Five-Year Financial Plan

Five Years
2023-2024-2025-2026-2027

FY 2024 Version

FOR THE

Biosimilar User Fee Act Program

FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Five-Year Plan Overview

A. Scope

The purpose of the five-year financial plan is to communicate the anticipated financial position of the Biosimilar User Fee Act (BsUFA) program over the current five-year authorization period (BsUFA III). This document addresses the plan for implementation and use of BsUFA user fees by the Food and Drug Administration (FDA or the Agency) during the period of October 1, 2022, through September 30, 2027.

B. Five-Year Plan Commitments

In accordance with Biosimilar Biological Product Reauthorization Performance Goals and Procedures Fiscal Years 2023 through 2027 (BsUFA III Commitment Letter), Title III, Section B, FDA published a BsUFA five-year financial plan in the second quarter of fiscal year (FY) 2023. FDA will publish updates to the five-year plan no later than the second quarter of each subsequent fiscal year. The purpose of this document is to meet this commitment.

C. Updates to the Five-Year Plan

All estimates in the plan are subject to review and reassessment each fiscal year as the actual amounts for appropriations, obligations, and collections for the previous year become available. The five-year financial plan provides the baseline from which future changes will be made. Updates to the five-year financial plan will occur on an annual basis and cover the 5 years in the current reauthorization period.

Management Discussion

D. Organization Background

FDA is responsible for protecting the public's 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 and advancing public health. FDA helps to speed innovations that make medical products more effective, safe, and affordable; and helps the public get the accurate, science-based information needed to use medical products and consume foods to maintain and improve their health. FDA similarly plays a significant role in the nation's counterterrorism capability. FDA fulfills this responsibility by ensuring the security of the food supply and by fostering 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	Protects and advances the public health by helping to ensure that biological products are safe and effective, and are available to patients.
ORA	Protects consumers and enhances public health by maximizing compliance of FDA-regulated products and minimizing the risk associated with those products. ORA inspects regulated products and manufacturers, conducts sample analyses of regulated products and reviews imported products offered for entry into the United States.
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

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

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's 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.

Working Capital Fund/Cost Allocation

FDA utilizes a Cost Allocation and Recovery framework as part of the financial management of user fee resources. Congress authorized FDA to establish a Working Capital Fund (WCF) to finance centralized services (see section 722 of Division A of P.L. 115-141). The WCF benefits the financial management of Agency funds by:

- Increasing transparency through defining administrative activities performed for Centers and Offices and allocating costs based on Agency usage
- Strengthening accountability by improving the tracking and management of administrative costs, including costs charged to user fees for administrative services
- Promoting efficiency by optimizing customer usage and improving the management of user fee administrative costs over time
- Leveraging the WCF governance structure to ensure FDA leadership engagement in decision making relative to administrative costs, efficiency opportunities, recapitalization, and burden on all funding sources – including user fees

Internal Controls

The Department of Health and Human Services (HHS) provides guidance to its operating divisions (OpDivs) to implement The Federal Managers' Financial Integrity Act of 1982 (FMFIA) through its FMFIA Guidelines, which is intended to strengthen internal controls and accounting systems. 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. Additionally, FDA established an Enterprise Risk Management (ERM) Program, with an ERM Council as the governance body responsible for providing overall oversight and accountability. For further information regarding the Internal Controls and Enterprise Risk Management, please refer to the User Fee Program's Financial Report[1].

E. User Fee Background and Structure

Under BsUFA, FDA assesses and collects fees from biosimilar biological product manufacturers to fund the biosimilar biological product review process. The Federal Food, Drug, and Cosmetic Act (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.

Originally authorized in 2012, BsUFA was reauthorized in 2017 (BsUFA II), and most recently in 2022 (BsUFA III). The FDA User Fee Reauthorization Act of 2022 included

[1] BsUFA Financial Reports https://www.fda.gov/about-fda/user-fee-financial-reports/bsufa-financial-reports

the Biosimilar User Fee Amendments of 2022, also known as BsUFA III, which extended the program from October 1, 2022, through September 30, 2027.

The 5-year reauthorization authorizes 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 enhances 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.

The fee structure remains unchanged from BsUFA II. BsUFA III continues to maintain an efficient user fee structure comprised of initial and annual biosimilar biological product development (BPD) fees, BPD 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.
Biosimilar Biological Product Development: 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.
Biosimilar Biological Product Development: Reactivation	A sponsor that has discontinued participation in the BPD program for a product, or that has been administratively removed from such program for a product, and wants to resume participation in the BPD program for that product must pay all annual BPD fees previously assessed for such product and still owed and 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.
Application: Without Clinical Data	A biosimilar biological product application for which clinical data (other than comparative bioavailability studies) with respect to safety or effectiveness are not required for approval is assessed one-half of a full application fee.
Program	Biosimilar biological product program fees are assessed annually for eligible products.

The statute specifies how the fees must be calculated each fiscal year, including annual adjustments that must be made for inflation, strategic hiring and retention, capacity planning, operating reserve, and additional dollar amounts specified in the statute. The fee amounts are to be published in the Federal Register each year,[2] typically 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 A** for a detailed list of allowable and excluded activities.

F. Forward View

FDA developed the enhancements for BsUFA III through a process required by statute. Information on the BsUFA III commitments can be found on FDA's website.[3]

The BsUFA III Commitment Letter continues many commitments from BsUFA II and introduces new enhancements to the program. BsUFA III also made changes to the fee-setting mechanisms and provides additional user fee funding for the program. Over the five year period, FDA will focus on implementing the new commitments and changes to the program. Below are some of the key highlights of what FDA will be focusing on over the five-year period in the program.

Highlights of New Enhancements in BsUFA III

BsUFA III provides additional funding to FDA to implement new enhancements to the program while sustaining existing commitments. This new funding is provided through the strategic hiring and retention adjustment and additional dollar amounts outlined in statute, which will enable the program to hire 15 new employees and retain staff over the course of BsUFA III.

The funding will support enhancements to:

- Review performance, including the introduction of new BsUFA III supplement categories, review timelines, and performance goals
- Meeting management, including modifying two meeting types, introducing a new meeting type, and allowing for follow-up opportunities after meetings
- Review processes for biosimilar biological-device combination products regulated by CDER and CBER, by introducing new procedures and timelines for use-related risk analysis and human factor validation study protocols
- Regulatory science by introducing a new pilot research program broadly applicable to facilitating biosimilar and interchangeable biological product development

[2] The BsUFA user fee rates archive is available at: https://www.fda.gov/industry/biosimilar-user-fee-amendments/bsufa-user-fee-history

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

Changes to Fee-Setting Mechanisms in BsUFA III

BsUFA III includes changes to fee-setting mechanisms to provide predictable funding for the program and enhance flexibilities to sustain operations. Some of the changes include:

- Introduction of a new Strategic Hiring and Retention Adjustment to provide FDA with additional funding to cover the costs of retaining and hiring qualified scientific and technical staff for the process for the review of biosimilar biological product applications under BsUFA. This funding is phased in over the course of BsUFA III to reflect the needs of the program and a reasonable expectation of the timing of retention and new hire costs. The funding will be added to the base revenue each fiscal year.

