Financial Report to Congress

Biosimilar User Fee Act

FY 2024

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Executive Summary

The Federal Food, Drug, and Cosmetic (FD&C) Act requires the Food and Drug Administration (FDA) to report annually on the financial aspects of the Biosimilar User Fee Act (BsUFA) program implementation. This is the second report under the third authorization of BsUFA (BsUFA III) and covers fiscal year (FY) 2024.

The FD&C Act 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 costs of the process for the review of biosimilar biological product applications plus certain specified costs.

FDA met the two legal conditions in FY 2024, 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 2024, FDA had net collections of $34 million in BsUFA fees, spent $56 million in user fees for the BsUFA program, and carried $22 million forward for future fiscal years.

BsUFA user fees and non-user fee appropriations in FY 2024 supported 245 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 BsUFA Performance Report.[1]

[1] The BsUFA Performance Report is available at https://www.fda.gov/about-fda/user-fee-performance-reports/bsufa-performance-reports.

Report Overview

A. Scope

This financial report addresses the implementation and use of biosimilar biological product user fees by the Food and Drug Administration (FDA or Agency) during the period of October 1, 2023, through September 30, 2024. The report presents the legal conditions that FDA must satisfy to collect and spend biosimilar biological product user fees each fiscal year and documents how FDA has determined that those requirements were met. In addition, this report presents summary statements of FY 2024 user fee program financials, revenue, obligations, carryover, total costs of the process for the review of biosimilar biological product applications from both Biosimilar User Fee Act (BsUFA) fees and non-user fee appropriations, and full-time equivalents (FTEs).

B. Report Requirements

In accordance with section 744I(b) of the Federal Food, Drug, and Cosmetic (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 (September 30).

C. User Fee Background and Structure

Under BsUFA, FDA assesses and collects fees from biosimilar biological product manufacturers to help 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.

The FDA User Fee Reauthorization Act of 2022 included the Biosimilar User Fee Amendments of 2022, also known as BsUFA III, which reauthorized the program from October 1, 2022, through September 30, 2027. The 5-year reauthorization provides funding for FDA from FY 2023 through FY 2027 to continue to support the efficiency and effectiveness of the biosimilar biological product review program, and its performance goals, while implementing enhancements as committed to under the BsUFA III Commitment Letter.[2] BsUFA has enhanced FDA's capacity to facilitate timely access to safe and effective biosimilar medicines for patients.

[2] See https://www.fda.gov/media/152279/download.

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 1 outlines the BsUFA III user fee structure.

Exhibit 1: 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 published in the *Federal Register* 60 days before the start of each fiscal year.[3]

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 A** for a detailed list of allowable and excluded activities.

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 2 describes those legal conditions and provides a brief explanation as to how those legal conditions were met for FY2024.

Exhibit 2: BsUFA 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, 2024 (Public Law 118-42), which the President signed on March 9, 2024, specifies that $31,109,000 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, 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 plus certain specified costs. 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 2024 is $25,908,800. In FY 2024, FDA allocated and obligated $35,849,489 in appropriated funds (excluding user fees) for the BsUFA program plus certain specified costs. Thus, the second legal condition was satisfied.

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

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

Financial Information

This section provides an overview of the program financials for BsUFA for FY 2023 and FY 2024. These financials include user fee revenue, obligations, carryover, non-user fee appropriations, and FTEs.

D. User Fee Program Financials

Table 1 provides a summary of the BsUFA financial position for FY 2023 and FY 2024.

Table 1: Biosimilar Biological Product User Fee Program Financials for FYs 2023 and 2024

Budgetary Resources	FY 2023	FY 2024
Total Carryover, Beginning of Year	$43,317,275	$40,994,759
Net Collections	$59,629,003	$34,375,378
Recoveries	$1,014,458	$2,490,062
Total Budgetary Resources	**$103,960,736**	**$77,860,199**
Obligations	**FY 2023**	**FY 2024**
Total Payroll	$30,995,692	$32,806,350
Total Operating	$22,056,017	$17,526,637
Total Rent	$1,079,676	$255,388
Total Shared Services	$8,834,592	$5,215,252
Total Obligations	**$62,965,977**	**$55,803,627**
Carryover	**FY 2023**	**FY 2024**
Total Carryover, End of Year	**$40,994,759**	**$22,056,573**

Budgetary Resources: Total Budgetary Resources is the total user fee funding (i.e., the existing total carryover, user fee collections, and recoveries). Net Collections are the amounts collected during the fiscal year, net of refunds that have taken place. Recoveries account for funds de-obligated from prior year obligations. For example, recoveries could include funding from a contract that ended in a prior year and was not expended. See **Section E** for more on budgetary resources.

