Five-Year Financial Plan

Five Years
2023-2024-2025-2026-2027
FY 2026 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 financial plan no later than the second quarter of each subsequent fiscal year. The purpose of this document is to meet these commitments.

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 five years in the current reauthorization period.

D. Organization Background

FDA is responsible for protecting public health by helping to ensure the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation. FDA also has responsibility for regulating the manufacturing, marketing, and distribution of tobacco products 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 to consume foods to maintain and improve their health. In addition, FDA 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 Inspections and Investigation (OII), 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, effective, and are available to patients.
OII	Conducts rigorous, transparent, and science-based inspections and investigations, providing real-time evidence and insight essential in empowering fact-based regulatory decisions to protect public health.
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 user fee programs are executed. This 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 program 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 shared 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.

E. User Fee Background and Structure

Under BsUFA, FDA assesses and collects fees from biosimilar biological product sponsors and application holders to help fund the biosimilar biological product review process. The Federal Food, Drug, and Cosmetic (FD&C) Act, as amended by BsUFA, authorizes FDA to assess and collect fees from industry to supplement the 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 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 five-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 biological products 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 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 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

Fee Type	Definition
	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. The fee amounts are to be published in the Federal Register each year, typically at the beginning of August.[1]

BsUFA user fees are not a fee for service. User fees are pooled and may be used for allowable activities as defined 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.[2]

The BsUFA III Commitment Letter continues many commitments from BsUFA II and introduces additional 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 remainder of the five-year period, FDA will continue implementing the commitments to the program. Below are some of the key highlights of what FDA is focusing on over the five-year period in the program.

Highlights of Enhancements in BsUFA III

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

The funding supports enhancements to:

- Review performance, including the introduction of new BsUFA III supplement categories, review timelines, and performance goals

[1] The BsUFA user fee rates archive is available at: https://www.fda.gov/industry/biosimilar-user-fee-amendments/bsufa-user-fee-history
[2] https://www.fda.gov/media/152279/download

- 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

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 is added to the base revenue each fiscal year.

- Updating the BsUFA Capacity Planning Adjustment (CPA), which is a mechanism to ensure that FDA is able to manage the resources needed for sustained increases in review workload submitted by sponsors, 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 was 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 remainder of BsUFA III, FDA will continue 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 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 remainder of BsUFA III, FDA will continue to build on the financial management enhancements achieved in BsUFA II. 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,[3] 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. The annual updates will include additional topics related to changes in personnel compensation and to managing costs related to strategic hiring and retention after BsUFA III.

- Convening a public meeting[4] each fiscal year to discuss this five-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.

[3] Published March 2023. https://www.fda.gov/media/166677/download?attachment.
[4] FY 2025 BsUFA Public Meeting: https://www.fda.gov/drugs/news-events-human-drugs/financial-transparency-and-efficiency-prescription-drug-user-fee-act-biosimilar-user-fee-act-and

- In the annual updates to the five-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 remainder of BsUFA III, FDA will also continue activities to promote transparency of the use of financial resources in support of the BsUFA program.

Financial Information

This section provides a summary overview of the BsUFA financial outlook 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

Tables 1a, 1b, and 1c represent a summary of the estimated BsUFA financial position, as it relates to user fee budgetary resources, estimated obligations for which the user fee resources would be used, and carryover available to support the BsUFA program in future fiscal years. Annual updates to this plan will provide actual amounts for the prior fiscal years.