- Updating of the BsUFA Capacity Planning Adjustment to clarify the workload categories used in the forecasting methodology. These workload categories will include only the activities described in the BsUFA fee setting notice for FY 2021 and, as feasible, additional activities that are also directly related to the direct review of applications and supplements, including additional formal meeting types, the direct review of post marketing commitments and requirements, the direct review of risk evaluation and mitigation strategies, and the direct review of annual reports for approved biosimilar biological products.

- Modification of the Operating Reserve Adjustment to provide for a defined minimum and maximum required amount of operating reserves of carryover user fees for the process for the review of biosimilar biological product applications to be maintained each fiscal year to mitigate financial risks. This requires FDA to increase the annual revenue amount used to set fees, if needed, to provide for at least 10 weeks of such operating reserves. In addition, this requires FDA to decrease the annual revenue amount used to set fees, if needed, to provide for not more than the annual maximum amount of such operating reserves. The annual maximum amount of such operating reserves will be phased in over the first three years of BsUFA III (33 weeks in FY 2023, 27 weeks in FY 2024, and 21 weeks in FY 2025 and each subsequent fiscal year).

Over the 5-year period, FDA will focus on implementing and managing these changes to the fee-setting mechanisms to help FDA maintain a world-class workforce, manage sustained increases in workload, and mitigate financial risks to the BsUFA program.

Continued Efforts to Enhance Financial Management in BsUFA III

Under BsUFA II, FDA made numerous commitments to enhance the financial management of user fee resources in the program. This included establishing a resource capacity planning function and modernizing time reporting to enable better forecasting of workload in the program and the ability to translate forecasts into more targeted human resource and financial needs. Upon establishing the foundational resource capacity planning capability, FDA implemented the new capacity planning adjustment (CPA) methodology that adjusts the annual target revenue amount to

account for the resources required to respond to projected sustained changes in program workload. This helps ensure FDA has the resources it needs to deliver on its performance commitments in BsUFA.

FDA also made commitments in BsUFA II to enhance efficiency and transparency in the administration of BsUFA's financial resources. This included conducting a third-party evaluation of BsUFA program resource management in FY 2018, efforts to manage the carryover balance, publishing of a five-year plan with annual updates, and holding an annual public meeting to discuss the five-year financial plan, along with the Agency's progress in implementing resource capacity planning, modernized time reporting, and the impact of the user fee structure changes under BsUFA II.

Over the course of BsUFA III, FDA will build on the financial improvements achieved in BsUFA II to enhance financial management in the program. Some of the enhancements include:

- Publishing an implementation plan that will describe how resource capacity planning and time reporting will continue to be implemented during BsUFA III, hiring an independent contractor to evaluate the resource capacity planning capability, and, as appropriate, continuing to improve the resource capacity planning capability and CPA after reviewing the findings and recommendations of the evaluation

- Publishing a five-year financial plan with updates each year. FDA will publish an updated BsUFA 5-year financial plan on or before the end of the 2nd quarter of each fiscal year. The plan shall recognize that the retention of the strategic hiring and retention adjustment required by section 744H(b)(1)(C) of the FD&C Act is subject to renegotiation under a subsequent reauthorization of BsUFA. The annual updates will include the following topics: (a) The changes in the personnel compensation and benefit costs for the process for the review of biosimilar biological product applications that exceed the amounts provided by the personnel compensation and benefit costs portion of the inflation adjustment; and (b) FDA's plan for managing costs related to strategic hiring and retention after the adjustment required by section 744H(b)(1)(C) of the FD&C Act expires at the end of fiscal year 2027, as this adjustment is not expected to be reauthorized in a subsequent reauthorization

- Convening a public meeting each fiscal year to discuss this 5-year financial plan and the Agency's progress in implementing resource capacity planning, including the continual improvement of the CPA and time reporting, and the integration of resource capacity planning in resource and operational decision-making processes

- In the annual updates to the 5-year financial plan, providing updates on progress towards implementing FDA's plan to reduce the carryover balance as outlined in the FY 2022 BsUFA financial report and five-year financial plan

FDA is committed to ensuring the sustainability of BsUFA program resources and to enhancing the operational agility of the BsUFA program. The continued maturation of

the resource capacity planning function and CPA over BsUFA III will help ensure optimal use of user fee resources and is FDA's primary mechanism to acquire resources if there are sustained increases in workload in the program. Over the five year period, FDA will also continue activities to promote transparency of the use of financial resources in support of the BsUFA program.

Other Financial Impacts

Section 905(b) of the FDA Reauthorization Act of 2017 (FDARA) amended the FD&C Act such that the types of fee-coverable costs under the Prescription Drug User Fee Act (PDUFA) program, the Generic Drug User Fee Amendments (GDUFA) program, the Medical Devices User Fee Amendments (MDUFA) program, and the BsUFA program narrowed on October 1, 2023.

Due to a later provision in Food and Drug Omnibus Reform Act (as included in the Consolidated Appropriations Act, 2023), section 744H(f)(2) of the FD&C Act was amended to clarify that while BsUFA fees may no longer be used to pay for certain costs excluded by FDARA section 905(b), non-user fee appropriations spent on the excluded costs will count toward the non-user fee spending trigger. For further information, see **Note 4**.

There is not expected to be an impact on the agency's ability to meet the non-user fee spending trigger. The systems supporting these programs, however, are complex and multi-faceted. As such, FDA will continue to plan for and monitor the impacts of these changes to ensure minimal disruption to its user fee commitment and public health mission.

Financial Information

This section provides an overview of the financial outlook for BsUFA for the FY 2023 through FY 2027 authorization period including budgetary resources, obligations, carryover, non-user fee appropriations requirements, and planned hiring. The forecasts included in this section are driven by the initiatives and goals as outlined in the Forward View section of this plan.

G. User Fee Program Financial Summary

Table 1 represents a summary of the estimated BsUFA financial position, as it relates to user fee budgetary resources. This table also provides an overview of estimated obligations for which the user fee resources would be used. Annual updates to this plan provide actual amounts for the prior fiscal years. The financial notes referenced in this table can be found in **Appendix B**.

