FIVE-YEAR FINANCIAL PLAN

Fiscal Years
2018-2019-2020-2021-2022
2022 Update

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 Amendments of 2017 (BsUFA II) program over the current five-year authorization period, and to communicate how FDA plans to utilize user fee resources to execute the BsUFA II commitments and to continue building the biosimilars review program. 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, 2017, through September 30, 2022.

B. **Five-Year Plan Commitments**

In accordance with *Biosimilar Biological Product Reauthorization Performance Goals and Procedures Fiscal Years 2018 through 2022*, Section IV.B, FDA will publish a BsUFA five-year financial plan no later than the second quarter of fiscal year (FY) 2018. 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 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 5 years in the current reauthorization period.

Management Discussion

D. **Organization Background**

FDA is responsible for protecting public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation. FDA also has responsibility for regulating the manufacturing, marketing, and distribution of tobacco products. FDA is responsible for advancing the public health by helping to speed innovations that make medical products more effective, safer, and more affordable and by helping the public get accurate, science-based information needed to use medical products and consume foods to maintain and improve their health. FDA similarly plays a significant role in the nation's counterterrorism capability.

Program Organization

There are four major components that support the BsUFA program: the Center for Drug Evaluation and Research (CDER), the Center for Biologics Evaluation and Research (CBER), the Office of Regulatory Affairs (ORA), and Headquarters (HQ).

Exhibit 1 provides an overview of the mission for each of these components.

Exhibit 1: User Fee Program Components

Component	Mission
CDER	Protects and promotes public health by helping to ensure that human drugs are safe and effective, meet established quality standards, and are available to patients.
CBER	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 risk associated with those products.
HQ	Provides FDA-wide program direction and administrative services to ensure FDA's consumer and patient safety programs are effectively and efficiently managed.

User Fee Governance

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

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 who evaluate user fee resource needs, develop financial allocation plans, and forecast resource requirements – both programmatic and administrative – to support user fee financial decisions. The UFFMC is responsible for providing oversight and support of appropriate standards and policies to ensure FDA compliance with sound financial management practices, as well as compliance with statutory provisions that authorize FDA to collect and spend user fees. The UFFMC receives policy guidance and strategic direction directly from FDA's Executive Committee relative to how the Agency will forecast and react to industry trends, plans and manages its research agenda in support of the user fee programs, and forecasts 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.

E. User Fee Background and Structure

Under the BsUFA program, FDA collects user fees from the biosimilar biological product manufacturers to fund the biosimilar biological product review process. The Federal Food, Drug and Cosmetic Act (the FD&C Act), as amended by BsUFA, authorizes FDA to collect fees from industry to supplement non-user fee appropriations that the Agency spends on the process for the review of biosimilar biological product applications.

The FDA Reauthorization Act of 2017 (FDARA) includes the reauthorization of BsUFA, also known as BsUFA II, which extends from October 1, 2017, through September 30, 2022. The five-year reauthorization authorizes continued funding for FDA from FY 2018 through FY 2022 to support the efficiency and effectiveness of the biosimilar biological product review program. BsUFA II continues to enhance FDA's capacity to facilitate timely access to safe and effective biosimilar medicines for patients.

FDA spends BsUFA user fee collections and non-user fee appropriations to hire, support, and maintain personnel for the review of biosimilar biological product applications to help ensure that safe and effective biosimilar biological products are available to the American public.

BsUFA II establishes an efficient user fee structure comprised of initial and annual biosimilar biological product development (BPD) fees, reactivation fees, biosimilar biological product application fees, and

biosimilar biological product program fees. The structure is intended to enhance predictability of funding, reduce administrative inefficiency, and improve management of funding.

Exhibit 2 outlines the BsUFA II user fee structure.

Exhibit 2: BsUFA II Fee Structure

Fee Type		Definition
Biosimilar Biological Product Development (BPD)	*Initial*	Initial BPD fee is a one-time fee that is assessed to a sponsor to enter the BPD program.
	Annual	Beginning in the next fiscal year after a sponsor has paid the initial BPD fee, the sponsor must pay an annual fee for the product in each fiscal year.
	Reactivation	A sponsor that has discontinued participation in the BPD program for a product and seeks to resume participation in the BPD program for the product must pay a reactivation fee.
Application	*With Clinical Data*	A biosimilar biological product application for which clinical data (other than comparative bioavailability studies) with respect to safety or effectiveness are required for approval is assessed **a full application fee** when the application is submitted.
	Without Clinical Data	A biosimilar biological product application for which clinical data (other than comparative bioavailability studies) with respect to safety or effectiveness are not required for approval is assessed **one-half of a full application fee**.
Program		Biosimilar biological product program fees are assessed annually for eligible products.

