Financial Report to Congress

Biosimilar User Fee Act
FY 2023

U.S. FOOD & DRUG
ADMINISTRATION

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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 first report under the third authorization of BsUFA (referred to as BsUFA III) and covers fiscal year (FY) 2023.

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 2023, 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, as well as comparative data from prior years.

In FY 2023, FDA had net collections of $60 million in BsUFA fees, spent $63 million in user fees for the BsUFA program, and carried forward $41 million for future fiscal years.

BsUFA user fees and non-user fee appropriations in FY 2023 supported 210 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 2023 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 Agency) and FDA's use of biosimilar biological product user fees during the period of October 1, 2022, through September 30, 2023. 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 2023 fee collections, carryover, 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 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 (30 September). Additional details on financial reporting requirements and commitments addressed by this report are included in **Appendix A**.

C. Organization Background

FDA is responsible for protecting the public health by helping to ensure 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; for helping to speed innovations that make medical products more effective, safe, and affordable; and for helping the public get the accurate, science-based information they need 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 the 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 public health by helping to ensure that human drugs are safe and effective, meet established quality standards, and are available to patients.
CBER	Ensures the safety, purity, potency, and effectiveness of biological products including vaccines, allergenics, blood and blood products, cells, tissues, and gene therapies for the prevention, diagnosis, and treatment of human diseases, conditions, or injury.
ORA	Protects consumers and enhances public health by maximizing the compliance of FDA-regulated products and 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 the Agency's performance commitments associated with these fees, and the need for FDA to convey how these fees are executed calls for strong financial governance. This 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 (UFFMC), 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 UFFMC 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 UFFMC 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 UFFMC 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 III was authorized under the FDA User Fee Reauthorization Act of 2022 from October 1, 2022, through September 30, 2027. The 5-year reauthorization authorized continued funding for FDA from FY 2023 through FY 2027 to support the efficiency and effectiveness of the biosimilar biological product review program. BsUFA III enhanced 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 III reauthorized the user fee structure established under BSUFA II. This user fee structure is comprised of initial and annual biosimilar biological product development (BPD) fees, reactivation fees, biosimilar biological product application fees, and biosimilar biological product program fees.

Exhibit 2 outlines the BsUFA III user fee structure.

Exhibit 2: BsUFA III Fee Structure

Fee Type		Definition
Biosimilar Biological Product Development	*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 or has been administratively removed from the BPD program for a product and wants to resume participation in the BPD program for that product must pay any annual BPD fees previously assessed for that product that are still owed, as well as 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 (e.g., for inflation and for the resource capacity needs of the BsUFA program). 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 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.

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

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 2023.

Exhibit 3: BsUFA III 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, 2023 (Public Law 117-328), which the President signed on December 29, 2022, specifies that $41,600,000 shall be derived from biosimilar user fees and that biosimilar user fees collected in excess of this amount, if any, shall be credited to this account and remain available until expended. Thus, in FY 2023 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 an amount that is not more than 15 percent below the minimum level is spent.
	Met By	The specified minimum level for FY 2023 is $25,072,200. In FY 2023, FDA allocated and obligated $23,135,311 in appropriated funds (excluding user fees) for the BsUFA program, which is not more than 15 percent below the minimum level (see section 744H(f)(2)(C) of the FD&C Act). Thus, the second legal condition was satisfied.

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

F. Strategic Plan

Under BsUFA III, FDA is committed to ensuring effective scientific coordination and review consistency, as well as efficient governance and operations across the biosimilar biological product review program. To facilitate the timely development of biosimilar biological products (including interchangeable biosimilar biological products) and their

availability to patients, FDA will focus on a number of efforts, which are outlined in the BsUFA III Commitment Letter,[2] including the following:

- Enhancing biosimilar and interchangeable biosimilar biological product development and regulatory science
    - Promoting best practices in communication between FDA and sponsors during application review
    - Inspections and alternative tools to evaluate facilities
    - Advancing the development of biosimilar biological-device combination products regulated by CDER and CBER
    - Advancing the development of interchangeable biosimilar biological products
    - Regulatory science to enhance the development of biosimilar and interchangeable biosimilar biological products
- Continuing to enhance FDA's user fee resource management
    - Planning resource capacity
    - Providing financial transparency
    - Managing carryover balance
- Improving FDA's hiring and retention of review staff
    - Setting clear goals for biosimilar biological product review program hiring
    - Assessing hiring and retention on a comprehensive and continuous basis

FDA will continue to play a critical role in facilitating increased access to biosimilars through conducting efficient reviews; continuing and increasing education and outreach regarding biosimilars; utilizing and contributing to regulatory science information that will facilitate development; and collaborating with external stakeholders, both at home and abroad, to support biosimilar development, review, education, and outreach. FDA is committed to a transparent, science-based regulation of biosimilar biological products that maintains the dynamic balance between innovation and timely access, as Congress intended.

G. Performance Summary

Overall, there are 42 review and procedural and processing goals and 20 program enhancement commitments for BsUFA in the FY 2023 cohort.

Of the 42 review and procedural and processing goals, 10 of them received no submissions. For the remaining 32 review and procedural and processing goals, eight

[2] See Biosimilar Biological Product Reauthorization Performance Goals and Procedures Fiscal Years 2023 Through 2027 at https://www.fda.gov/media/152279/download?attachment.

are review goals and 24 are procedural and processing goals. By the end of FY 2023, FDA has the potential to meet or exceed eight of the eight applicable review goals, and the potential to meet or exceed 19 of the 24 applicable procedural and processing goals.