Table 1a: Biosimilar Biological Product Collections, Obligations, and Carryover for Fiscal Year 2023 through Fiscal Year 2027

Budgetary Resources	Notes	FY2023 Estimate	FY2023 Actual	FY2024 Estimate	FY2025 Estimate	FY2026 Estimate	FY2027 Estimate
Target Revenue	**Note 1**	**$41,600,000**	**$41,600,000**	**$31,019,000**	**$53,347,000**	**$55,731,000**	**$58,216,000**
Net Collections		$41,600,000	$59,629,003	$31,019,000	$53,347,000	$55,731,000	$58,216,000
Recoveries	Note 2	$600,000	$1,014,458	$590,000	$590,000	$590,000	$590,000
Total Carryover, Beginning of Year		$43,317,275	$43,317,275	$40,994,759	$14,245,046	$13,636,964	$13,089,641
Total Budgetary Resources		**$85,517,275**	**$103,960,736**	**$72,603,759**	**$68,182,046**	**$69,957,964**	**$71,895,641**

Table 1b: Biosimilar Biological Product Collections, Obligations, and Carryover for Fiscal Year 2023 through Fiscal Year 2027

Obligations	Notes	FY2023 Estimate	FY2023 Actual	FY2024 Estimate	FY2025 Estimate	FY2026 Estimate	FY2027 Estimate
Total Payroll & Operating	Note 3	$49,425,286	$53,051,709	$53,160,733	$49,137,945	$51,243,195	$53,544,230
Total Rent	Note 4	$1,372,237	$1,079,676	$255,388	$257,941	$260,522	$263,126
Total Shared Services	Note 5	$4,152,722	$8,834,592	$4,942,041	$5,149,019	$5,364,665	$5,589,342
Total Obligations		**$54,950,245**	**$62,965,977**	**$58,358,162**	**$54,544,905**	**$56,868,382**	**$59,396,698**

Table 1c: Biosimilar Biological Product Collections, Obligations, and Carryover for Fiscal Year 2023 through Fiscal Year 2027

Carryover	Notes	FY2023 Estimate	FY2023 Actual	FY2024 Estimate	FY2025 Estimate	FY2026 Estimate	FY2027 Estimate
Total Carryover, End of Year		**$30,567,030**	**$40,994,759**	**$14,245,046**	**$13,636,964**	$13,089,641	$12,498,090
Future Year Refunds Allowance, Set Aside	Note 6	($1,000,000)	($1,000,000)	($873,000)	($873,000)	($873,000)	($873,000)
Carryover Net of Set Aside, End of Year		**$29,567,030**	**$39,994,759**	**$13,372,046**	**$12,763,964**	**$12,216,641**	**$11,625,090**

Net Collections Estimates have 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 1a** illustrates the sum of total user fee funding estimates for FY 2023 through FY 2027 and the actual sum of total user fee funding for FY 2023. Budgetary resources include net collections, recoveries, and carryover amounts.

Budgetary resources are discussed in more detail in **Section H**.

Obligations: The Obligations component of **Table 1b** shows the planned expenditures for FY 2023 through FY 2027 and the actual expenditures for FY 2023 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 A**.

Obligations are discussed in more detail in **Section I**.

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.

Carryover is discussed in more detail in **Section J**.

H. Budgetary Resources

Budgetary resources include net collections, recoveries, and carryover amounts. Net collections are a function of the annual target revenue amount and the number of fees paid. This section describes the process for the setting of the annual target revenue amount and then describes the estimated total budgetary resources.

Annual updates to this plan will update the actual revenue amount for the current fiscal year and the actual collections amount from the preceding fiscal years.

Table 2 outlines the estimated annual target revenue amount for FY 2025 through FY 2027 and the actual revenue target amount for FY 2023 and FY 2024. The financial notes referenced in this table can be found in **Appendix B**.

Table 2: Biosimilar Biological Product User Fee Target Revenue for FY 2023 through FY 2027

Budgetary Resources	Notes	FY2023 Actual	FY2024 Actual	FY2025 Estimate	FY2026 Estimate	FY2027 Estimate
Statutory Base		$43,376,922	$48,700,243	$51,058,823	$53,347,218	$55,731,453
Inflation Adjustment	Note 8	$744,435	$1,888,011	$2,138,395	$2,234,235	$2,334,089
Strategic Hiring and Retention Adjustment		$150,000	$150,000	$150,000	$150,000	$150,000
Capacity Planning Adjustment	Note 9	$0	$0	TBD	TBD	TBD
Additional Dollar Amount Adjustment	Note 11	$4,428,886	$320,569	$0	$0	$0
Operating Reserve Adjustment	Note 10	($7,099,898)	($20,039,980)	TBD	TBD	TBD
Target Revenue Total	**Note 1**	**$41,600,345**	**$31,018,843**	**$53,347,218**	**$55,731,453**	**$58,215,542**
Target Revenue Total (Rounded)		**$41,600,000**	**$31,019,000**	**$53,347,000**	**$55,731,000**	**$58,216,000**

Numbers have been rounded to the nearest dollar

For FY 2024, actual values are used based on fee setting from July 2023

Target Revenue: The process for setting the annual target revenue is defined in the statute and is described below.

- **Statutory Base:** The base amount for FY 2023 is specified in the statute and is adjusted for the factors described below. The sum of the Statutory Base, Inflation Adjustment, Strategic Hiring and Retention Adjustment, Capacity Planning Adjustment, and Additional Dollar Amounts becomes the base revenue for each subsequent fiscal year. See **Note 1** for a diagram of this process.

- **Inflation Adjustment:** The inflation adjustment adjusts the base amount to maintain the purchasing power of fee funds in consideration of inflation. The adjustment is a composite measure that weights operating expenses by changes in the CPI and payroll-related expenses by changes in FDA's average personnel compensation and benefits amounts. The actual inflation adjustment utilized in FY 2024 was 3.8768 (rounded) percent. Inflation for FY 2025 is estimated to be 4.1881% and future years are set to match the estimated FY 2025 percent increase. For more information, see **Note 8**.

- **Strategic Hiring Adjustment:** The strategic hiring and retention adjustment increases the inflation-adjusted base 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 is $150,000.

  FDA recognizes that the retention of the strategic hiring and retention adjustment is subject to renegotiation under a subsequent reauthorization of BsUFA.

  Under BsUFA III, FDA committed to reporting on the following items annually starting with the FY 2024 version of the BsUFA Five-Year Financial Plan:

  - The changes in the personnel compensation and benefits costs for the process for the review of biosimilar biological product applications that exceed the amounts provided by the personnel compensation and benefit portion of the inflation adjustment

  - FDA's plan for managing costs related to strategic hiring and retention after the adjustment required by section 744H(b)(1)(C) of the FD&C Act expires at the end of fiscal year 2027.

