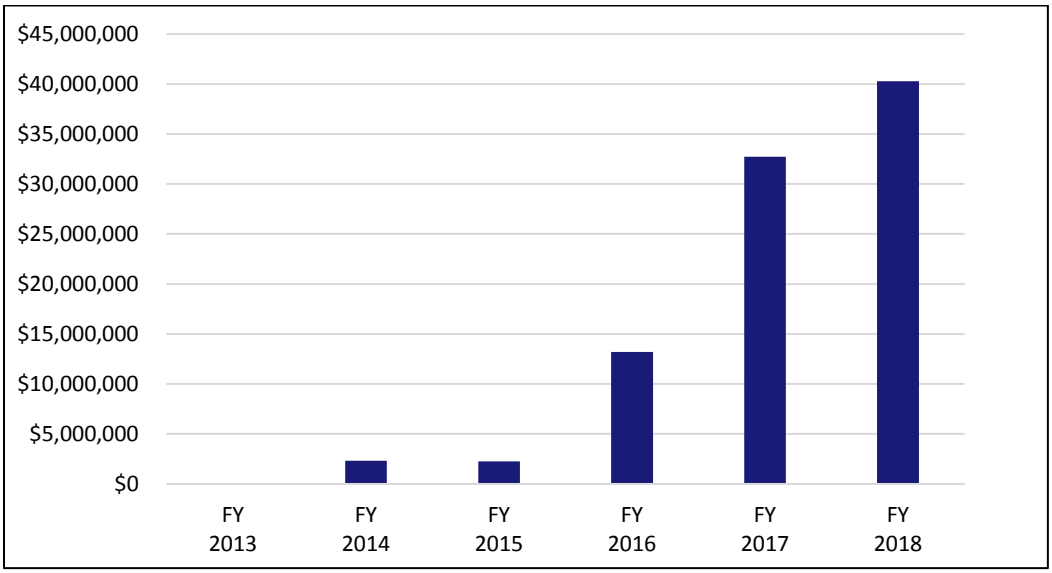
Table 5: BsUFA Program – Historical Trend of Total Costs by Organization as of September 30 of Each Fiscal Year

Costs		FY 2014	FY 2015	FY 2016	FY 2017	FY 2018
Total Spent		$23,391,649	$34,817,217	$45,569,429	$55,814,043	$62,604,122
CBER	Spent	$490,174	$39,841	$203,767	$155,952	$465,335
	Percent	2%	0%	0%	0%	1%
CDER	Spent	$21,087,708	$30,604,475	$40,284,316	$48,863,293	$55,471,096
	Percent	90%	88%	88%	88%	89%
ORA	Spent	$0	$1,136,046	$1,516,990	$2,629,013	$1,909,924
	Percent	0%	3%	3%	5%	3%
HQ	Spent	$1,813,767	$3,036,855	$3,564,356	$4,165,785	$4,757,767
	Percent	8%	9%	8%	7%	8%

Numbers have been rounded to the nearest dollar.

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

Exhibit 4: Historic User Fee Obligations by Fiscal Year



As demonstrated by this graph, there was a significant increase in BsUFA fee expenditures over the last 2 years of BsUFA I and into the first year of BsUFA II. This is because of a greater reliance on user fees over non-user fee appropriations than in the early years of the program. As the program matures, there is less uncertainty about hitting the non-user fee spending trigger and, as a result, more user fee funding is released to cover program costs. Historically, FDA has experienced a ramp-up in early years of a new authorization period, which has resulted in new carryover because the hiring of new staff tends to lag the availability of financial resources.

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. Carryover balances serve as operating reserves and as a risk mitigation strategy to combat the operational impact of significant variations in workload and fee collections.

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 the 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 (PDUFA) or the Generic Drug User Fee Amendments (GDUFA). 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 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 is demonstrated best in **Table 1** above.

Table 6 provides the BsUFA carryover balances, recoveries, claims, and restrictions for FY 2017 and FY 2018.