Table 1a: Biosimilar Biological Product User Fee Budgetary Resources for FY 2023 through FY 2027

Budgetary Resources	FY 2023 Actual	FY 2024 Actual	FY 2025 Estimate	FY 2025 Actual	FY 2026 Estimate	FY 2027 Estimate
Total Carryover, Beginning of Year	$43,317,275	$40,994,759	$22,056,573	$22,056,573	$29,098,392	$34,332,266
Net Collections	$59,629,003	$34,375,378	$56,012,000	$57,838,759	$55,841,000	$61,769,000
Recoveries	$1,014,458	$2,490,062	$1,279,000	$486,242	$1,330,000	$1,330,000
Total Budgetary Resources	**$103,960,736**	**$77,860,199**	**$79,347,573**	**$80,381,574**	**$86,269,392**	**$97,431,266**

Table 1b: Biosimilar Biological Product User Fee Obligations for FY 2023 through FY 2027

Obligations	FY 2023 Actual	FY 2024 Actual	FY 2025 Estimate	FY 2025 Actual	FY 2026 Estimate	FY 2027 Estimate
Total Payroll	$30,995,692	$32,806,350	$33,639,292	$34,879,223	$30,312,140	$32,394,773
Total Operating	$22,056,017	$17,526,637	$12,490,107	$9,323,981	$14,059,073	$15,180,758
Total Rent	$1,079,676	$255,388	$283,181	$283,181	$295,634	$316,602
Total Shared Services	$8,834,592	$5,215,252	$6,051,811	$6,796,797	$7,270,279	$7,591,012
Total Obligations	**$62,965,977**	**$55,803,627**	**$52,464,391**	**$51,283,182**	**$51,937,126**	**$55,483,145**

Table 1c: Biosimilar Biological Product User Fee Carryover for FY 2023 through FY 2027

Carryover	FY 2023 Actual	FY 2024 Actual	FY 2025 Estimate	FY 2025 Actual	FY 2026 Estimate	FY 2027 Estimate

Total Carryover, End of Year	$40,994,759	$22,056,573	$26,883,182	$29,098,392	$34,332,266	$41,948,121
Future Year Refunds Allowance, Set Aside	($1,000,000)	($873,000)	($873,000)	($873,000)	($1,441,00)	($1,441,00)
Carryover Net of Set Aside, End of Year	**$39,994,759**	**$21,183,573**	**$26,010,182**	**$28,225,392**	**$32,891,266**	**$40,507,121**

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 H** for more detail on budgetary resources.

Obligations: Total Obligations is the annual expenditure of BsUFA fee funds broken out by major expense categories. BsUFA fees may be expended only for certain 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**. See **Section I** for more details on obligations.

Carryover: BsUFA fees collected, appropriated, and not obligated at the end of a 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." See **Section J** for more details on carryover.

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 target revenue amount for the current fiscal year and the actual collections amount from the preceding fiscal years.

Table 2 outlines the annual target revenue amounts for each fiscal year.

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

Budgetary Resources	FY2023 Actual	FY2024 Actual	FY2025 Actual	FY2026 Actual	FY2027 Estimate
Annual Base Revenue Amount	$43,376,922	$48,700,243	$51,058,823	$56,011,943	$58,926,749
Inflation Adjustment	$744,435	$1,888,011	$2,138,395	$2,764,806	$2,692,540
Strategic Hiring and Retention Adjustment	$150,000	$150,000	$150,000	$150,000	$150,000
Capacity Planning Adjustment	$0	$0	$2,664,725	$0	TBD
Additional Dollar Amount Adjustment	$4,428,886	$320,569	$0	$0	$0

Operating Reserve Adjustment	($7,099,898)	($20,039,980)	$0	(3,085,841)	TBD
Target Revenue Total (Rounded)	**$41,600,000**	**$31,019,000**	**$56,012,000**	**$55,841,000**	**$61,769,000**

Annual Base Revenue Amount: The base amount for FY 2023 is specified in the statute. The base amount for all other years is the target revenue from the prior year, not including any operating reserve adjustment from the prior year.

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 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 adjustments for future years are projected using the most recent fiscal year percent increase. See **Appendix B.1.** for details on inflation adjustment rates.

The inflation adjustment utilized in FY 2026 was 4.9361 percent.

Strategic Hiring and Retention 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, as specified in statute, 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; and

- 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.

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

Capacity Planning Adjustment: The CPA adjusts for changes in the resource capacity needs for the process for the review of biosimilar biological product applications. This adjustment helps ensure that FDA can expand its review capacity to meet additional workload demands.