  These items are addressed in **Section M**. Additional Reporting Requirements.

- **Capacity Planning Adjustment:** The capacity planning adjustment adjusts for changes in the resource capacity needs of the BsUFA program. An adjustment to the fee amounts by the CPA was not made in FY 2023 or FY 2024.

  The intent of the CPA is to enable annual adjustments if needed to ensure that the Agency is appropriately resourced to be able to address sustained increases in the forecasted amount of direct review work. The CPA is a structured process utilizing validated forecasts models trained with the most recently available data

and includes managerial decision points.[4] While BsUFA has yet to experience an adjustment from the CPA, it is evaluated every year and future years may experience an adjustment. FDA does not maintain expectations for future year CPA amounts as these are dependent on shifting industry activity. As such, FDA will not utilize placeholder estimates for the purposes of the financial plan. The actual CPA amounts will be updated each year.

- **Additional Dollar Amount:** BsUFA III provides an additional dollar amount for additional full-time equivalents to support enhancements outlined in the BsUFA III commitment letter. These costs are phased in over the first two years of BsUFA III: $4,428,886 in FY 2023 and $320,569 in FY 2024.

- **Operating Reserve Adjustment:** BsUFA III establishes a defined increase threshold and a defined decrease threshold for the operating reserve adjustment. The operating reserve adjustment was established to provide a mechanism to support the management of the carryover balance from year to year. FDA is required to increase the fee revenue and fees, if needed, to provide for at least 10 weeks of operating reserves for each fiscal year starting in FY 2023. 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 in FY 2023; 27 weeks in FY 2024; and 21 weeks in FY 2025 and subsequent years. For more information on how the operating reserve is calculated, see **Note 10**. FDA applied a downward operating reserve adjustment of $7,099,898 in FY2023, an amount equivalent to a reduction of approximately 8 weeks of operations. FDA applied a downward operating reserve adjustment of $20,039,980 for FY 2024 and projects no operating reserve adjustment for FY 2025 to bring the operating reserves of carryover user fees to be not more than the threshold amount. This amount may change when fees are set for FY 2025 based on more updated information on FY 2024 obligations and collections.

Table 3 connects the target revenue to the net collections while showing the estimated total budgetary resources for each fiscal year. The financial notes referenced in this table can be found in **Appendix B.**

Table 3: Biosimilar Biologic User Fee Budgetary Resources FY 2023 through FY 2027

Budgetary Resources	Notes	FY2023 Estimate	FY2023 Actual	FY2024 Estimate	FY2025 Estimate	FY2026 Estimate	FY2027 Estimate
Target Revenue	**Note 1**	**$41,600,000**	**$41,600,000**	**$31,019,000**	**$53,347,000**	**$55,731,000**	**$58,216,000**
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Total Budgetary Resources		**$85,517,275**	**$103,960,736**	**$72,603,759**	**$68,182,046**	**$69,957,964**	**$71,895,641**

[4] For more information on the CPA process, see here: https://www.fda.gov/media/158999/download

Net Collections Estimates have been rounded to the nearest thousand dollars.
All other numbers have been rounded to the nearest dollar.

Budgetary Resources: Budgetary resources include net collections, recoveries, and carryover amounts.

- **Net Collections:** FDA generally assumes, for planning purposes, that net collections will equal the target revenue amount. In practice, 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.

- **Recoveries:** For the purposes of this plan, future year recoveries are estimated using a three-year average of actual recoveries from the most recently completed prior fiscal years. Recoveries vary from year to year and the result could be actuals either higher or lower that the current estimate. FDA estimated this to be $600,000 in FY23 and $590,000 annually for FY24-FY27. Additional details on recoveries are included in **Note 2**.

- **Totally Carryover, Beginning of Year:** Total carryover represents the balance of unspent BsUFA fee funds at the beginning of the fiscal year. The total year carryover at the end of one fiscal year equals the total carryover at the beginning of the subsequent fiscal year. Carryover is discussed in more detail in **Section J**.

Net Collections vs. Cohort Year Collections: User fee collections are reported in two different ways:

- **Net Collections:** Net collections are the actual dollar amounts collected in a fiscal year, regardless of the fiscal year the fee was due.
    - **Table 1** and **Table 3** report net collections

- **Cohort Year Collections:** Cohort year collections represent the fiscal year for which the fee was originally due.
    - **Table 4** reports cohort year collections.

Example: Assume a fee was due in FY 2023 but was paid in FY 2024. This would be reported as a net collection in FY 2024 and a cohort year collection in FY 2023.

Table 4 presents the estimated total annual BsUFA fee collections by fee type and cohort year along with the total actual annual BsUFA fee collections by fee type for FY 2023. Refer to **Section E** for more background and information on the BsUFA III fee structure.

Table 4: BsUFA III Fee Collections by Fee Type and Cohort Year

Fee Type	Cohort Year 2023 Estimated	Cohort Year 2023Actuals	Cohort Year 2024 Estimate
Application Fees	$13,973,960	$17,904,136	$13,498,477
BPD Fees	$5,726,376	$6,461,792	$1,199,999
Program Fees	$21,899,664	$16,120,586	$16,320,524
Total Cohort Collections	**$41,600,000**	**$40,486,514**	**$31,019,000**

Numbers have been rounded to the nearest dollar

I. User Fee Obligations

BsUFA fees may be expended only for certain 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 A**.

Table 5 provides a breakout of planned user fee obligations by expense category for the five years represented in this plan. The annual updates to this plan will provide actual amounts for the preceding fiscal year, as well updated planned amounts for the remaining fiscal years. The financial notes can be found in **Appendix B**.

Table 5: Biosimilar Biological Product User Fee Obligations by Expense Category for FY 2023 through FY 2027

User Fee Obligations	Notes	FY2023 Estimate	FY2023 Actual	FY2024 Estimate	FY2025 Estimate	FY2026 Estimate	FY2027 Estimate
Payroll & Operating	**Note 3**						
CBER		$762,722	$82,007	$800,291	$750,221	$777,035	$813,054
CDER		$45,188,359	$50,009,960	$49,752,200	$45,955,805	$47,945,809	$50,151,897
ORA		$1,516,326	$1,145,055	$1,621,111	$1,491,474	$1,547,672	$1,619,310
HQ		$1,957,880	$1,814,687	$987,132	$940,446	$972,679	$959,969
Total Rent	Note 4	$1,372,237	$1,079,676	$255,388	$257,941	$260,522	$263,126
Total Shared Services	Note 5	$4,152,722	$8,834,592	$4,942,041	$5,149,019	$5,364,665	$5,589,342
Total Obligations		**$54,950,245**	**$62,965,977**	**$58,358,162**	**$54,544,905**	**$56,868,382**	**$59,396,699**

Numbers have been rounded to the nearest dollar

Total obligations include payroll and operating, rent, and shared services costs funded by BsUFA fee funds. Non-user fee funds supporting the BsUFA program are not included here. 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. Such payroll and operating 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. Payroll and operating are presented by each major organizational component relevant to 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 (see **Note 4**). Rental rates vary based on the type and location of the space provided.