Of the 20 program enhancement commitments applicable to BsUFA in the FY2023 cohort, FDA met 18 commitments and missed two commitments during the fiscal year. The missed commitments included hiring drug review staff and publishing the 5-year financial plan. Except for these missed commitments, all other commitments were completed on time. Details on the program performance can be found in the FY 2023 BsUFA Performance Report.

Financial Information

This section provides an overview of the program financials for BsUFA for FYs 2022 and 2023. 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 2022 and FY 2023. The financial notes can be found in **Appendix E**.

Table 1: Biosimilar Biological Product User Fee Collections, Obligations, and Carryover for FYs 2022 and 2023

Budgetary Resources	Notes	FY 2022	FY 2023
Target Revenue	Note 1	**$40,040,000**	**$41,600,000**
Total Carryover, Beginning of Year		$45,956,772	$43,317,275
Net Collections		$43,106,548	$59,629,003
Recoveries	Note 2	$333,532	$1,014,458
Total Budgetary Resources		**$89,396,852**	**$103,960,736**

Obligations	Notes	FY 2022	FY 2023
Total Payroll & Operating	Note 3	$39,450,517	$53,051,709
Total Rent	Note 4	$1,372,237	$1,079,676
Total Shared Services	Note 5	$5,256,823	$8,834,592
Total Obligations		**$46,079,577**	**$62,965,977**

Carryover	Notes	FY 2022	FY 2023
Total Carryover, End of Year		**$43,317,275**	**$40,994,759**

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

Budgetary Resources: The "Total Budgetary Resources" component of **Table 1** illustrates the total user fee funding (i.e., the existing total carryover and additional user fee collections). 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, net of refunds that have taken place.

BsUFA III specifies how the fees must be calculated for each fiscal year, including various annual adjustments. 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 III. For more information on the allowable and excluded costs, see **Appendix B.**

Carryover: BsUFA fees collected, appropriated, and not obligated at the end of the fiscal year remain available to support the BsUFA program in future fiscal years. In this report, such fee funds are referred to as the "total carryover" or "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, so that FDA can continue program operations under such financial constraints.

I. User Fee Revenue

Table 2 outlines the estimated annual target revenue amount for FY 2023. The financial notes referenced in this table can be found in **Appendix E**.

FDA assumes, for planning purposes, that net collections will equal the target revenue amount. Net collections may differ from the annual target revenue amount if the actual number of fee-paying units differ from the number of fee-paying units estimated when fees are set each year.

Table 2: Biosimilar Biological Product User Fee Revenue for FY 2023

Target Revenue	Notes	FY 2023
Base Amount		$43,376,922
Inflation Adjustment	Note 6	$744,435
Strategic Hiring and Retention Adjustment	Note 12	$150,000
Capacity Planning Adjustment	Note 7	$0
Operating Reserve Adjustment	Note 8	($7,099,898)
Additional Dollar Amount	Note 11	$4,428,886
Target Revenue Total	**Note 1**	**$41,600,000**

Target Revenue Total 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 2023 is defined in the statute and is adjusted for the following factors: inflation adjustment, strategic hiring and retention adjustment, capacity planning adjustment (CPA), operating reserve adjustment, and the additional dollar amount.

Please refer to the respective notes for more details and a definition of each adjustment.

Cohort Year
The year in which user fee collections are originally due and reported. For example, a fee originally due in FY 2022 but received in FY 2023 is attributed to the FY 2022 cohort year collections.

Under BsUFA III, 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. Net collections differ between the fiscal year and the cohort year. Cohort year collections reflect collections for a single year (e.g., FY 2023) across multiple fiscal years. **Tables 3a**, **3b**, and **3c** display transactions such as late collections or refunds processed in a different fiscal year (e.g., a refund processed during FY 2023 for an FY 2023 payment); other data tables use fiscal year data that solely show the activity within that single fiscal year. To ensure the quality of the information provided in this financial report, FDA annually updates the prior years' numbers.

FDA issued invoices for FY 2024 BPD and program fees in August for fees that were due on October 1. FDA will issue additional invoices in December 2023 to sponsors that qualify for the FY 2024 annual BPD fee after the August 2023 billing. FDA will issue additional invoices in December 2024 for any products that qualify for the FY 2024 annual program fee after the August 2023 billing.

Under BsUFA, fees collected and appropriated but not spent by the end of the fiscal year continue to remain available for FDA to spend in future years because they are classified as "no-year funding." The funds carried over from year to year are described in **Section K – User Fee Carryover**.

Tables 3a, **3b**, and **3c** outline BsUFA collections by fee source and cohort year. Refer to **Section D** for more background and information on the BsUFA III fee structure.

Table 3a: Biosimilar Biological Product User Fee Collections by Fee Source for Cohort Year 2022

Fees Collected	Estimated†	Actual	% Dif.
Application Fees	$12,227,215	$17,904,136	46%
BPD Fees	$7,433,931	$6,461,792	(13%)
Program Fees	$20,378,854	$16,120,586	(21%)
Reactivation Fees	$0	$0	-
Total Collections	**$40,040,000**	**$40,486,514**	**1%**

Numbers have been rounded to the nearest dollar.
† Estimated values were taken from the Biosimilar User Fee Rates for Fiscal Year 2022 at https://www.federalregister.gov/documents/2021/07/28/2021-16084/biosimilar-user-fee-rates-for-fiscal-year-2022.