No CPA was made in the setting of FY 2026 fees.

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 forecast models trained with the most recently available data and includes managerial decision points.[5] The CPA amount will fluctuate from year to year. FDA does not maintain expectations for future year CPA amounts as these are largely 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 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 statute.

Operating Reserve Adjustment: BsUFA III establishes a defined increase threshold and a defined decrease threshold for the operating reserve adjustment. 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 **Appendix B.3**.

FDA applied a downward operating reserve adjustment of $3,085,841 in FY 2026. The current estimated total carryover, end of year amount for FY 2026 exceeds the operating reserve defined maximum threshold. FDA does not maintain expectations for future year operating reserve adjustment amounts as these are dependent on uncertain collections, shifting industry activity, and obligations. As such, FDA will not utilize placeholder estimates for the purposes of the financial plan. The actual operating reserve adjustment amounts will be updated each year.

FDA will closely monitor collections and obligations throughout 2026. If they align to the estimates in this plan FDA expects a downward operating reserve adjustment when fees are set for FY 2027. If an operating reserve adjustment is made, it would impact the collections estimates throughout this plan as well as the carryover estimates in Table 6. For more information, see **Section J**.

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 2026, 34 percent of the target revenue is to be derived from applications fees; 63 percent is to be derived from program fees; and the remainder of the target revenue of 3 percent is to be derived from BPD fees.

[5] For more information on the CPA process, see slides 16 – 38 from the 2022 Public Meeting on Financial Transparency and Efficiency of the Prescription Drug User Fee Act, Biosimilar User Fee Act, and Generic Drug User Fee Amendments: https://www.fda.gov/media/158999/download

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 on the number of fees paid in any given year.

Table 3 connects the target revenue to the net collections while showing the estimated total budgetary resources for each fiscal year.

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

Budgetary Resources	FY2023 Actual	FY 2024 Actual	FY 2025 Estimate	FY 2025 Actual	FY2026 Estimate	FY2027 Estimate
Target Revenue Total (Rounded)	**$41,600,000**	**$31,019,000**	**$56,012,000**	**$56,012,000**	**$55,841,000**	**$61,769,000**
Total Carryover, Beginning of Year	$43,317,275	$40,994,759	$22,056,573	$22,056,573	$29,098,392	$34,332,266
Net Collections	$59,629,003	$34,375,378	$56,012,000	$57,838,759	$55,841,000	$61,769,000
Recoveries	$1,014,458	$2,490,062	$1,279,000	$486,242	$1,330,000	$1,330,000
Total Budgetary Resources	**$103,960,736**	**$77,860,199**	**$79,347,573**	**$80,381,574**	**$86,269,392**	**$97,431,266**

Total 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: 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 during the fiscal year, regardless of the year the fee was due. 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 either higher or lower than the current estimate. For FY26-27, FDA estimates recoveries to be $1,330,000 annually.

Table 4 presents the actual and estimated total annual BsUFA fee collections by fee type and cohort year. 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 Actuals	Cohort Year 2024 Actuals	Cohort Year 2025 Estimate	Cohort Year 2025 Actuals	Cohort Year 2026 Estimate
Application Fees	$34,061,528	$15,153,952	$23,905,668	$24,641,227	$19,212,704
BPD Fees	$5,631,675	$1,260,000	$1,110,000	$1,470,000	$1,500,000

Program Fees	$23,724,636	$16,497,921	$30,996,328	$32,021,000	$35,128,296
Total Cohort Collections (Rounded)	**$63,418,000**	**$32,912,000**	**$56,012,000**	**$58,132,000**	**$55,841,000**

Cohort Year Collections: User fee collections are generally recognized and reported in the 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 plan, FDA annually updates prior years' numbers to account for any new collections or refunds.

The annual updates to this plan will provide the actual collection amounts by cohort year for the preceding year(s) as well as an updated planned amount for the current year.

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 as updated planned amounts for the remaining fiscal years.