The statute specifies how the fees must be calculated each fiscal year, including annual adjustments (e.g., for inflation and for the resource capacity needs of the BsUFA program). The fee amounts are to be published in the Federal Register each year; this typically occurs at the beginning of August (BsUFA User Fee Rates Archive).

BsUFA user fees collected are not a fee-for-service. The user fees that are collected are pooled and may be used for the allowable activities as set forth in the FD&C Act. Refer to **Appendix A** for a detailed list of allowable and excluded activities.

Appendix B provides more information on the history of the user fee program.

F. Forward View

The current authorization for the BsUFA program will expire at the conclusion of FY 2022 (September 30, 2022). The future of the program is dependent on timely reauthorization. The Agency has developed a package of recommendations developed through a process required in statute and the Secretary has transmitted these recommendations to the authorizing Committees. Information on this reauthorization process is available here: https://www.fda.gov/industry/biosimilar-user-fee-amendments/bsufa-iii-fiscal-years-2023-2027.

As the current program is set to expire and is pending reauthorization at the time of publication of this plan, FDA cannot currently project the financial position of the program after FY 2022.

FDA does expect that many of the recent external factors impacting the program are likely to continue to impact the program in the coming years. This includes potential impact from the COVID-19 pandemic, and continued competition for the necessary scientific and technical talent needed to deliver BsUFA performance commitments and related public health priorities.

Discussion of Workload and Other activities in BsUFA

At the beginning of BsUFA I, the regulatory pathway for biosimilar biological products was relatively new in the U.S. and thus much of FDA's work was focused on providing development-stage advice to sponsors of biosimilar biological products through FDA's BPD Program. During BsUFA I, FDA received fewer original biosimilar biological product application submissions than the Agency had initially expected to receive, which resulted in the collection of relatively more BPD fees than expected and fewer application, establishment, and product fees. This unexpected higher distribution of fee collections from historically more volatile revenue sources (e.g., BPD fees), in addition to challenges in hiring staff for the program and uncertainty meeting the non-user fee spending trigger provisions, contributed to a greater than expected carry-over balance at the end of BsUFA I. Many of the development programs started in BsUFA I have continued to convert to original submissions in BsUFA II, contributing to an increase in application review work relative to BsUFA I. Furthermore, the number of development programs and number of reference products for which proposed biosimilars are being developed have increased over the course of BsUFA II and is expected to increase further with the transition of biological products that had been approved under new drug applications (e.g. insulin) to biologics license applications (BLAs). Specifically, on March 23, 2020, as required by the Biologics Price Competition and Innovation Act of 2009 (BPCI Act), approved marketing applications for biological products under section 505 of the FD&C Act were deemed to be approved biologics license applications under section 351 of the Public Health Service Act. Additionally, FDA expects that the accruing number of approved biosimilar biological product applications will generate an exponential number of supplements to such applications.

In the BsUFA II commitment letter, FDA committed to enhancing capacity for biosimilar regulations and guidance development, reviewer training, and timely communication as well as strengthening staff capacity to deliver information concerning the date of first licensure and the reference product exclusivity expiry date, to be included in the Purple Book[1]. As committed, through the first 4 years of BsUFA II, FDA has enhanced capacity for addressing these important elements. This occurred through the growth of the Therapeutic Biologics and Biosimilars Staff, and its reorganization into the Office of Therapeutic Biologics and Biosimilars. By increasing the number of staff dedicated to biosimilar activities during BsUFA II, FDA has been able to accomplish many significant desired milestones, including finalization of almost all guidance documents specified in the BsUFA II commitment letter, modernization of the Purple Book with an enhanced and user-friendly interface, and creation of an integrated multidisciplinary review template to enhance review consistency. Furthermore, FDA has expanded on education and outreach efforts during BsUFA II, creating new materials, webinars, and increasing attendance at outreach events. As the number of biosimilar biological products available on the market increases, and more stakeholders have the opportunity to use biosimilar products, outreach and education will be fundamental to facilitating an accurate understanding of these products and their acceptance and use among key stakeholders.