  Section 744H(f)(2)(B)(ii) of the FD&C Act provides that "beginning on October 1, 2023, the authorities under section 744G(9)(C) shall include only leasing and necessary scientific equipment." The impact of the change means that certain costs related to facilities, fixtures, furniture, materials, and supplies will no longer be able to be funded by BsUFA user fee funds.

  The rent cost beginning in FY 2024 is adjusted at a rate of 1%. The reduction in user-fee funded costs due to the above statutory change results in a lower FY 2024 rent cost than FY 2023.

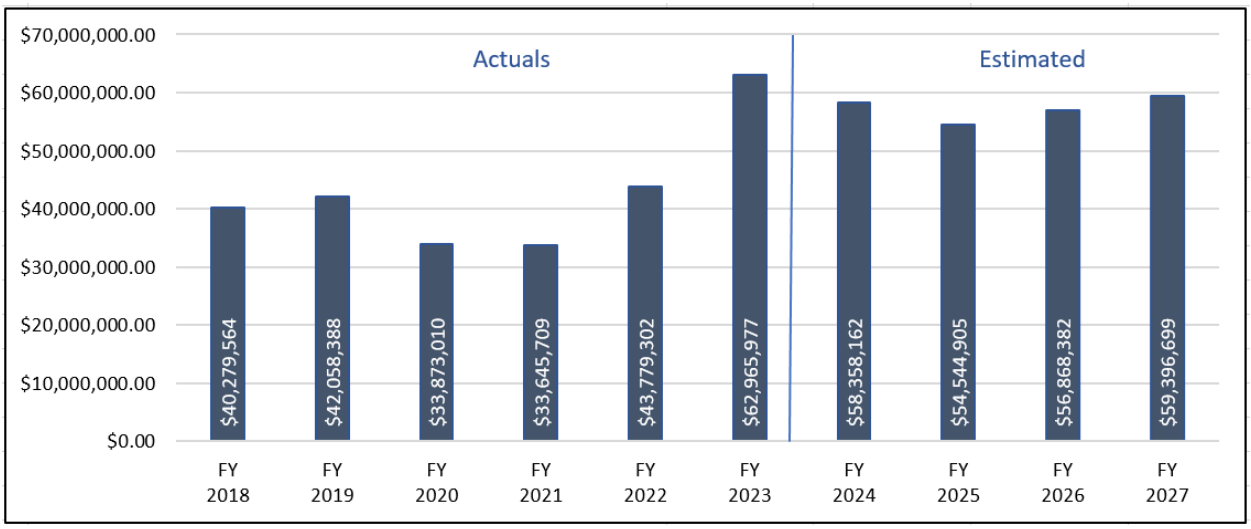
- **Shared Services:** FDA has several shared service organizations that provide support across the user fee programs, such as human resources and information technology (IT). Shared services are located within the Working Capital Fund (WCF). **Note 5** provides a full list of what is contained in the WCF.

  FY 2024 Shared Service amounts use the inflation adjustment, offset by some one-time adjustments that occurred in FY 2023. For FY 2025 through FY 2027, the Shared Services future year amounts are assumed to have an increase of 4.1438 percent annually.

Rent and Shared Services projections are informed by prior year actuals. Yearly costs are determined by the Cost Allocation and Recovery framework discussed previously.

Exhibit 3 below provides an illustration of actual BsUFA obligations and estimated BsUFA III needs.

Exhibit 3: Actual and Estimated User Fee Obligations by Fiscal Year



As demonstrated by this graph, annual BsUFA III obligations are expected to exceed the annual obligations during the BsUFA II authorization period. After an initial increase early in BsUFA III, which was primarily a result of one-time investments in BsUFA regulatory science activities in FY 2023, obligations are expected to decline and then experience moderate inflationary growth for the remainder of the authorization period.

J. User Fee Carryover

BsUFA fees collected, appropriated, and not obligated at the end of the fiscal year remain available to FDA to support the BsUFA program 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, so that FDA can continue performing activities related to the process for the review of biosimilar biological product applications under such financial constraints. FDA may set aside available user fee funds in the carryover for certain purposes, including, for example, for processing future year refunds.

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.

In the annual updates to this five-year financial plan, FDA will provide updates on its progress towards implementing FDA's plan to reduce the carryover balance as outlined in the FY 2022 BsUFA financial report and five-year financial plan.

FDA used the operating reserve adjustment in FY 2024 to reduce the target revenue amount by $20,039,980. Additionally, based on current estimates, FDA does not expect

to use the operating reserve adjustment in FY 2025. The final adjustment amount may change when fees are set for 2025.

Table 6 provides estimates of BsUFA carryover balances at the end of each fiscal year. Estimates will be updated with actual amounts in future Five-Year Financial Plan annual updates. The financial notes can be found in **Appendix B**.

Table 6: BsUFA Carryover by Fiscal Year

Carryover	Notes	FY2023 Estimate	FY2023 Actual	FY2024 Estimate	FY2025 Estimate	FY2026 Estimate	FY2027 Estimate
Total Carryover, End of Year		**$30,567,030**	**$40,994,759**	**$14,245,046**	**$13,636,964**	**$13,089,641**	**$12,498,090**
Future Year Refunds Allowance, Set Aside	Note 6	($1,000,000)	($1,000,000)	($873,000)	($873,000)	($873,000)	($873,000)
Carryover Net of Set Aside, End of Year		**$29,567,030**	**$39,994,759**	**$13,372,046**	**$12,763,964**	**$12,216,641**	**$11,625,090**