Table 6: BsUFA Carryover Balances for Fiscal Years 2017 and 2018

Carryover	Notes	FY 2017	FY 2018
Total Carryover, End of Year		**$48,723,308**	**$38,757,343**
Refunds	Note 10	($500,000)	($500,000)
Carryover Unavailable for Use, End of Year		**($500,000)**	**($500,000)**
Carryover Available for Use, End of Year		**$48,223,308**	**$38,257,343**

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 10** 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 2018 resulted in a net decrease of the total carryover balance of $9,965,965, from $48,723,308 at the end of FY 2017 to $38,757,343 at the end of FY 2018. The primary driver of this reduction in the available carryover balance was that net collections in FY18 were approximately $11 million less 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

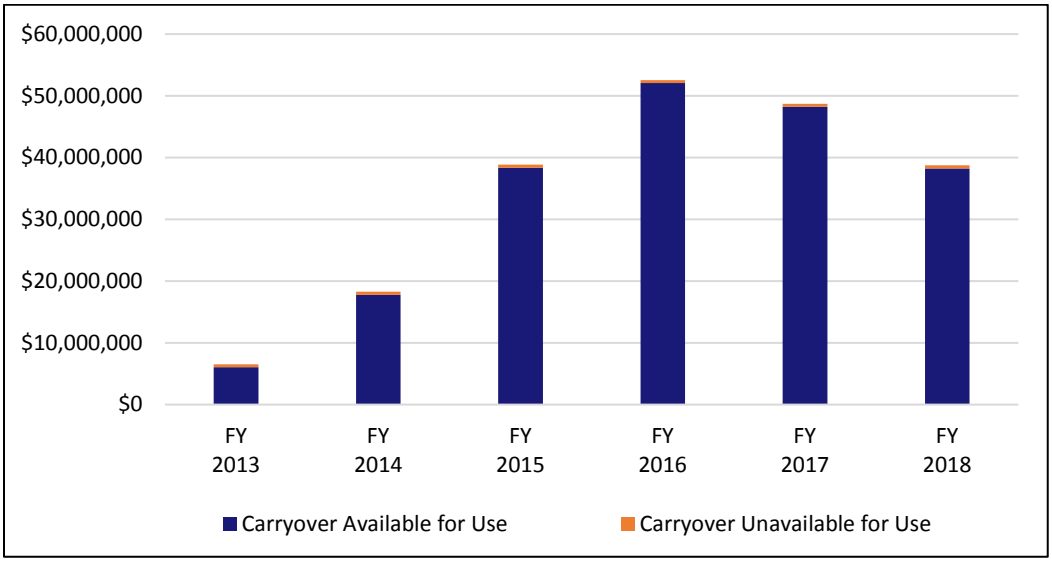
Carryover	Notes	BsUFA I	BsUFA II
		FY 2013 – 2017	FY 2018
Total Carryover, Beginning of Year		**$0**	**$48,723,308**
Net Collections		$99,201,695	$29,238,601
Recoveries	Note 2	$39,497	$1,074,997
Total Obligations		($50,478,387)	($40,279,564)
Total Carryover, End of Year		**$48,723,308**	**$38,757,343**

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 previously trended upward until recently. This is because FDA implemented

mitigation strategies in order to manage the carryover balance. This is illustrated by the decrease in the carryover amount for the past 2 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 that fiscal year. This is often referred to as a "non-user fee spending trigger."[2] The spending trigger was $21,342,840 for FY 2017 and $21,711,380 for FY 2018.

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 ($20,000,000) times the adjustment factor for the fiscal year. See **Note 11** 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.

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

Obligations		FY 2014	FY 2015	FY 2016	FY 2017	FY 2018
Total Obligated		$23,391,649	$34,817,217	$45,569,430	$55,814,043	$62,604,122
Non-User Fee Appropriations	Total	$21,074,247	$32,550,420	$32,353,416	$23,096,373	$22,324,558
	Percent	90%	93%	71%	41%	36%
User Fee Revenue	Total	$2,317,402	$2,266,797	$13,216,014	$32,717,670	$40,279,564
	Percent	10%	7%	29%	59%	64%

Numbers have been rounded to the nearest dollar.