Table 4b: Biosimilar Biological Product User Fee Collections by Fee Source for Cohort Year 2023

Fees Collected	Estimated†	Actual	% Dif.
Application Fees	$13,973,960	$34,061,528	144%
BPD Fees	$5,726,376	$5,679,000	(1)%
Program Fees	$21,899,664	$22,507,988	3%
Reactivation Fees	$0	$0	0%
Total Collections	**$41,600,000**	**$62,248,516**	**50%**

Numbers have been rounded to the nearest dollar.
† Estimated values were taken from the Biosimilar User Fee Rates for Fiscal Year 2023 at https://www.federalregister.gov/documents/2022/10/07/2022-21965/biosimilar-user-fee-rates-for-fiscal-year-2023.

Table 5c: Biosimilar Biological Product User Fees Receivable by Fee Source for Cohort Years 2022 and 2023

Fees Receivable	Cohort Year 2022 Actual	Cohort Year 2023 Actual
Application Fees	$0	$0
BPD Fees	$57,184	$47,325
Program Fees	$0	$0
Reactivation Fees	$0	$0
Total Receivables	**$57,184**	**$47,325**

Numbers have been rounded to the nearest dollar.

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 III. 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 6: Biosimilar Biological Product User Fee Obligations by Expense Category for FYs 2022 and 2023

User Fee Obligations	Notes	FY 2022	FY 2023
Payroll & Operating	Note 3		
CDER		$36,930,952	$50,009,960
CBER		$0	$82,007
ORA		$1,212,289	$1,145,055
HQ		$1,307,276	$1,814,687
Total Rent	Note 4	$1,372,237	$1,079,676
Total Shared Services	Note 5	$5,256,823	$8,834,592
Total Obligations		**$46,079,577**	**$62,965,977**

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 are 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 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, such as human resources and information technology (IT), that provide support across the user fee programs.

In FY 2023, BsUFA obligations increased approximately $17 million from FY 2022. The increase in BsUFA fee fund obligations was largely attributable to increases in payroll.

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

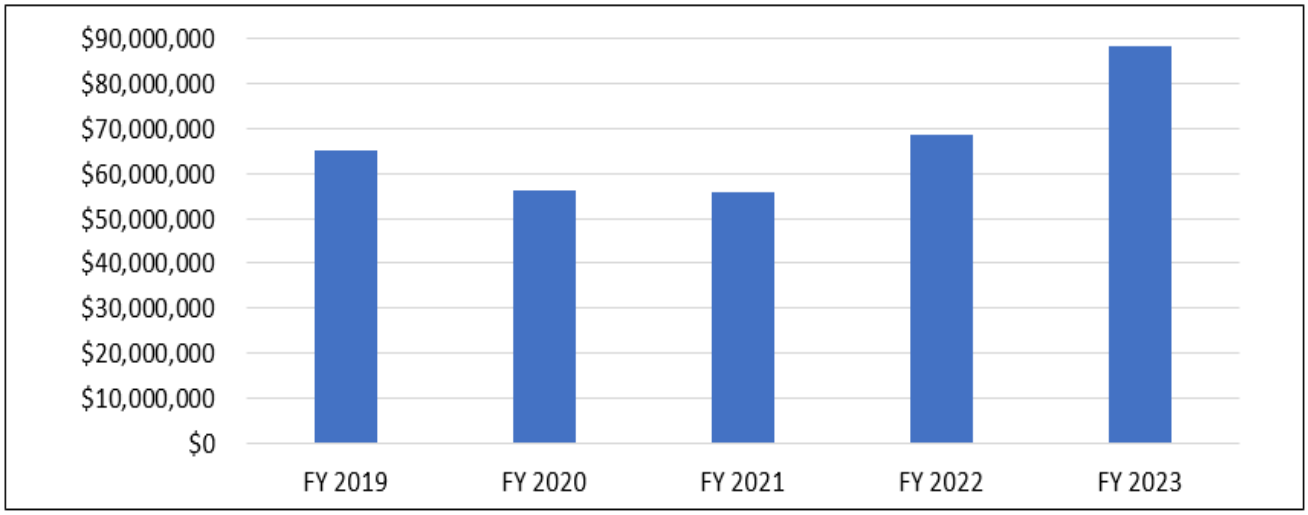
Table 7: BsUFA Program – Historical Trend of Total Costs by Organization as of September 30 for FYs 2019 to 2023

	FY 2019	FY 2020	FY 2021	FY 2022	FY 2023
CDER Spent ($)	$58,878,375	$51,033,432	$50,417,359	$61,573,460	$78,667,320
CDER Percent (%)	90%	91%	90%	90%	86%
CBER Spent ($)	$963,752	$208,083	$177,351	$624,621	$240,942
CBER Percent (%)	1%	0%	0%	1%	1%
ORA Spent ($)	$1,226,634	$2,120,231	$1,835,453	$2,418,467	$2,207,348
ORA Percent (%)	2%	4%	3%	4%	3%
HQ Spent ($)	$4,141,706	$2,973,007	$3,497,912	$3,905,142	$4,985,677
HQ Percent (%)	6%	5%	6%	6%	6%
Total Spent	**$65,210,467**	**$56,334,753**	**$55,928,075**	**$68,521,689**	**$86,101,288**

Numbers have been rounded to the nearest dollar.
† Adjustment due to correction of CBER's cost in FY 2020.

Exhibit 4 provides an illustration of historical BsUFA user fee obligations.