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

User Fee Obligations	FY2023 Actual	FY 2024 Actual	FY 2025 Estimate	FY 2025 Actual	FY 2026 Estimate	FY 2027 Estimate
Payroll	**$30,995,692**	**$32,806,350**	**$33,639,292**	**$34,879,223**	**$30,312,140**	**$32,394,773**
CBER	$82,007	$0	$0	$0	$0	$0
CDER	$28,975,314	$30,956,807	$32,189,539	$33,400,430	$28,352,876	$30,392,434
OII	$1,033,630	$1,145,173	$962,794	$976,205	$417,404	$428,313
HQ	$904,741	$704,370	$486,959	$502,588	$1,541,860	$1,574,026
Operating	**$22,056,017**	**$17,526,637**	**$12,490,107**	**$9,323,981**	**$14,059,073**	**$15,180,758**
CBER	$0	$0	$131,116	$0	$133,545	$143,440
CDER	$21,034,646	$16,911,298	$11,835,600	$8,999,677	$13,391,292	$14,514,896
OII	$111,425	$377,472	$287,636	$273,757	$249,225	$268,551
HQ	$909,946	$237,867	$235,755	$50,547	$285,011	$253,871
Total Rent	**$1,079,676**	**$255,388**	**$283,181**	**$283,181**	**$295,634**	**$316,602**
Total Shared Services	**$8,834,592**	**$5,215,252**	**$6,051,811**	**$6,796,797**	**$7,270,279**	**$7,591,012**
Total Obligations	**$62,965,977**	**$55,803,627**	**$52,464,391**	**$51,283,182**	**$51,937,126**	**$55,483,145**

[6] For example, a fee originally due in FY 2025 but received in FY 2026 is attributed in FY 2025 cohort year collections. However, when displaying net collections, that fee would be counted in FY 2026 because the payment was received in FY 2026.

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 certain payroll and operating costs for which BsUFA fees may be expended to support the process for the review of biosimilar biological product applications, as defined 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, OII 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 the appropriate proportion of the benefit from such activity that accrues to biosimilar biological product activities.

- **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.

  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 are no longer funded by BsUFA user fee funds.

- **Shared Services:** FDA has several shared service programs, supported by the WCF, that provide support for activities across the Agency, such as human resources and information technology (IT). **Appendix B.2.** provides a full list of what is contained in the WCF.

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

Future BsUFA III obligations will reflect the effects of inflation.

J. User Fee 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.

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, to the extent of available carryover. 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 is demonstrated best in **Table 1c** 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.

An operating reserve adjustment for FY 2026 was required. The operating reserve of carryover user fees at the end of FY 2025 of $29,098,392 was above the 21-week threshold allowable operating reserve of carryover user fees for FY 2026 of $23,797,341. FDA does not maintain expectations for future year operating reserve adjustment amounts as these are dependent on uncertain collections, shifting industry activity, and obligations. As such, FDA will not utilize placeholder estimates for the purposes of the financial plan. The actual operating reserve amounts will be updated each year.

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.

Table 6: BsUFA Carryover by Fiscal Year

Carryover	FY 2023 Actual	FY 2024 Actual	FY 2025 Estimate	FY 2025 Actual	FY 2026 Estimate	FY 2027 Estimate
Total Carryover, End of Year	**$40,994,759**	**$22,056,573**	**$26,883,182**	**$29,098,392**	**$34,332,266**	**$41,948,121**
Future Year Refunds Allowance, Set Aside	($1,000,000)	($873,000)	($873,000)	($873,000)	($1,441,000)	($1,441,000)
Carryover Net of Set Aside, End of Year	**$39,994,759**	**$21,183,573**	**$26,010,182**	**$28,225,392**	**$32,891,266**	**$40,507,121**

Future Year Refunds are rounded to the nearest thousand

These terms are defined below:

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. Starting in FY 2024 FDA estimated future year refund set-asides 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 FY 2026 and FY 2027 estimated amount is $1,441,000 in fee funds that are available for obligation is being set aside annually. See **Appendix B.5.** for additional details.