[2] The statute provides that this requirement is met if at least an amount that is 15 percent below the FY 2018 minimum level is spent (see section 744H(f)(2)(C) of the FD&C Act).

M. Full Time Equivalents (FTEs)

FTE employment or 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 relates to BsUFA specifically, FTEs are referred to as "Process FTEs." This 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.

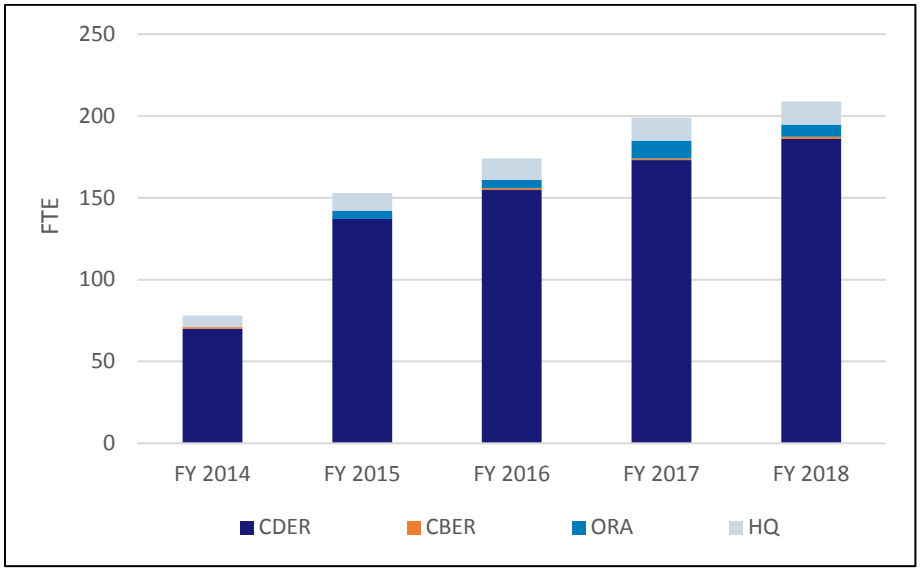
Table 9 presents total Process FTE levels, paid from user fee and non-user fee appropriations, that support the BsUFA program. The data covers the past 5 years and is arranged by FDA organizational components (CDER, CBER, ORA, and HQ). Staff in the consolidated shared services organizations (facilities, 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 2014	FY 2015	FY 2016	FY 2017	FY 2018
CBER	1	0	1	1	1
CDER	70	137	155	173	186
ORA	0	5	5	11	7
HQ	7	11	13	14	14
Total	**78**	**153**	**174**	**199**	**209**

Exhibit 6 provides the historical trend of FTE distribution and levels across FDA organizations for the past 5 years. There is a steady increase in FTEs, but the distribution has remained relatively the same across organizations.

Exhibit 6: Historical Total Process FTE Levels by FDA Organization



Planned Hiring

CDER plans to hire 15 new FTEs to support BsUFA II performance goals. In FY 2018, eight FTEs were hired under BsUFA II. Systemic issues with the Agency's hiring process, as noted in the report, *Initial Assessment of FDA Hiring and Retention – A Path Forward*,[3] impact BsUFA hiring. Addressing these systemic issues will take time, and FDA does not expect to see significant improvement in hiring early in BsUFA II.

FDA is competing with the private sector in a tight labor market for medical and pharmaceutical professionals. 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 FY 2018 planned hires. For more information on planned hiring, please see the BsUFA Performance Report.

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.

Management Assurance

N. Internal Controls

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

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 supports sound financial management, including programmatic and operational controls and controls over financial reporting. The Government Accountability Office (GAO) *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 2018 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 A-123 assessments, and to foster an environment that promotes strong internal control. The SAT is chaired by the FDA Chief Financial Officer (CFO) and co-chaired by the

[3] https://www.fda.gov/media/108866/download

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. 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 the enterprise risk profile and facilitated risk response planning for five priority enterprise risks. To accomplish this, Centers and Offices are engaged through senior leadership interviews, as well as 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 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 requirements and requirements of the Federal Financial Management Improvement Act (FFMIA) of 1996. In addition, FDA's Integrated Budget and Acquisition Planning System (IBAPS) meets FDA and HHS 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 2018 audit found that the financial statements present fairly, in all material respects, the consolidated financial position of HHS as of September 30, 2018 and 2017, and its consolidated net cost, changes in net position, budgetary resources, and related notes are in accordance with U.S. generally accepted accounting principles.