Exhibit 4: Historical BsUFA Total Costs by Fiscal Year



As demonstrated by this graph, BsUFA user fee obligations increased from FY 2022 to FY 2023. The increase in BsUFA fee fund obligations was largely attributable to increased payroll.

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.

Maintaining an appropriate level of carryover enables FDA to mitigate financial risks to the BsUFA program, including, for example, the risk of under-collecting fees and the risk of a lapse in appropriations. Please see the additional discussion of this topic in **Section O**.

In BsUFA III, FDA committed to reducing the carryover balance to no greater than 21 weeks of the target revenue by the end of FY 2025.[3] In addition, BsUFA requires the carryover amount to be no more than an amount equivalent to 33 weeks of operations for FY 2023, and an amount of 27 weeks for FY 2024. As demonstrated in **Table 6**, the total carryover amount at the end of FY 2023 is $40,994,759, which exceeds the 33-week threshold allowable operating reserve of carryover user fees for FY 2023 of $26,400,000.[4] In the setting of FY 2024 BsUFA fee amounts, FDA applied a downward operating reserve adjustment of $20,039,980 with the intent of aligning the operating reserve amounts within the committed and required range.[5]

The net change in the carryover 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 at the end of FY 2022 and FY 2023. The financial notes can be found in **Appendix E**.

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[3] See section IV.C. on page 33 of the BsUFA III goals letter at https://www.fda.gov/media/100573/download.
[4] The FY 2023 target revenue was estimated at $41,600,000, which, divided by 52 weeks, results in a cost of $800,000 per week of operations.
[5] See Biosimilar User Fee Rates for Fiscal Year 2024 at https://www.federalregister.gov/documents/2023/07/28/2023-15918/biosimilar-user-fee-rates-for-fiscal-year-2024.

Table 8: BsUFA Carryover for FYs 2022 and 2023

Carryover	Notes	FY 2022	FY 2023
Total Carryover, End of Year		**$43,317,275**	**$40,994,759**
Future Year Refunds Allowance, Set Aside	Note 9	($1,000,000)	($1,000,000)
Carryover Net of Set Aside, End of Year		**$42,317,275**	**$39,994,759**

Numbers have been rounded to the nearest dollar.

These terms are defined as follows:

- **Total Carryover, End of Year:** This is the total amount of unobligated fee funds at the end of the fiscal year.

- **Future Year Refunds Allowance, Set Aside:** As a matter of prudent operations, FDA maintains a small amount to provide for any refunds. For that purpose, a total of $1,000,000 in fee funds available for obligation is being set aside annually. See **Note 9** for additional details.

- **Carryover Net of Set Aside, End of Year:** This is the total carryover less any carryover funds subject to set asides.

The operations in FY 2023 resulted in a net decrease of the total carryover of $2,322,516, from $43,317,275 at the end of FY 2022 to $40,994,759 at the end of FY 2023. The primary driver of the decreased carryover was the increase in obligations. As noted above, the increase in BsUFA fee fund obligations was largely attributable to increased time reporting and payroll annualization increasing payroll expenses.

Tables 7a and **7b** reflect the historical amounts of fees collected and obligated during the previous and current reauthorization periods.

Table 9a: Historical Biosimilar Biological Product User Fee Carryover by Reauthorization Period

Program	Notes	BsUFA I(FY 2013 2017)	BsUFA II(FY 2018 2022)
Total Carryover, Beginning of Year		**$0**	**$48,723,308**
Net Collections		$99,201,695	$187,708,788
Recoveries	Note 2	$39,497	$2,821,427
Obligations		($50,478,387)	($195,936,248)
Total Carryover, End of Year		$48,723,308	$43,317,275

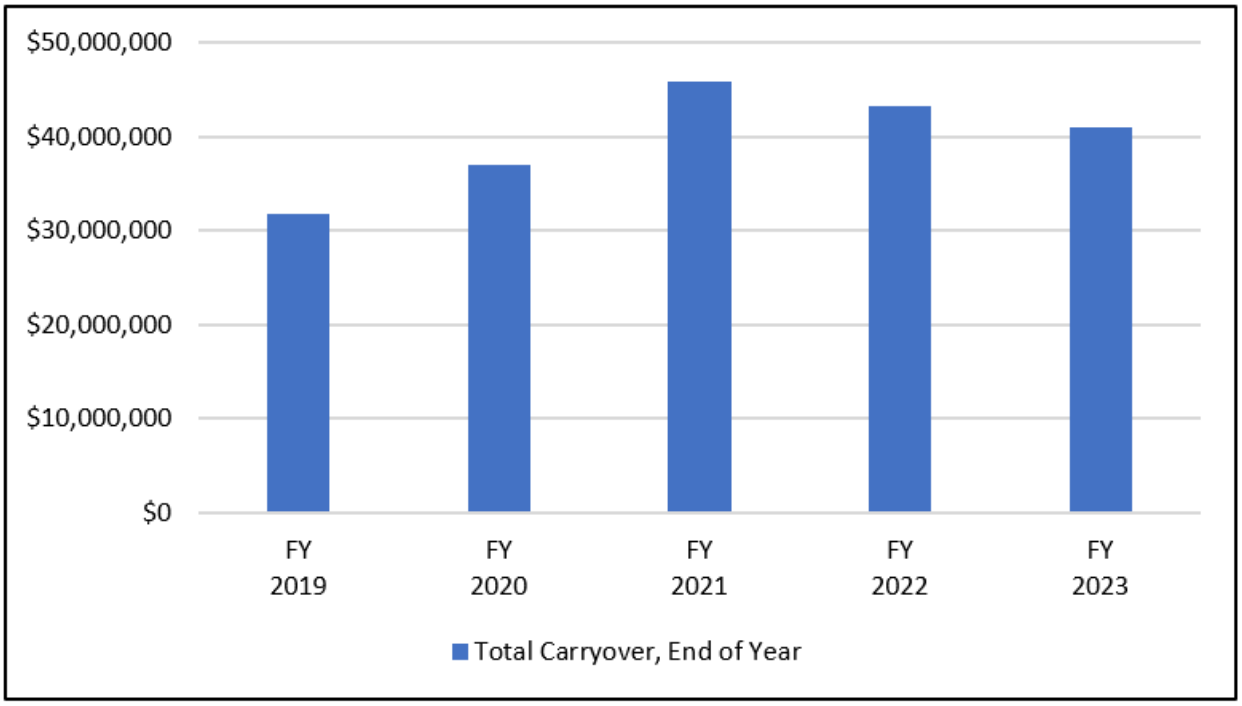
Table 10b: Historical Biosimilar Biological Product User Fee Carryover for Current Authorization Period