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

Looking forward, the operating reserve adjustment will be used, as needed, to ensure carryover remains between the minimum and maximum levels specified by statute. FDA will monitor the operating reserve levels and will apply the operating reserve adjustment, as needed, when setting BsUFA fees. Current estimates indicate the total carryover at the end of FY 2027 will exceed the operating reserve decrease threshold. This will be assessed with the latest numbers at the time FY 2027 fees are set.

See **Table 7** below for the operating reserve threshold amounts. For the methodology and calculation of the threshold amounts, see **Appendix B.3**.

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

Operating Reserve	FY 2023 Actual	FY 2024 Actual	FY 2025 Actual	FY 2026 Actual	FY 2027 Estimate
1-Week Operating Amount	$800,007	$981,900	$1,077,153	$1,133,207	$1,187,871
Operating Reserve Statutory Increase Threshold (weeks)	10	10	10	10	10
Operating Reserve Statutory Increase Threshold ($)	$8,000,066	$9,819,004	$10,771,528	$11,332,067	$11,878,709
Total Carryover Available for Use, Beginning of Year	**$43,317,275**	**$40,994,759**	**$22,056,573**	**$29,098,392**	**$34,332,266**
Operating Reserve Statutory Decrease Threshold (weeks)	33	27	21	21	21
Operating Reserve Statutory Decrease Threshold ($)	$26,400,219	$26,511,312	$22,620,208	$23,797,341	$24,945,290

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."[7] **Table 8** presents the actual and forecasted non-user fee spending triggers for FY 2023 through FY 2027.

[7] 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 8: Minimum Allocation of BsUFA Non-User Fee Appropriations by Fiscal Year

FY 2023 Actual	FY 2024 Actual	FY 2025 Actual	FY 2026 Actual	FY 2027 Estimate
$25,072,196	$25,908,807	$26,589,758	$27,254,121	$27,799,203

The non-user fee spending trigger amount is determined by multiplying a base amount ($20 million) times the adjustment factor applicable to that fiscal year.

Section 744G(1) of the FD&C Act defines the term "adjustment factor" applicable to a fiscal year as 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.

As a result of amendments under section 905(b) of FDA Reauthorization Act of 2017, starting in FY 2024, certain costs shifted from user fee-coverable spending to non-user fee-coverable 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 counted towards the spending trigger.

FDA is committed to spend at least the required minimum from non-user fee appropriations in each fiscal 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 ensure 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 for the hiring of 15 new positions to support the biosimilar biological product review program. CDER will continue to actively hire for the remaining FY 2023 and FY 2024 vacancies. **Table 9** presents the hiring targets for these new positions for each fiscal year of BsUFA III.[8]

Table 9: Target New Hires by Organization for BsUFA III

Organization	FY 2023 Actual	FY 2024 Actual	FY 2025 Estimate	FY 2025 Actual	FY 2026 Estimate	FY 2027 Estimate
CDER	7	6	2	0	2	0
Total New Hires	**7**	**6**	**2**	**0**	**2**	**0**

[8] 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 3.1 percent from FY 2024 to FY 2025 This is shown in **Table 10a** below.

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

BsUFA PC&B Costs	FY 2024	FY 2025	Change from FY 2024 to FY 2025
Process PC&B	$55,198,837	$55,760,957	1.02%
Process FTEs	245	**239**	-2.45%
Average Total Cost per FTE	**$225,301**	**$233,309**	**3.55%**

The change in the amounts provided by the PC&B portions of the inflation adjustment for FY 2025 is 3.9%[9] (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 2024[5]

PC&B Costs	FY 2021	FY 2022	FY 2023	3 Year Average
Total PC&B	$3,039,513,000	$3,165,477,000	$3,436,513,000	
Total FTE	18,501	18,474	$18,729	
PC&B per FTE	$164,289	$171,348	$183,486	
Percentage Change from Previous Year	**0.18%**	**4.30%**	7.08%	**3.85%**

The changes in the personnel compensation and benefits costs for the process for the review of biosimilar biological product applications (**Table 10a**) does not exceed the amounts provided by the personnel compensation and benefit portion of the inflation adjustment (**Table 10b**),

The FY 2025 actual average cost of a BsUFA FTE increased by 0.3% less than the amount provided by the PC&B portion of the BsUFA inflation adjustment in FY 2025.