Obligations: Total Obligations is 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 section 744G(13) of the FD&C Act. For more information on the allowable and excluded costs and activities, see **Appendix A.**

Carryover: BsUFA fees collected, appropriated, and not obligated at the end of the fiscal year remain available to support biosimilar biological product activities in future fiscal years. In this report, such fee funds are referred to as the "total carryover" or "BsUFA carryover." See **Section G** for more on carryover.

E. User Fee Revenue

User fees are set each year based on the target revenue amount. The process for setting the annual target revenue is defined in the statute and described below. **Table 2** outlines the annual target revenue amounts for FY 2023 and FY 2024.

Table 2: Biosimilar Biological Product User Fee Revenue for FYs 2023 and 2024

Target Revenue	FY 2023	FY 2024
Annual Base Revenue Amount	$43,376,922	$48,700,243
Inflation Adjustment	$744,435	$1,888,011
Strategic Hiring and Retention Adjustment	$150,000	$150,000
Capacity Planning Adjustment	$0	$0
Additional Dollar Amount	$4,428,886	$320,569
Operating Reserve Adjustment	($7,099,898)	($20,039,980)
Target Revenue Total	**$41,600,000**	**$31,019,000**

Target Revenue Total is rounded to the nearest thousand dollars.

Annual Base Revenue Amount: The base amount for FY 2024 was the target revenue from FY 2023, excluding any operating reserve adjustment.

Inflation Adjustment: The inflation adjustment maintains the purchasing power of fee funds in consideration of inflation. This adjustment is a composite measure that adjusts operating expenses by changes in the Consumer Price Index (CPI) and payroll-related expenses by changes in FDA's average personnel compensation and benefits amounts.

The inflation adjustment utilized in FY 2024 was 3.8768 percent.

Strategic Hiring and Retention Adjustment: The strategic hiring and retention adjustment increases the inflation-adjusted base revenue amount to cover the costs of hiring and retaining highly qualified scientific and technical staff for the process for the review of biosimilar biological product applications. For each fiscal year, the amount of this adjustment, as specified in statute, is $150,000.

Capacity Planning Adjustment: The capacity planning adjustment (CPA) adjusts for changes in the resource capacity needs for the process for the review of biosimilar biological product applications.

The CPA authorizes annual adjustments to ensure that the Agency is appropriately resourced to be able to address the forecasted amount of direct review work. The capacity planning methodology is a structured process utilizing validated forecast models trained with the most recently available data and includes managerial decision points.[4]

An adjustment to the fee revenue amounts by the CPA was not made in FY 2024.

Additional Dollar Amounts: BsUFA III provides for the hiring of 15 new positions to support the workload associated with negotiated enhancements. The dollar amounts for the new positions committed to being hired each year are specified in the statute. For FY 2024, the additional dollar amount is $320,569.

Operating Reserve Adjustment: The operating reserve adjustment provides a mechanism to enhance the flexibility of the BsUFA program to manage financial risks while ensuring the program avoids accruing unnecessarily high carryover balances. For each fiscal year starting in FY 2023, FDA is required to increase the fee revenue and fees, if needed, 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. Additionally, FDA is required to decrease the fee revenue and fees, if needed, to provide for not more than the following week-based levels of operating reserves: 33 weeks of operating reserves for FY 2023, 27 weeks for FY 2024, and 21 weeks for FY 2025 and subsequent years. See **Appendix C.2** for additional details**.**

Target Revenue Total: This is the summation of the base revenue and the adjustments described above, rounded to the nearest thousand dollars. This is the amount that is intended to be collected in fees for the respective fiscal year and serves as the basis for setting the fee amounts. The percentage allocated to each fee type is adjusted annually to help balance the fee amounts. For FY 2024, 44 percent of the target revenue was derived from application fees, 53 percent was derived from program fees, and the remainder of the target revenue of four percent was derived from BPD fees.[5]

FDA does not automatically receive the target revenue amount. Fees are collected throughout the fiscal year, and the actual amount of fee dollars collected will vary from the target revenue based the number of fees paid in any given year.

Collections

Net Collections: Although the amount of actual collections varies, FDA generally assumes, for planning purposes, that net collections will equal the target revenue amount. Net collections represent the total collections minus any refunds that occurred

[4] For more information on the capacity planning adjustment, see slides 8-38 at https://www.fda.gov/media/158999/download.