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 its control assessments. This continuous monitoring program allows for management oversight of targeted remediation efforts and 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 that total appropriation comes in considerably lower than anticipated. Below is a listing of foreseeable risks associated with the collections and obligations of funds for which FDA has identified contingency plans in order to move forward in the best interest of the program.

- **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 since non-user fee fund levels are often uncertain for a good portion of the fiscal year. This is due to prolonged Continuing Resolutions (CRs), versus enactment of annual appropriations bills early in the fiscal year. Fluctuations in submissions from year to year can change the total program cost. This creates a situation where, due to 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 revenue due 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.[4]

- **Lapse in Non-User Fee Appropriations:** FDA is mitigating this risk to the program by maintaining a certain level of carryover. In BsUFA II, FDA can maintain up to 21 weeks of an operating reserve so it can continue program operations in the event of a lapse of appropriations. See **Note 8** for additional details.

- **Under-Executing Planned Spend:** FDA's historical experience with ramping up a new user fee program has resulted in new carryover, as hiring new staff tends to lag the availability of financial resources. Comfort in FDA's ability to comply with the non-user fee spending trigger also impacts the program's ability to execute planned spend. To minimize this risk, FDA is enhancing its planning and execution around the hiring of new staff and contract actions. By putting more emphasis on the initial planning of initiatives in the first year 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:** Since the BsUFA program experiences variation 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 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 towards. 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 the Integrated Budget and Acquisition Planning System (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

[4] 21 U.S.C 379j-52(f)(2)(C)

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 hiring and retention of scientific staff as described in the BsUFA II commitment 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.

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.
Biosimilar Biological Product Reauthorization Performance Goals and Procedures FY 2018 through 2022, section IV.A.4.	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 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:

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 where 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 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:

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 allocate for the review of submissions in connection with biosimilar biological product development, biosimilar product application, 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 sections 505(o) and (p) of the FD&C Act; 2. Post-approval compliance activities not related to the enforcement of sections 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 sections 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 the assessment of the second condition. The term "adjustment factor" is defined for purposes of BsUFA II as follows:[5]

> 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 September of the preceding fiscal year divided by such Index for September 2011.

The Consumer Price Index (CPI) for September 2017, the September of the fiscal year preceding FY 2018, was 160.293. The CPI for September 2011 was 147.658. Dividing the CPI of September 2017 by the CPI of September 2011 yields an adjustment factor of 1.085569 (rounded to the sixth decimal place) for FY 2017.