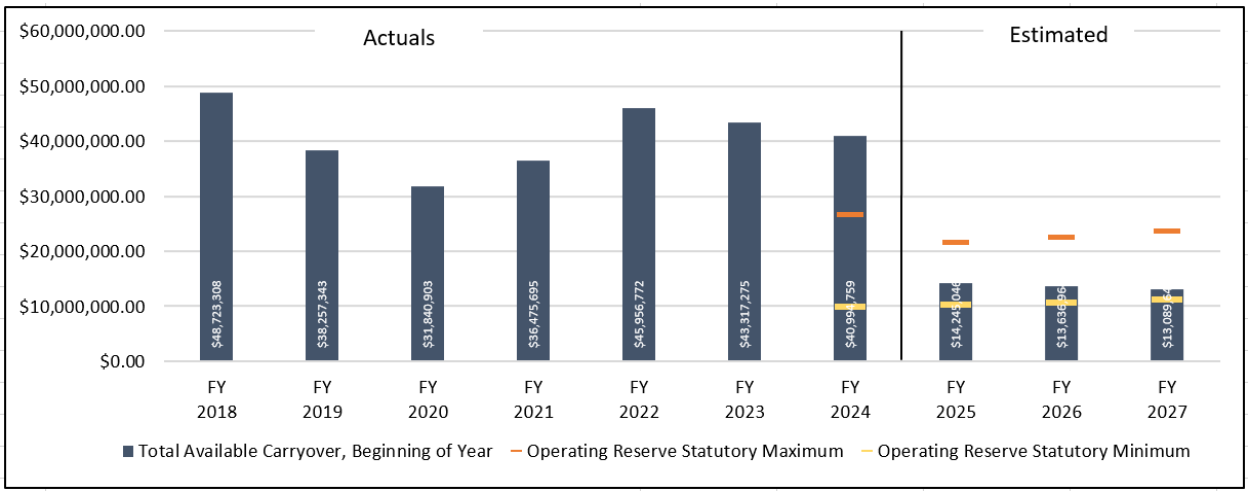
Numbers are rounded to the nearest dollar

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:** FDA maintains a small amount to provide for any refunds, as a matter of prudent operations. In FY 2023 FDA used a flat amount for the set-aside allowance. In FY 2024 FDA decided, for the purposes of this plan, that future year refunds set asides are to be estimated using a three-year average of actual refunds from the most recently completed prior fiscal years. This change was made for future years due to the uncertain nature of refunds, which could impact total year-end carryover. The estimated amount is $873,000 in fee funds that are available for obligation is being set aside annually. See **Note 6** for additional details.
- **Carryover Net of Set Aside, End of Year:** This is the total carryover less any carryover funds subject to set asides.

Exhibit 4 below shows the actual trend of carryover in BsUFA II and the actual carryover for FY 2023 and estimated carryover for FY 2024 through FY 2027 in BsUFA III. The forecasted values reflect the use of the operating reserve adjustment for FY 2023, FY 2024, and FY 2025.

Exhibit 4: Actual and Estimated Carryover by Fiscal Year



The carryover amounts reflect the actual operating reserve adjustments made in FY 2023 and FY 2024. Looking forward into BsUFA III, the operating reserve adjustment will be used, as needed, to ensure carryover remains between the minimum 10-week and the specified maximum levels. FDA will monitor the operating reserve levels and will apply the operating reserve adjustment, as needed, when setting BsUFA fees.

See **Table 7** below for the operating reserve threshold amounts. For the methodology and calculation of the threshold amounts, see **Note 10**.

Table 7: BsUFA Operating Reserve Amounts for FY 2023 through FY 2027

Operating Reserve	FY2023 Actual	FY2024 Actual	FY2025 Estimate	FY2026 Estimate	FY2027 Estimate
1-Week Operating Amount	$800,007	$981,900	$1,025,908	$1,071,759	$1,119,530
Operating Reserve Statutory Increase Threshold (weeks)	10	10	10	10	10
Operating Reserve Statutory Increase Threshold ($)	$8,000,066	$9,819,004	$10,259,080	$10,717,587	$11,195,297
Operating Reserve Statutory Decrease Threshold (weeks)	33	27	21	21	21
Operating Reserve Statutory Decrease Threshold ($)	$26,400,219	$26,511,312	$21,544,069	$22,506,933	$23,510,123
Total Carryover Available for Use, Beginning of Year	**$43,317,275**	**$40,994,759**	**$14,245,046**	**$13,636,964**	**$13,089,641**

Numbers are rounded to the nearest dollar

K. 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. **Table 8** presents the actual non-user fee spending triggers for FY

2023 and FY 2024 and the forecasted non-user fee spending triggers for FY 2025 through FY 2027.

Table 8: Minimum Allocation of BsUFA Non-User Fee Appropriations by Fiscal Year

FY2023 Actual	FY2024 Actual	FY2025 Estimate	FY2026 Estimate	FY2027 Estimate
$25,072,200	$25,908,800	$26,426,976	$26,955,516	$27,494,626

Numbers have been rounded to the nearest dollar

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), multiplied by the adjustment factor applicable to that fiscal year. See **Note 7** for more details on the adjustment factor.

As a result of section 905(b) of FDARA, starting in FY 2024, certain costs associated with the process for the review of biosimilar biological product applications will be shifted from user fee spending to non-user fee appropriations spending. Due to amendments to section 744H(f)(2) of the FD&C Act made by Food and Drug Omnibus Reform Act of 2022, non-user fee appropriations spending on the shifted costs will be counted towards the spending trigger. FDA plans to spend at least the required minimum from non-user fee appropriations each year. In years when FDA programs do not receive appropriations to cover costs of inflation and mandatory pay increases, FDA activities other than biosimilar biological product review may be reduced to assure that the allocation of non-user fee appropriations to the process for the review of biosimilar biological product applications meets the requirements of this trigger.

L. Planned Hiring

BsUFA III provides FDA additional user fee funding to hire additional 15 new positions to support the biosimilar biological product review program. CDER will continue to actively hire for the remaining FY23 vacancies and the additional vacancy for FY24. **Table 9** presents the hiring targets for these new positions for each fiscal year of BsUFA III.[5]

Table 9: Target New Hires by Organization for BsUFA III

Organization	FY2023 Target Estimate	FY2023 Actual	FY2024 Target Estimate	FY2025 Target Estimate	FY2026 Target Estimate	FY2027 Target Estimate
CDER	14	7	1	0	0	0
Total New Hires	**14**	**7**	**1**	**0**	**0**	**0**

[5] BsUFA III Commitment Letter Sect IV.A Program Hiring: https://www.fda.gov/media/152279/download

M. Additional Reporting Requirements.

Under BsUFA III, FDA committed to reporting on the following items annually starting with the FY 2024 version of the BsUFA Five-Year Financial Plan:

1. The changes in the personnel compensation and benefits costs for the process for the review of biosimilar biological product applications that exceed the amounts provided by the personnel compensation and benefit portion of the inflation adjustment:

   The percentage change in the average personnel compensation and benefits costs (PC&B) per full-time equivalent for the process for the review of biosimilar biological product applications (the BsUFA program) was 7.6% percent from FY 2022 to FY 2023. This is shown in Table 10a below.