[5] The actual allocation percentages used to set fees sum to 100 percent. The percents described here are rounded.

during the fiscal year, regardless of the year the fee was due. The net collections are reported in **Table 1** above.

Cohort Year Collections: User fee collections are generally recognized and reported in the fiscal year that the fee was originally due (referred to as the "cohort year").[6] Totals reported are after any refunds for the cohort year. To ensure the quality of the information provided in this financial report, FDA annually updates prior years' numbers, which are then described in the current report, to account for any collections or refunds processed after publication of the prior year reports.

Tables 3a and **3b** outline BsUFA collections by fee type and cohort year. **Table 3c** shows the outstanding amounts that are still owed for Cohort Years 2023 and 2024 (the "Fees Receivable"). Refer to **Section C** 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 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	$23,724,636	8%
Reactivation Fees	$0	$0	0%
Total Collections	**$41,600,000**	**$63,465,164**	**53%**

† 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 3b: Biosimilar Biological Product User Fee Collections by Fee Source for Cohort Year 2024

Fees Collected	Estimated†	Actual	% Dif.
Application Fees	$13,498,477	$16,809,425	25%
BPD Fees	$1,199,999	$1,260,000	5%
Program Fees	$16,320,524	$15,078,745	(8%)
Reactivation Fees	$0	$0	0%
Total Collections	**$31,019,000**	**$33,148,170**	**7%**

† Estimated values were taken from the 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.

[6] For example, a fee originally due in FY 2023 but received in FY 2024 is attributed in FY 2023 cohort year collections.

Table 3c: Biosimilar Biological Product User Fees Receivable by Fee Source for Cohort Years 2023 and 2024

Fees Receivable	Cohort Year 2023 Actual	Cohort Year 2024 Actual
Application Fees	$0	$0
BPD Fees	$47,325	$0
Program Fees	$0	$0
Reactivation Fees	$0	$0
Total Receivables	**$47,325**	**$0**

F. 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 section 744G (13) of the FD&C Act. For more information on the allowable and excluded costs, see **Appendix A.**

In FY 2024, BsUFA obligations decreased approximately $7 million from FY 2023. Fee-funded payroll increased slightly while fee-funded operating obligations decreased by about $9 million from the prior year. In FY 2024, total rent-related obligations of BsUFA fees decreased from FY 2023 as, under the statute, certain expenses previously eligible for BsUFA fee funding are no longer eligible and have shifted to non-user fee appropriations.[7]

Table 4 provides a comparison of user fee obligations by expense category during the past 2 fiscal years.

[7] See section 744H(f)(2)(B)(ii).

Table 4: Biosimilar Biological Product User Fee Obligations by Expense Category for FYs 2023 and 2024

User Fee Obligations	FY 2023	FY 2024
Payroll	**$30,995,692**	**$32,806,349**
CBER	$82,007	$0
CDER	$28,975,314	$30,956,807
ORA	$1,033,630	$1,145,173
HQ	$904,741	$704,370
Operating	**$22,056,017**	**$17,526,637**
CBER	$0	$0
CDER	$21,034,646	$16,911,298
ORA	$111,425	$377,472
HQ	$909,946	$237,867
Total Rent	**$1,079,676**	**$255,388**
Total Shared Services	**$8,834,592**	**$5,215,252**
Total Obligations	**$62,965,977**	**$55,803,627**

Payroll and Operating Costs: These obligations provide for certain payroll and operating costs that support the allowable activities for which BsUFA fees may be expended, as set forth in the statute. These allowable activities include, 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. See **Appendix A** for a listing of those activities. The payroll and operating costs associated with the BsUFA program are based on obligations attributed to CBER, CDER, ORA and HQ.

Center employees are required to report their time in an activity-based reporting system. This allows FDA to ensure that user fee funds are only supporting payroll proportional to the time invested in allowable activities.

For operating activities (e.g., certain contracting services), user fee funds are allocated based on the proportion to which those activities support the BsUFA program. If an operating activity solely supports the process for the review of biosimilar biological product applications, it can be fully funded by BsUFA fees (and/or non-user fee appropriations). If the operating activity supports multiple user fee programs, BsUFA fees may fund the activity up to an appropriate proportion.

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. Since rent is an allowable 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.

Shared Services: FDA has several shared service programs, located within the Working Capital Fund (WCF), that provide support for activities across the Agency, such as human resources and information technology (IT). **Appendix C.1** provides a full list of the offices that constitute the WCF.