[9]https://www.federalregister.gov/documents/2024/07/31/2024-16884/biosimilar-user-fee-rates-for-fiscal-year-2025

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. Some slight variation between the inflation adjustment and growth in the cost of an FTE is expected year to year, given the lagging nature of the inflation adjustment. If growth of those costs exceeds funding provided by the inflation adjustment over multiple years, FDA will leverage all available tools to manage those costs.

Challenges, Risk, and Mitigation

As is the case with most agency 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 that 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 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 had to spend 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.

- **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 available operating reserves of 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 forecasted estimates.

Appendices

A. Included and Excluded Costs and Activities 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:

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. The monitoring of research conducted in connection with the review of biosimilar biological product applications.	6. Post-market safety activities with respect to biological products 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 this process for the following:

Exhibit 4: 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;[10] 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:

Exhibit 5: Excluded Products 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; and 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. 3. 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.

B. Supplemental Financial Information

B.1. Inflation Adjustment

Inflation Adjustment Rates:

- FY 2023: 1.7162 percent

[10] Section 905(b) of the FDA Reauthorization Act of 2017 (FDARA) amended the FD&C Act to provide under section 744H(f)(2)(B)(ii) that "[b]beginning 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."

- FY 2024: 3.8768 percent
- FY 2025: 4.1881 percent
- FY 2026: 4.9361 percent
- FY 2027: 4.5693 percent

B.2 Shared Service Costs

FDA has several shared service programs, supported by the WCF, that provide support for activities across the Agency. The shared service programs in FY 2026 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 Equal Employment Opportunity:** Promotes a work environment that ensures equal employment opportunity and fosters a professional culture that values and empowers individuals so they can participate and contribute to their fullest potential.
- **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, and Acquisitions:** 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 open communication, personal accountability, trust, and mutual respect.
- **Office of Management and Enterprise Services:** Provides strategic and tactical enterprise-wide services through development and implementation of administrative policies, programs, and initiatives.
- **Office of Occupational Safety and Health:** Reinforces FDA's expectations for workplace health and safety, laboratory safety and security, laboratory quality and efficiency, enhances communications among FDA safety staff, and provides program support.

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

- **Office of Security and Passport 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. Delivers efficient passport and visa services and 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 the FDA to hire a talented and qualified workforce.

B.3. 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 was 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 2025-2027) to determine the threshold amount.

The need for a FY 2026 operating reserve adjustment was assessed in FY 2025 as part of BsUFA's annual fee setting. To calculate the 10-week and 21-week operating reserve threshold amounts for FY 2026, the adjusted revenue amount was divided by

52, resulting in a $1,133,207 cost of operation for 1 week. The unrounded 1-week value was then multiplied by 10 weeks to generate the 10-week operating reserve increase threshold amount for FY 2026 of $11,332,067. The unrounded 1-week value was multiplied by 21 to generate the 21-week operating reserve decrease threshold amount for FY 2026 of $23,797,341. The estimated operating reserve of carryover user fees for the end of FY 2025 (which is also the beginning of FY 2026) was $26,883,182, which was above the 21-week threshold allowable operating reserve of carryover user fees of $23,797,341.

As such, FDA applied a downward operating reserve adjustment in FY 2026 fee setting of $3,085,841 (rounded to the nearest dollar), an amount equivalent to a reduction of approximately three weeks of operations, to bring the operating reserve of carryover user fees to 21 weeks of operations at the start of FY 2026. The resulting target revenue amount was $56,012,000.

B.4. Additional Dollar Amounts Adjustment

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

B.5. 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 2023	FY 2024	FY 2025	3-Year Average*
Actual Refunds	$2,619,973	$0	$1,702,799	$1,441,000

**3-Year Average is rounded to the nearest thousand*

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