Category	Notes	FY 2023
Total Carryover, Beginning of Year		$43,317,275
Net Collections		$59,629,003
Recoveries	Note 2	$1,014,458
Total Obligations		($62,965,977)
Total Carryover, End of Year		$40,994,759

Numbers have been rounded to the nearest dollar.

Exhibit 5 provides a historical perspective of the carryover for the last 5 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."[6] The spending trigger was $23,536,120 for FY 2022 and $25,072,200 for FY 2023.

[6] The statute provides that this requirement is met if an amount that is not more than 15 percent below the minimum level is spent (see sections 744H(f)(2)(B)(i) and 744H(f)(2)(C) of the FD&C Act).

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 fiscal years and the dollar amount and percentages derived from user fees and non-user fee appropriations.

Table 11: Historical Biosimilar Biological Product User Fee Obligations by Funding Source as of September 30 for FYs 2019 to 2023

Funding Source	FY 2019	FY 2020	FY 2021	FY 2022	FY 2023
Non-User Fee Appropriations Obligated: Total ($)	$23,152,080	$22,461,743	$22,282,365	$22,442,112	$23,135,311
Non-User Fee Appropriations Obligated: Percent (%)	36%	40%	40%	33%	27%
User Fee Funds Obligated: Total ($)	$42,058,388	$33,873,010	$33,645,709	$46,079,577	$62,965,977
User Fee Funds Obligated: Percent (%)	64%	60%	60%	67%	73%
Total Obligated	**$65,210,468**	**$56,334,753**	**$55,928,074**	**$68,521,525**	**$86,101,288**

Numbers have been rounded to the nearest dollar.
† Adjustment due to correction of CBER's cost in FY 2020.

BsUFA III provides for a 15-percent range in which FDA can comply with the non-user fee spending trigger requirement.[7] As shown in **Table 8** above, for FY 2023, FDA's non-user fee appropriations spent on the process for the review of biosimilar biological product applications was $23,135,311, which is not more than 15 percent below the minimum level of $25,072,200. Accordingly, FDA is considered to have met the non-user fee spending trigger requirement for FY 2023.

M. Full-Time Equivalents

"FTE employment" (often referred to as "staff year"), as defined by section 85 of the Office of Management and Budget (OMB) Circular A-11, 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 they relate 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

[7] See section 744H(f)(2)(C) of the FD&C Act.

does not represent an accounting of individual people but rather an estimate of labor hours expended on BsUFA activities. Funding is distributed to FDA's 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 fiscal years and are arranged by FDA's 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.

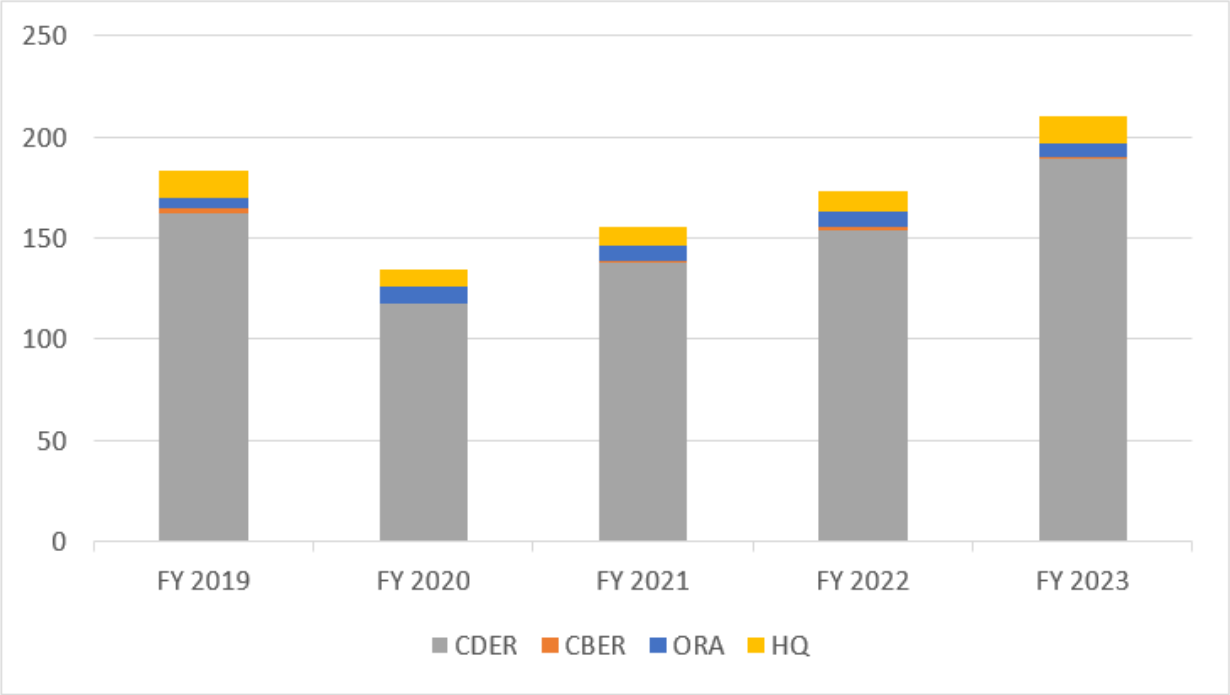
Table 9: Historical Trend of Total Process FTEs Utilized by Organization as of September 30 for FYs 2019 to 2023