Table 5 provides the total amount obligated by each relevant FDA organization on the BsUFA program for the past 5 fiscal years, including both user fee and non-user fee appropriations. As illustrated by the table, costs have increased over time, and the percentage spent by each FDA organizational component has remained relatively steady.

Table 5: BsUFA Program – Historical Trend of Total Costs by Organization as of September 30 for FYs 2020 to 2024

Total Cost by Organization	FY 2020	FY 2021	FY 2022	FY 2023	FY 2024
CDER Spent ($)	$51,033,432	$50,417,359	$61,573,460	$78,667,320	$82,813,707
CDER Percentage (%)	91%	90%	90%	91%	91%
CBER Spent ($)	$208,083	$177,351	$624,621	$240,942	$179,997
CBER Percentage (%)	0%	0%	1%	0%	0%
ORA Spent ($)	$2,120,231	$1,835,453	$2,418,467	$2,207,348	$2,602,982
ORA Percentage (%)	4%	3%	4%	3%	3%
HQ Spent ($)	$2,973,007	$3,497,912	$3,905,142	$4,985,677	$5,470,286
HQ Percentage (%)	5%	6%	6%	6%	6%
Total Spent	**$56,334,753**	**$55,928,075**	**$68,521,689**	**$86,101,288**	**$91,066,972**

G. 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 "total carryover" or "BsUFA carryover."

The net change in the BsUFA carryover each year is equal to net collections minus net obligations. This is demonstrated best in **Table 6** below.

Table 6: Biosimilar Biological Product User Fee Carryover for the Current Reauthorization Period (BsUFA III)

Current Carryover	FY 2023	FY2024
Total Carryover, Beginning of Year	**$43,317,275**	**$40,994,759**
Net Collections	$59,629,003	$34,375,378
Recoveries	$1,014,458	$2,490,062
Total Obligations	($62,965,977)	($55,803,627)
Total Carryover, End of Year	**$40,994,759**	**$22,056,573**

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 financial challenges associated with a potential lapse in appropriations, so that FDA can continue performing activities related to the process for the review of biosimilar biological product applications under such financial constraints, to the extent carryover remains available. FDA may also set aside available user fee funds in the carryover for certain purposes, including, for example, for processing future year refunds.

As noted in **Section E** above, the statute requires a downward adjustment if the carryover amount exceeds certain levels. These levels are 27 weeks of operating reserves in FY 2024 and 21 weeks of operating reserves in FY 2025 and subsequent years. The statute also requires an upward adjustment if such an adjustment is necessary to provide for at least 10 weeks of operating reserves. **Appendix C.2** provides more details on how the need for any operating reserve adjustment is assessed.

Table 7 presents the status of the BsUFA carryover at the end of FY 2023 and FY 2024.

Table 7: BsUFA User Fee Carryover for FYs 2023 and 2024

Carryover	FY 2023	FY 2024
Total Carryover, End of Year	**$40,994,759**	**$22,056,573**
Future Year Refunds Allowance, Set Aside	($1,000,000)	($873,000)
Carryover Net of Set Aside, End of Year	**$39,994,759**	**$21,183,573**

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. In FY 2024, FDA estimated future year refund set-asides using a 3-year average of actual refunds from the most recently completed prior fiscal years. The estimated amount of $873,000 in fee funds available

for obligation is being set aside. See **Appendix C.3** 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 2024 resulted in a net decrease of the carryover of $18,938,186, from $40,994,759 at the end of FY 2023 to $22,056,573 at the end of FY 2024. This was a result of the approximately $20 million downward operating reserve adjustment implemented in FY 2024 fee-setting in compliance with the operating reserve cap. The end-of-year total carryover is below the 27-week threshold allowable operating reserve of carryover user fees for FY 2024 of $26,400,000 (see **Table 6**).

Table 8 reflects the historical amounts of fees collected, obligated, and carried over during the previous authorization periods.

Table 8: Historical Biosimilar Biological Product User Fee Carryover by Reauthorization Period

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

H. 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 plus certain other costs during that fiscal year. This is often referred to as a "non-user fee spending trigger."[8] The spending trigger was $25,908,800 for FY 2024, less than the $35,849,411 for non-user fee appropriations obligated for FY 2024, meaning the trigger was met.

The non-user fee spending trigger amount is determined by multiplying a base amount ($20 million) times the adjustment factor for the applicable fiscal year. See **Appendix B.1** for more details on the adjustment factor.