Looking forward through the end of BsUFA II, FDA will continue its focus on improving the efficiency of the biosimilar product development and approval process; maximizing scientific and regulatory clarity for the biosimilar product development community; developing effective communications to improve understanding of biosimilars among patients, clinicians, and payors; and supporting market competition by reducing gaming of FDA requirements or other attempts to unfairly delay competition. Activities may include regulatory science projects to support the efficient development and review of biosimilar biological product applications, increasing review support for certain types of biosimilar labeling

[1] https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/purple-book-lists-licensed-biological-products-reference-product-exclusivity-and-biosimilarity-or

supplements, enhancing capacity for regulation and guidance development, and continued expansion of outreach and education efforts.

FDA completed its BsUFA II hiring commitment in FY2020. FDA is also working to improve the Agency's ability to attract, hire, and retain the top scientific talent that is needed for the review of biosimilar biological product applications. This includes delivering on a BsUFA II commitment to establish a dedicated function to enhance hiring and retention of scientific staff, and also includes FDA's implementation of a new pay authority provided by the 21st Century Cures Act (Cures). FDA continues to utilize user fee resources to build staff capacity for its Office of Therapeutic Biologics and Biosimilars, establish the new scientific staffing capability, and implement the new pay authority provided by Cures.

Changes to Fee Structure and Fee-Setting Mechanisms in BsUFA II

The changes to the BsUFA II fee structure discussed in **Section E** were intended to improve the stability and predictability of funding, improve efficiency by simplifying the administration of user fees, and enhance flexibility of financial mechanisms to improve management of BsUFA program funding. Nonetheless, as the biosimilar biological product industry has continued to mature, FDA did anticipate uncertainty in year to year cash collections, workload, and associated costs during BsUFA II. As such, FDA and Industry recognized the need to take a flexible approach to managing the program finances to ensure stable FDA funding and sponsor fee levels. This flexible approach included:

- The application of a capacity planning adjustment, first implemented for the setting of FY 2021 fee amounts, which is discussed in greater detail later in this section, to adjust the target revenue to keep pace with sustained increases in program workload.
- An operating reserve adjustment when setting fees each fiscal year so that FDA may adjust the annual target revenue to utilize the program's carryover balance to minimize fluctuations in sponsor fee amounts and manage volatility in fee collections.

Efforts to Enhance Financial Management

Under BsUFA II, FDA made commitments to establish a resource capacity planning function and to modernize its time reporting approach. CDER and CBER have now implemented modernized time reporting and have also established the foundational resource capacity planning capability. This capability will continue to mature over the coming years as more data is collected and workload forecasts are continually refined. This will enable better forecasting of workload and the ability to translate forecasts into more targeted human resource and financial needs, helping to ensure FDA has the resources it needs to deliver on all its performance commitments in BsUFA.

With the foundational resource capacity planning capability now in place, FDA has implemented the new capacity planning adjustment methodology.[2] This methodology adjusts the annual target revenue amount to account for the resources needed to respond to projected sustained changes in program workload. FDA implemented the capacity planning adjustment methodology through the process set forth in statute which included a third-party evaluation[3] and a review of public comments on the evaluation. FDA also made commitments in BsUFA II to enhance efficiency and transparency in the administration of BsUFA's financial resources. This included a third-party evaluation of BsUFA program

[2] https://www.federalregister.gov/documents/2020/08/04/2020-16858/biosimilar-user-fee-rates-for-fiscal-year-2021

[3] https://www.fda.gov/media/136606/download

resource management during FY 2018.[4] It also included the publishing of a five-year plan (this plan), to be updated annually. FDA also has held annual public meetings to discuss this five-year financial plan and report on the contribution of the BsUFA spending trigger to the BsUFA program, along with the Agency's progress in implementing resource capacity planning, modernized time reporting, and the modernized user fee structure.[5]

Working Capital Fund/Cost Allocation

FDA has a Cost Allocation and Recovery framework to improve financial management of user fee resources for BsUFA, the Prescription Drug User Fee Act (PDUFA), and the Generic Drug User Fee Amendments (GDUFA). Congress authorized FDA to establish a Working Capital Fund (WCF) to finance centralized services (see 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.