	FY 2019	FY 2020	FY 2021	FY 2022	FY 2023
CDER	163	117	138	154	189
CBER	2	1	1	2	1
ORA	5	8	8	8	7
HQ	14	9	9	10	13
Total	**184**	**135**	**155**	**173**	**210**

Numbers have been rounded to the nearest whole number.

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

Exhibit 6: Historical Total Process FTE Levels by FDA Organization



Planned Hiring

FDA will continue to hire additional dedicated staff as needed to address the program workload and achieve performance goals. 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 of 1982 (FMFIA) provides the statutory basis for management's responsibility for and assessment of accounting and administrative internal controls. OMB Circular A-123, Management's Responsibility for Enterprise Risk Management and Internal Control, implements the FMFIA requirements. FMFIA requires that management establish and maintain effective internal controls to achieve the following objectives:

1. Effective and efficient operations
2. Reliable reporting
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. HHS's OpDivs, including FDA, are responsible for developing and maintaining internal control and compliance programs that include programmatic and operational controls, as well as reporting controls to support sound financial management. The Government Accountability Office's 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 Circular A-123 requires an annual internal control assessment, and FMFIA requires the head of each executive agency to report annually on the effectiveness of the internal controls and any identified material weaknesses in those controls.

In alignment with FMFIA, OMB Circular A-123, OMB Circular A-11, the Green Book, and HHS guidelines, FDA established an Enterprise Risk Management (ERM) Program, with an ERM Council (ERMC) as the governance body responsible for providing overall oversight and accountability. ERMC's purview includes deciding on and managing the Agency's Enterprise Risk Profile and ensuring integration with FDA's FMFIA, budget formulation, and strategic planning activities. The ERMC has senior executive representatives from each FDA Center and Office and is chaired by FDA's Chief Operating Officer, with a Center Director as Co-Chair and FDA's Chief Financial Officer (CFO) as President Pro Tempore. FDA's ERM Program supports the ERMC in managing the Agency's Enterprise Risk Profile, facilitates risk response planning, collaborates with Center and Office senior leaders and staff in conducting a range of analyses to manage risks, and provides communications and training opportunities that promote a risk-informed culture.

Additionally, FDA has an established Senior Assessment Team (SAT) to act as the governance body responsible for providing oversight and accountability for FDA's internal control over reporting, including overseeing the FMFIA and OMB Circular A-123

assessments, and for fostering an environment that promotes strong internal controls and reduces the risk of fraud, waste, and abuse. The SAT is chaired by FDA's 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 Officer appointed by the CFO. The SAT members are representatives from each FDA Center and Office.

FDA's internal control program includes integrated management controls covering the OMB A-123 appendices. Specifically:

1. Reporting controls (including business and IT controls) are implemented in accordance with Appendix A, Management of Reporting and Data Integrity Risk

2. Charge card controls are implemented in accordance with Appendix B, A Risk Management Framework for Government Charge Card Programs

3. Controls over financial disbursements are implemented in accordance with Appendix C, Requirements for Payment Integrity Improvement

4. Financial system controls are implemented in accordance with Appendix D, Compliance with the Federal Financial Management Improvement Act of 1996

In FY 2023, FDA's annual assessment of internal controls included tests of 94 business and IT controls across 9 major transaction cycles and 21 transaction sub-cycles to identify recommendations to strengthen internal controls and compliance. This assessment included 11 IT controls related to the User Fee System. Further, in FY 2023, FDA enhanced its integration with HHS to focus on IT controls, align with HHS's standardized IT controls guidance, and collaborate overall with HHS.

Annually, FDA conducts an improper payments risk assessment and performs improper payment testing to assess financial disbursements. In FY 2023, FDA completed the FDA FY 2023 Improper Payments risk assessment to identify FDA Programs that were susceptible to significant improper payments. Six FDA Programs—including Foods, Human Drugs, Biologics, CURES Activities, Reimbursable Program (Federal Sources), and Opioids – IMF Programs—were deemed to not be susceptible to significant improper payments. The Biologics Program and the Devices and Radiological Health Program were selected for improper payments transactional testing. Neither the Biologics nor the Devices and Radiological Health Programs were found to be susceptible to significant improper payments.

The Unified Financial Management System FDA-set-of-books—which is the Integrated Budget and Acquisition Planning Systems (IBAPS) —and the User Fee System are compliant with HHS guidelines and with Appendix D, Compliance with the Federal Financial Management Improvement Act of 1996, of OMB Circular A-123.