Table 10a. Change in Average Total PC&B Cost per Full-Time Equivalent for BsUFA

Revenue/Cost	FY 2022	FY 2023	Change from FY 2022 to FY 2023
Process PC&B	$35,117,925	$45,893,774	+31%
Process FTEs	173	210	+21%
Average Total Cost per FTE	**$202,994**	**$218,542**	**+7.6%**

The change in the amounts provided by the PC&B portions of the inflation adjustment for FY 2023 is 1.4%[6] (rounded). This is shown in Table 10b below.

Table 10b. Change in Average Total PC&B Cost per Full-Time Equivalent for FDA used in the BsUFA Inflation Adjustment for FY 2023[5]

PC&B Costs	FY 2019	FY 2020	FY 2021	3-Year Average
Total PC&B	$2,620,052,000	$2,875,592,000	$3,039,513,000	
Total FTE	17,144	17,535	18,501	
PC&B per FTE	$152,826	$163,992	$164,289	
Percentage Change from Previous Year	-3.3120%	7.3063%	0.1811%	**1.3918%**

The changes in the personnel compensation and benefits costs for the process for the review of biosimilar biological product applications (Table 10a) that exceed the amounts provided by the personnel compensation and benefit

[6]https://www.federalregister.gov/documents/2022/10/07/2022-21965/biosimilar-user-fee-rates-for-fiscal-year-2023

portion of the inflation adjustment (Table 10b) equals 6.2%. The actual average cost of a BsUFA FTE increased by 6.2% more in FY 2023 than the amount provided by the PC&B portion of the BsUFA inflation adjustment in FY 2023.

2. FDA's plan for managing costs related to strategic hiring and retention after the adjustment required by section 744H(b)(1)(C) of the FD&C Act expires at the end of FY 2027:

   The strategic hiring and retention adjustment provides resources to cover the costs of retaining and hiring highly qualified scientific and technical staff for the process for the review of biosimilar biological product applications. FDA will continue to monitor payroll costs in the BsUFA program and, if growth of those costs continues to exceed funding provided by the inflation adjustment, leverage all available tools to manage those costs.

Challenges, Risk 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 estimate 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.

- **Under-Executing Planned Spend**: Historically, 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 continues to enhance 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.

- **Uncertainty of User Fees and Non-User Fee Appropriations Levels**: It is difficult to predict the amount of non-user fee appropriations that will be approved by Congress, which creates financial planning challenges for the program since non-user fee fund levels are often uncertain for a good portion of the fiscal year. 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.

- **Lapse in Non-User Fee Appropriations**: FDA cannot control this risk; however, FDA is required to increase the fee revenue and fees, if needed, to provide for at least 10 weeks of operating reserves, which can be used to continue program operations in the event of a lapse of appropriations. FDA is also required to decrease the fee revenue and fees, if needed, to provide for not more than the maximum levels of operating reserves specified in the statute.

- **Under collecting and Over collecting Fees**: If FDA does not receive the estimated number of industry submissions, there may be an excess or deficit in collections relative to the 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 mitigates these risks in BsUFA III. 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.

- **Section 744H(f)(2)(B)(ii) (amended by section 905(b) of FDARA):** FDA cannot use user fees on certain previously allowable expenses. Section 744H(f)(2)(B)(ii) of the FD&C Act provides that "beginning on October 1, 2023, the authorities under section 744G(9)(C) shall include only leasing and necessary scientific equipment." The impact of the change means that certain costs related to facilities, fixtures, furniture, materials, and supplies will no longer be able to be funded by BsUFA user fee funds. This change will have an impact on the finances of the program. FDA is monitoring the impacts to the program's funding.

Appendices

A. 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.	6. Post-market safety activities with respect to biological products approved under biosimilar biological product applications or supplements, including the following activities:

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.	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).

For FY 2023, 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 this process 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 • A biological product for further manufacturing use only. • An application or licensure under section 262(k) of title 42 that is submitted by a state or federal government entity for a product that is not distributed commercially	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.

Section 744H(f)(2)(B)(ii) of the FD&C Act was added by section 905 of FDARA to limit the scope of expenses described of in section 744G(9)(C) to include only expenditures for leasing and necessary scientific equipment starting in FY 2024. Therefore, beginning in FY 2024, the "costs of resources allocated for the process for the review of biosimilar biological product applications" means the expenses in connection with this process 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 and necessary scientific equipment; 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.

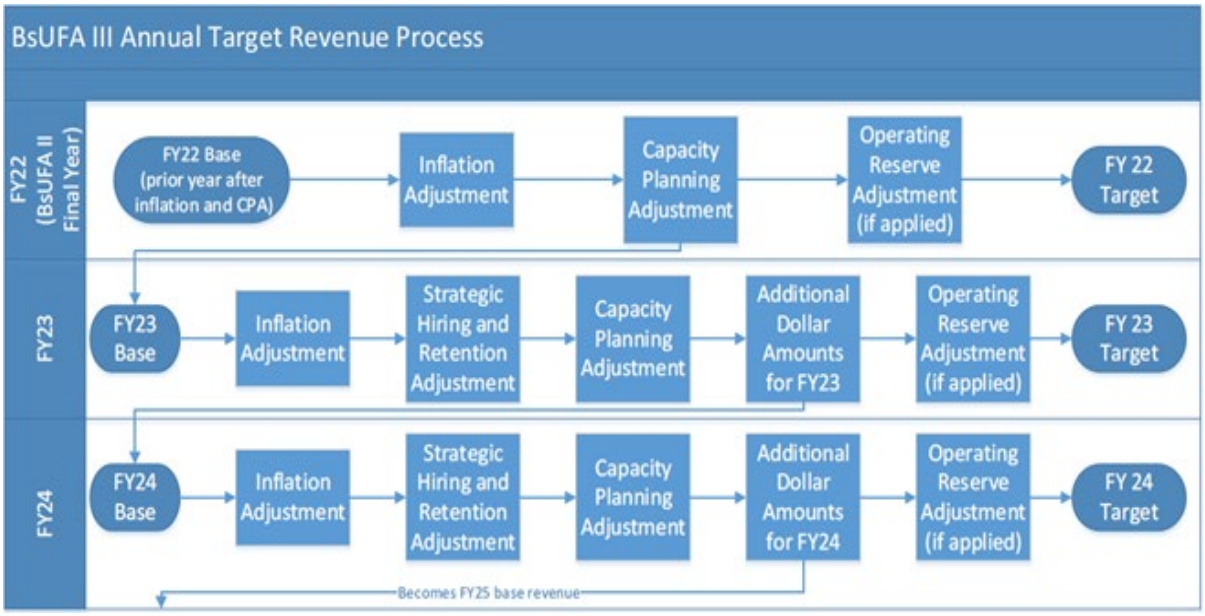
Beginning in FY 2024, in addition to the costs excluded under the FDARA section 905 amendments, the BsUFA program will continue to exclude costs as outlined above.