Table 9 provides the total amounts spent on the BsUFA program for the past 5 fiscal years, as well as the dollar amounts and percentages derived from user fee and non-user fee appropriations.

[8] 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).

Table 9: Historical Biosimilar Biological Product User Fee Obligations by Funding Source as of September 30 for FYs 2020 to 2024

Obligations by Funding Source	FY 2020	FY 2021	FY 2022	FY 2023	FY 2024
Non-User Fee Appropriations Obligated: Total ($)	$22,461,743	$22,282,365	$22,442,112	$23,135,311	$35,263,345
Non-User Fee Appropriations Obligated: Percent (%)	40%	40%	33%	27%	39%
User Fee Funds Obligated: Total ($)	$33,873,010	$33,645,709	$46,079,577	$62,965,977	$55,803,627
User Fee Funds Obligated: Percent (%)	60%	60%	67%	73%	61%
Total Obligated	**$56,334,753**	**$55,928,074**	**$68,521,689**	**$86,101,288**	**$91,066,972**

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

Table 10 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 programs (e.g., procurement, IT services, etc.) are included in the FTE levels for various components.

Table 10: Historical Trend of Total Process FTEs Utilized by Organization as of September 30 for FYs 2020 to 2024

	FY 2020	FY 2021	FY 2022	FY 2023	FY 2024
CDER	117	138	154	189	223
CBER	1	1	2	1	0
ORA	8	8	8	7	8
HQ	9	9	10	13	14
Total	**135**	**155**	**173**	**210**	**245**

Management Assurance

FDA maintains a strong internal control culture in order to support data-driven decision making, reliable financial forecasting, and accountability for resource use and to ensure compliance with laws, including:

- Federal Managers' Financial Integrity Act (FMFIA) – This act requires agencies to establish internal controls that provide a reasonable assurance of effective and efficient operations, compliance with applicable laws, and reliable financial reporting. This act requires agencies to comply with federal financial management systems requirements, ensuring that transactions are properly recorded, and financial reports are reliable.

- Office of Management and Budget (OMB) Circular A-123 – This sets the standards for internal controls and requires agencies to implement internal control assessments, including managing risks and ensuring accountability.

- Government Accountability Office Standards for Internal Control (Green Book) – This provides the framework for designing, implementing, and operating an effective internal control system within the federal government.

- Improper Payments Elimination and Recovery Act – This requires agencies to identify and reduce improper payments and recover overpayments when they occur.

- Federal Information Security Modernization Act – This addresses internal controls related to information security, ensuring the protection of federal information systems.

Additionally, FDA established three councils to govern oversight and accountability:

- Office of Finance, Budget, Acquisitions, and Planning (OFBAP) Strategic Council: The OFBAP Strategic Council strengthens FDA's financial management processes, enhancing integrity, accountability, and compliance with federal regulations. Membership: Chief Financial Officer (CFO) serves as the Executive Sponsor and the Deputy Chief Financial Officer chairs the council, with OFBAP Directors and representatives from each FDA Center and Office.

- Enterprise Risk Management Council: The council oversees FDA's Enterprise Risk Management Program, managing the Agency's Enterprise Risk Profile and ensuring alignment with FMFIA, OMB Circular A-123, OMB Circular A-11, the Green Book, and Department of Health and Human Services guidelines. Membership: The Council is chaired by the Chief Operating Officer, with a Center Director as Co-Chair and the Chief Financial Officer (CFO) as President Pro Tempore. Senior executive representatives from each FDA Center and Office serve as members.

- User Fee Financial Management Committee: The committee oversees and ensures FDA's compliance with sound financial management practices and statutory provisions governing user fees, providing oversight for resource needs, financial planning, and forecasting. The CFO serves as the committee Chairman, a Program Representative serves as the Program Vice Chairman, and voting members include the Executive Officers from each FDA Center and Office.

Appendices

A. Allowable and Excluded Costs and Activities for BsUFA

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.