FDA has also implemented other internal control procedures, including the performance of Organizational Risk Reviews, which are reviews of targeted financial and non-financial management processes to identify potential recommendations to enhance

internal controls. Also, FDA maintains a Continuous Monitoring Program to oversee the timely implementation of corrective action plans for any deficiencies identified through any of its control assessments.

As a component of HHS, FDA's financial data is presented in HHS's consolidated financial statements. The FY 2023 HHS audit found that FDA's financial statements fairly present, in all material respects, the consolidated financial position of HHS as of September 30, 2023, and 2022, and related notes are in accordance with generally accepted accounting principles in the United States. Further, FDA's FY 2023 Assurance Statements found no material weaknesses or financial system nonconformances.

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. Below is a list of foreseeable risks associated with the collections and obligations of funds for which FDA has identified contingency plans; these contingency plans help ensure FDA is able to move forward in the best interests 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 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 III provides for a 15 percent range in which FDA can comply with its non-user fee spending trigger requirements.[8]

- **Lapse in Non-User Fee Appropriations:** FDA is mitigating this risk to the

[8] See section 744H(f)(2)(C) of the FD&C Act.

program by maintaining a certain level of carryover so that it can continue program operations in the event of a lapse of appropriations. The operating reserve adjustment provides FDA with a tool to help ensure an appropriate amount of carryover is maintained, in part, to mitigate the risk of a lapse in appropriations. This carryover amount includes an operating reserve minimum equivalent to 10 weeks of operations. See **Note 8** for additional details.

- **Under-Executing Planned Spend:** In some prior years, 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 enhanced its planning and execution around the hiring of new staff and contract actions to the extent possible while adhering to non-user fee spending trigger requirements. FDA will continue to enhance its planning and execution of BsUFA resources to minimize this risk.

- **Under-Collecting and Over-Collecting Fees:** Because the BsUFA program experiences variations in workload, it is difficult to forecast the required revenue and to therefore 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 to maintain continuity in operations. When FDA over-collects, the carryover may increase without additional planned expenditures being identified to obligate those funds. The operating reserve adjustment provides a tool to adjust the annual revenue target amount to maintain the operating reserves within the statutory bounds. Resource capacity planning helps improve fee setting and allows FDA to adjust for sustained increases in workload. In addition, FDA monitors collections throughout the fiscal year, and the UFFMC and other FDA senior leaders determine how to mitigate any instances when the user fee revenues deviate from the forecasted estimate.

In addition to these mitigation strategies, FDA implemented IBAPS to enable a 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 the Agency's resources.

Appendices

A. Reporting Requirements

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

Reference	Details
Section 744I(b) of the FD&C Act	FDA must submit a fiscal report, 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 III.A.1 of the BsUFA III 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. The 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 Applications	Excluded Activities
1. An application that cites 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 product; 2. An application with respect to the following: ○ Whole blood or a blood component for transfusion; ○ An in vitro diagnostic biological product; or ○ 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 FDA User Fee Reauthorization Act of 2022 (BsUFA III) 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 III as follows:[9]

> The term "adjustment factor" applicable to a fiscal year that 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.

As a result of a geographical revision made by the Bureau of Labor 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 is 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.

The CPI for September 2022, the September of the fiscal year preceding FY 2023, was 296.808. The CPI for September 2011 was 238.725. Dividing the CPI of September 2022 by the CPI of September 2011 yields an adjustment factor of 1.243305 (rounded to the sixth decimal place) for FY 2023.

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

Legal Conditions

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

Exhibit 7: Legal Conditions

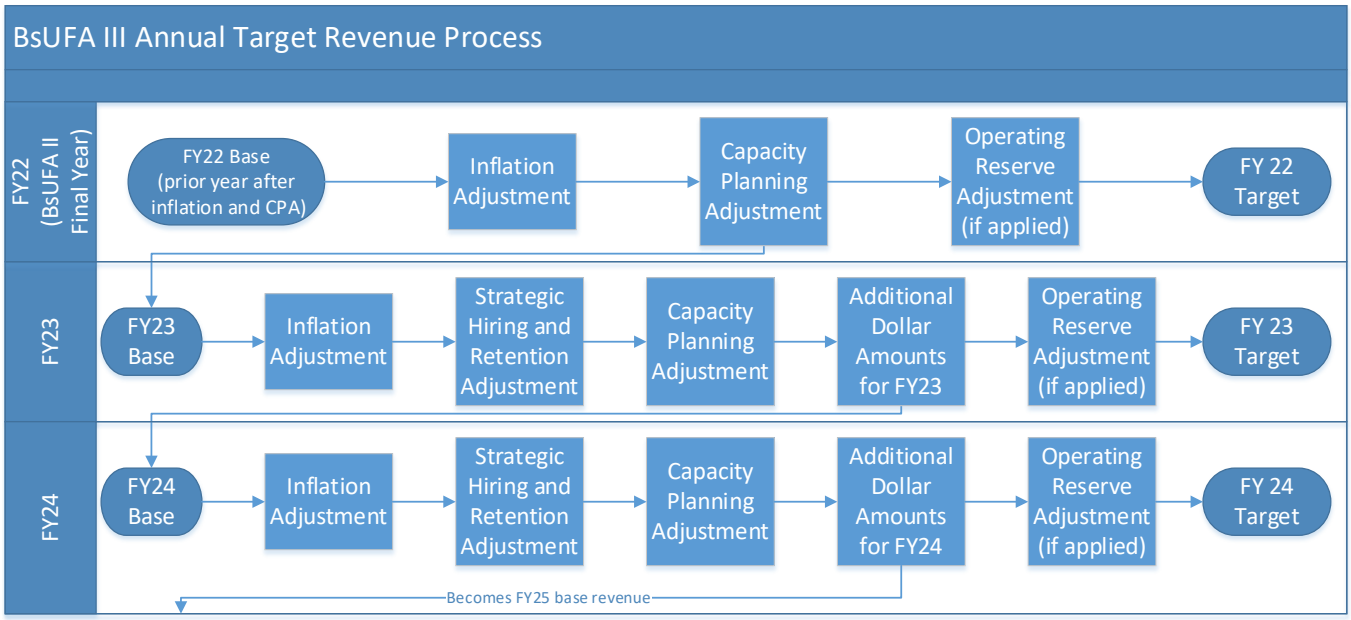
Legal Condition #	FD&C Act Section	Details
1	744H(f)(2)(A)	"Subject to subparagraphs (C) and (D), the fees authorized by this section shall be collected and available in each fiscal year in an amount not to exceed the amount specified in appropriation Acts, or otherwise made available for obligation for such fiscal year."
2	744H(f)(2)(B)(i)	"The fees authorized by this section shall be available for fiscal year 2023 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 outlines the BsUFA III Annualized Base and Target Revenue Methodology.