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

Legal Conditions

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

Exhibit 7: Legal Conditions

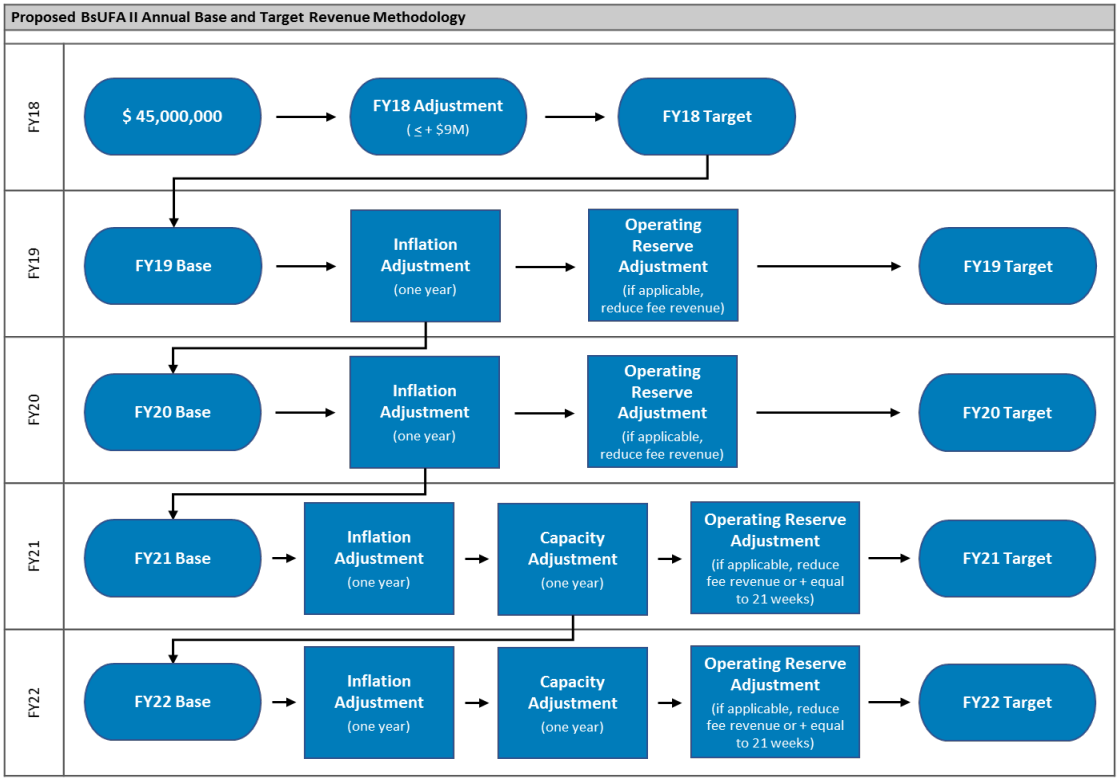
Legal Condition #	FD&C Act Section	Details
1	744H(f)(2)(A)	Subject to subparagraphs (C) and (D), the fees authorized by this section shall be collected and available in each fiscal year in an amount not to exceed the amount specified in appropriation Acts, or otherwise made available for obligation for 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.

E. Financial Notes

Note 1. Annual Target Revenue Methodology

Exhibit 8, below, 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

The General Services Administration (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. Since 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.

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 (ERIC)**: Provides support to all FDA users requesting administrative, IT, facilities, human resources, and other employee services.
- **Employee Safety & Environmental Management (ESEM)**: Provides safety, health, and environmental compliance for all FDA employees.
- **Office of Acquisitions and Grants Services (OAGS)**: Manages contracts, grants, and other agreements.
- **Office of External Affairs (OEA) – History**: Provides the development, coordination, and dissemination of FDA communications and outreach to the news media and various stakeholders.
- **Office of Equal Employment Opportunity (OEEO)**: 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 (OFEMS)**: Provides FDA employees with office and laboratory facilities.
- **Office of Financial Management (OFM):** Provides financial managerial services and policy guidance.
- **Office of Human Resources (OHR)**: Supports workforce relations, client services, executive resources, accountability programs, policy and program development, and systems data and management.
- **Office of Information Management and Technology (OIMT)**: 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.

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 Consumer Price Index and payroll-related expenses by changes in FDA's average personnel compensation and benefits amounts.

An inflation adjustment was not utilized in FY 2018.

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 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 to this amount. Beginning in FY 2019, FDA may use the operating reserve adjustment to lower the annual target revenue in order to help manage to 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. FY 2018 Adjustment

The FY 2018 adjustment enabled FDA to adjust the base amount set for BsUFA II based on its best and most timely available workload estimates at the time the FY 2018 fees were to be set.

FDA considered a range of factors including its best estimated level of submissions and activities (e.g., forecasts of new BPDs, new 351(k)s, resubmitted 351(k)s, advisory committee meetings, interchangeability supplements, industry meetings, inspection activity, science and research activities, policy work, and other activities). FDA reduced the base amount by 10.636 percent.

Note 10. Refunds

If a person submits a biosimilar biological product application before October 1 of the fiscal year and the 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 11. 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 the purposes of BsUFA II, the following definition of "adjustment factor" is applied (see section 744G(1) of the FD&C Act): "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 September of the preceding fiscal year divided by such Index for September 2011."