Exhibit 3: Included Activities

Included Activities	
1. The activities necessary for the review of submissions in connection with biosimilar biological product development, biosimilar biological product applications, and supplements. 2. Actions related to submissions in connection with biosimilar biological product development, the issuance of action letters which approve biosimilar biological product applications or which set forth in detail the specific deficiencies in such applications, and when appropriate, the actions necessary to place such applications in condition for approval. 3. The inspection of biosimilar biological product establishments and other facilities undertaken as part of FDA's review of pending biosimilar biological product applications and supplements. 4. Activities necessary for the release of lots of biosimilar biological products under section 351(k) of the Public Health Service Act. 5. Monitoring of research conducted in connection with the review of biosimilar biological product applications.	6. Post-market safety activities with respect to biologics approved under biosimilar biological product applications or supplements, including the following activities: a. Collecting, developing, and reviewing safety information on biosimilar biological products, including adverse-event reports. b. Developing and using improved adverse-event data-collection systems, including IT systems. c. Developing and using improved analytical tools to assess potential safety problems, including access to external databases. d. Implementing and enforcing section 505(o) of the FD&C Act (relating to post-approval studies and clinical trials and labeling changes) and section 505(p) of the FD&C Act (relating to risk evaluation and mitigation strategies). e. Carrying out section 505(k)(5) of the FD&C Act (relating to adverse-event reports and post-market safety activities).

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

Exhibit 4: Included Expenses

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 and necessary scientific equipment;[9] 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:

Exhibit 5: Excluded Applications and Activities

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: a. Whole blood or a blood component for transfusion; b. An in vitro diagnostic biological product; or c. 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.

B. Conditions for Assessment and Use of Fees

[9] Section 905(b) of the FDA Reauthorization Act of 2017 amended the FD&C Act to provide under section 744H(f)(2)(B)(ii) that "[b]eginning on October 1, 2023, the authorities under section 744G(9)(C) shall include only leasing and necessary scientific equipment." The referenced authorities had otherwise listed expenses for "leasing, maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, scientific equipment, and other necessary materials and supplies."

B.1 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:[10]

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

The CPI for September 2023, the September of the fiscal year preceding FY 2024, was 309.254. The CPI for September 2011 was 238.725. Dividing the CPI of September 2023 by the CPI of September 2011 yields an adjustment factor of 1.295440 (rounded to the sixth decimal place) for FY 2024.

B.2 Legal Conditions

Exhibit 6 provides the details regarding each legal condition contained in the FD&C Act.

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

Exhibit 6: 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)(II)	"The fees authorized by this section shall be available for fiscal year 2024 and each subsequent fiscal year, 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 sum of the amounts allocated by the Secretary for such costs, excluding costs paid from fees collected under this section, plus other costs for the maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, and other necessary materials and supplies in connection with the process for the review of biosimilar biological product applications, is no less than $20,000,000, multiplied by the adjustment factor applicable to the fiscal year involved."

C. Supplemental Financial Information

C.1 Shared Service Costs

FDA has several shared service programs, located within the WCF, that provide support across the user fee programs. The shared service programs in FY 2024 include:

- **Office of Digital Transformation:** Provides the vision and leadership in IT, data, and cybersecurity needed to advance FDA's mission and strategic priorities.
- **Office of Enterprise Management Services:** Provides strategic and tactical enterprise-wide services through development and implementation of administrative policies, programs, and initiatives.
- **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 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 Facilities, Engineering, and Mission Support Services:** Provides FDA employees with office and laboratory facilities.

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

- **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 public health by enhancing the safety and security of all personnel, facilities, and information.

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

C.2 Operating Reserve Adjustment

BsUFA III establishes a defined increase threshold and a defined decrease threshold for the operating reserve adjustment. The operating reserve adjustment provides a mechanism to support the management of the carryover balance from year to year. For each fiscal year starting in FY 2023, FDA is required to increase the fee revenue and fees, if needed, 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. Additionally, FDA is required to decrease the fee revenue and fees, if needed, to provide for not more than the following week-based levels of operating reserves: 33 weeks of operating reserves for FY 2023, 27 weeks for FY 2024, and 21 weeks for FY 2025 and subsequent fiscal years.

In FY 2024, FDA applied a downward operating reserve adjustment of $20,039,980, an amount equivalent to a reduction of approximately 20 weeks of operations.

C.3 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.

Table 11 outlines the actual refunds by fiscal year that are used to calculate the estimated refund set aside.

Table 11: Biosimilar Biological Product Actual Refunds Used to Calculate Estimated Future Year Refunds Allowance, Set Aside

Estimated Refunds Set-aside	FY 2021	FY 2022	FY2023	3-Year Average
Actual Refunds	$0	($284)	($2,619,973)	($873,000)

The Actual Refunds 3 Year Average is rounded to the nearest thousand dollars.

The FY 2024 actual refunds for BsUFA was $0.

This report was prepared by FDA's Office of Financial Management.
For information on obtaining additional copies, please contact:

U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

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