Exhibit 8: BsUFA III 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. Payroll and Operating Costs

For payroll, Center 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 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 square footage occupied by that Center.

Note 5. Shared Service Costs

FDA has several shared service organizations, located with the Working Capital Fund, that provide support across the user fee programs. The shared service organizations in FY 2023 include the following:

- **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.

- **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 Digital Transformation:** 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. Provides support to all FDA employees requesting administrative, IT, facilities, human resources, and other employee services.

- **Division of Budget Execution and Control:** Initiates, monitors, and analyzes FDA's budget resources. The Agency's 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.

- **Office of Finance, Budget, Acquisitions, and Planning:** Leads FDA's budget, acquisitions, and financial management functions while ensuring the financial integrity of FDA's resources.

- **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.

- **Office of Laboratory Safety:** Reinforces FDA's expectations for safety and laboratory security, enhances communications among FDA's safety staff, and provides program support.

- **Office 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.

- **Office of Enterprise Management Services:** Provides strategic and tactical enterprise-wide services through the development and implementation of administrative policies, programs, and initiatives.

- **Office of Human Capital Management:** Provides human resource services that promote collaboration and a work environment that is characterized by diversity, fairness, open communication, personal accountability, trust, and mutual respect.

- **Office of Talent Solutions:** Provides high quality and efficient human resource solutions that enable FDA to hire a talented and qualified workforce.

- **Office of Planning, Evaluation, and Risk Management:** Partners with FDA's leaders to achieve organizational excellence by improving program performance, governance, operational efficiency, and risk management.

Note 6. Inflation Adjustment

The inflation adjustment adjusts the base revenue 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 2023 was 1.7162 percent.

Note 7. Capacity Planning Adjustment

The statute specifies a capacity planning adjustment to adjust the BsUFA target revenue amount to reflect changes in the resource capacity needs for the process for the review of biosimilar biological product applications.

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.

BsUFA III sets forth an operating reserve adjustment to the fee revenue and fees. Specifically, for FY 2023, the statute directs FDA (1) to increase the fee revenue and fees if such an adjustment is necessary to provide for at least 10 weeks of operating reserves of carryover user fees for the process for the review of biosimilar biological product applications and, (2) if FDA has carryover balances for such process in excess of 33 weeks of such operating reserves, to decrease such fee revenue and fees to provide for not more than 33 weeks of such operating reserves.

To determine the end-of-year operating reserve amount, the Agency must assess its actual operating reserve at the end of the third quarter of the fiscal year and forecast collections and obligations in the fourth quarter of the fiscal year. The estimated end-of-year FY 2022 operating reserve at the time that the FY 2023 fees were set was $38,005,821.

Because that $38,005,821 exceeds the 33-week allowable operating reserve threshold for carryover user fees for FY 2023, which was $30,905,923, FDA applied a downward operating reserve adjustment of $7,099,898 (rounded to the nearest dollar), an amount equivalent to a reduction of approximately 8 weeks of operations; this adjustment was applied to bring the operating reserve of carryover user fees to $30,905,923 or 33 weeks of operations at the start of FY2023. With this operating reserve adjustment, the estimated adjusted revenue amount of $48,700,243 was lowered by $7,099,898, yielding the FY 2023 target revenue amount of $41,600,000.

Note 9. Future Year Refunds Allowance, Set Aside

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 BsUFA III, the following definition of “adjustment factor” is applied:

> The term “adjustment factor” applicable to a fiscal year that 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.[10]

As a result of a geographical revision made by the Bureau of Labor 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 is 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.

Note 11. Additional Dollar Amount Adjustment

BsUFA III, as a result of negotiated enhancements, provides additional dollar amounts for costs associated with new personnel. These costs are phased in over the first 2 years of BsUFA III: $4,428,886 in FY 2023 and $320,569 in FY 2024.

Note 12. Strategic Hiring and Retention Adjustment

For each fiscal year, after the annual base revenue under subsection (b)(1)(A) is adjusted for inflation in accordance with paragraph (1), the Secretary shall further increase the fee revenue and fees by $150,000.

[10] Section 744G(1) of the FD&C Act.

This report was prepared by FDA's Office of Financial Management.
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