B. Financial Notes

Note 1. Annual Target Revenue Methodology

Exhibit 5 is a flowchart that outlines the BsUFA III Annual Target Revenue Methodology.

Exhibit 5: 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

Payroll and operating costs associated with the BsUFA program are based on obligations attributed to CBER, CDER, ORA, and HQ.

For payroll, employees are required to report their time in an activity-based reporting system, which allows FDA to identify activities that user fees can be used to support. See **Appendix A** 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 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.

Section 905(b) of the FDA Reauthorization Act of 2017 (FDARA) amended the FD&C Act such that the types of fee-coverable costs under the PDUFA program, the GDUFA program, the MDUFA program, and the BsUFA program narrowed on October 1, 2023.

Specifically, section 744H(f)(2)(B)(ii) of the FD&C Act was added by FDARA to limit the scope of expenses described in section 744G(9)(C) to include only expenditures for leasing and necessary scientific equipment. The impact of the change means that certain costs related to facilities, fixtures, furniture, materials, and supplies are no longer able to be funded by BsUFA user fee funds.

Note 5. Shared Service Costs

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

- **FDA Central**: Provides for Center-wide and Agency-wide services such as telecommunications, training, printing, mail and document management, IT systems, employee health units, and other support and miscellaneous services.
- **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 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.

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

- **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 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 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 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 the FDA to hire a talented and qualified workforce.

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

Note 6. Future Year Refunds Allowance, Set Aside

If an applicant submits a marketing application for a biosimilar biological product before October 1 of the fiscal year and that application is subsequently accepted for filing, the applicant may request a refund of the annual BPD fee paid by the applicant for the

product 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.

Table 11: BsUFA 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	$873,419

Note 7. Adjustment Factors

FDA must calculate and incorporate adjustment factors in establishing fees.

For the purposes of calculating the "non-user fee spending trigger" amount for FY 2023 and subsequent years, an "adjustment factor" is utilized, which is defined in section 744G(1) of the FD&C Act as follows: "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."

Note 8. Inflation Adjustment

For purposes of calculating BsUFA fees for FY 2023 and subsequent fiscal years, section 744H(c)(1)(B)(ii) of the FD&C Act utilizes an inflation adjustment that includes the following: "the average annual percent change that occurred in the Consumer Price Index for urban consumers (Washington-Arlington-Alexandria, DC–VA–MD–WV; Not Seasonally Adjusted; All items; Annual Index) for the first 3 years of the preceding 4 years of available data."

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 2024 was 3.8768 percent.

Note 9. Capacity Planning Adjustment

The statute specifies a process to establish and implement 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.

Following a process required in the statute, FDA established a new CPA methodology and first applied it in the setting of FY 2021 fees. The establishment of this methodology is described in the *Federal Register* at 85 FR 47220 (August 4, 2020). This methodology includes a continuous, iterative improvement approach, under which the Agency intends to refine its data and estimates for the core review activities to improve their accuracy over time.

Beginning in FY 2023, updates were made to refine the time reporting categories included within the CPA. As such, time reporting data and baseline capacity have been revised to match the refinements; in the coming fiscal years, additional updates are anticipated to be made to account for additional activities that are also directly related to the direct review of biosimilar biological product applications and supplements, including additional formal meeting types and the direct review of post marketing commitments and requirements, the direct review of risk evaluation and mitigation strategies, and the direct review of annual reports for approved biosimilar biological products.

FDA did not use the CPA to adjust the fee amounts in FY 2023 or FY 2024.

Note 10. 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.

In BsUFA III, the operating reserve adjustment provides for a defined increase threshold and defined decrease threshold required amounts of operating reserves of carryover user fees for the process for the review of biosimilar biological product applications to be maintained each fiscal year. This requires FDA to increase the annual revenue amount used to set fees, if needed, to provide for at least 10 weeks of such operating reserves. In addition, this requires FDA to decrease the annual revenue amount used to set fees, if needed, to provide for not more than the annual decrease threshold amount of such operating reserves.

The annual decrease threshold amount of such operating reserves will be phased in over the first three years of BsUFA III as follows: 33 weeks in FY 2023, 27 weeks in FY 2024, and 21 weeks in FY 2025 and each subsequent fiscal year.

To calculate the dollar amounts of the defined increase and decrease threshold amounts of such operating reserves for a fiscal year, applicable adjustments (inflation, strategic hiring and retention, capacity planning, and additional dollar amount) are applied to the base revenue. This estimated adjusted revenue amount is then divided by 52 to generate the one-week operating amount. The one-week operating amount is multiplied by 10 weeks to determine the 10-week operating reserve threshold amount (the minimum amount) and is multiplied by the applicable number of weeks (33 weeks for FY 2023, 27 weeks for FY 2024, and 21 weeks for FY 2025) to determine the threshold amount.

The FY 2024 operating reserve adjustment was calculated in FY 2023 as part of BsUFA's annual fee setting. To calculate the 10-week and 27-week threshold amounts for the FY 2024 operating reserve adjustment, the adjusted revenue amount was

divided by 52, resulting in a $981,900 cost of operation for 1 week. The unrounded 1-week value was then multiplied by 10 weeks to generate the 10-week operating reserve threshold amount for FY 2024 of $9,819,004. The unrounded 1-week value was multiplied by 27 to generate the 27-week operating reserve threshold amount for FY 2024 of $26,511,312. To calculate the estimated operating reserve of carryover user fees at the end of FY 2023, FDA estimated the operating reserves of carryover at the end of July 2023. The balance of operating reserves of carryover at the end of July 2023 was combined with the forecasted collections and obligations for the remainder of FY 2023 to generate a full year estimate for FY 2023. The estimated operating reserve of carryover user fees at the end of FY 2023 (which is also the beginning of FY 2024) was $46,551,292, which exceeded the 27-week threshold allowable operating reserve of carryover user fees of $26,511,312.

As such, FDA applied a downward operating reserve adjustment of $20,039,980 (rounded to the nearest dollar), an amount equivalent to a reduction of approximately 20 weeks of operations, to bring the operating reserve of carryover user fees to 27 weeks of operations at the start of FY 2024. The resulting target revenue amount was $31,019,000.

Note 11. Additional Dollar Amounts Adjustment

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

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