Financial Information

This section provides an overview of the financial outlook for BsUFA through the FY 2018 – FY 2022 reauthorization period including user fee revenue, obligations, carryover, non-user fee appropriations requirements, and planned hiring. Refer to prior year BsUFA Five-Year Financial Plans for additional information on prior year estimates.[6]

G. **User Fee Program Financials**

Table 1 represents a summary of the forecasted BsUFA financial position, as it relates to user fee resources (collections and carryover). This table also provides an overview of planned obligations for which the user fee resources would be used. The financial notes can be found in **Appendix C**.

[4] https://www.fda.gov/drugs/development-resources/fiscal-year-2018-financial-management-evaluation-human-drug-user-fees-assessment-report
[5] https://www.fda.gov/drugs/news-events-human-drugs/financial-transparency-and-efficiency-prescription-drug-user-fee-act-biosimilar-user-fee-act-and
[6] https://www.fda.gov/about-fda/user-fee-reports/user-fee-five-year-financial-plans

Table 1: Biosimilar Biological Product Collections, Obligations, and Carryover for Fiscal Year 2018 through Fiscal Year 2022[7]

Budgetary Resources	Notes	FY18 Actual	FY19 Actual	FY20 Actual	FY21 Estimate	FY21 Actual	FY22 Estimate
Target Revenue	**Note 1**	**$40,214,000**	**$38,847,000**	**$41,923,000**	**$42,493,000**	**$42,493,000**	**$40,040,000**
Cash Collections		$29,238,601	$34,685,713	$37,971,967	$42,493,000	$42,705,959	$40,040,000
Recoveries	Note 2	$1,074,997	$456,236	$535,834	$600,000	$420,828	$600,000
Total Carryover, Beginning of Year		$48,723,308	$38,757,343	$31,840,903	$36,475,695	$36,475,695	$45,956,772
Total Budgetary Resources		**$79,036,907**	**$73,899,291**	**$70,348,704**	**$79,568,695**	**$79,602,481**	**$86,596,772**

Obligations	Notes	FY 2018 Actual	FY 2019 Actual	FY 2020 Actual	FY 2021 Estimate	FY 2021 Actual	FY 2022 Estimate
Total Payroll & Operating	Note 3	$34,535,211	$35,210,375	$28,367,423	$36,173,369	$28,662,703	$39,264,905
Total Rent	Note 4	$1,104,785	$1,382,811	$732,615	$1,551,504	$866,814	$1,567,019
Total Shared Services	Note 5	$4,639,568	$5,465,202	$4,772,972	$4,474,100	$4,116,192	$2,947,378
Total Obligations		**$40,279,564**	**$42,058,388**	**$33,873,010**	**$42,198,973**	**$33,645,709**	**$43,779,302**

Carryover	Notes	FY 2018 Actual	FY 2019 Actual	FY 2020 Actual	FY 2021 Estimate	FY 2021 Actual	FY 2022 Estimate
Total Carryover, End of Year		$38,757,343	$31,840,903	$36,475,695	$37,369,722	$45,956,772	$42,817,470
Future Year Refunds Allowance, Set Aside		($500,000)	($500,000)	($1,000,000)	($1,000,000)	($1,000,000)	($1,000,000)
Carryover Net of Set Aside, End of Year		**$38,257,343**	**$31,340,903**	**$35,475,695**	**$36,369,722**	**$44,956,772**	**$41,817,470**

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

Budgetary Resources: The "Total Budgetary Resources" component of **Table 1** illustrates the total user fee funding (i.e., the existing total carryover and additional user fee collections) for FY 2018 through FY 2021 actuals and the estimate for FY 2021 and 2022. The target revenue is the annual revenue amount established when fees for the fiscal year are set. Cash collections are the actual amount collected during the fiscal year and are estimated to be equal to the target revenue. BsUFA II specifies how the fees must be calculated each fiscal year, including annual adjustments (e.g., for inflation and changes in workload).

For the purposes of this plan, future year recoveries are estimated to be $600,000 annually. Additional details on recoveries are included in **Note 2**.

Obligations: The obligations component of **Table 1** shows the FY 2018 through FY 2021 actual expenditure and planned annual expenditure for FY 2022 of BsUFA fee funds broken out into major expense categories. BsUFA fees may be expended only for costs to support the "process for the review of biosimilar biological product applications," as defined in BsUFA II.

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

[7] The values in this table provide a year-to-year evaluation. Values are updated on a yearly basis. In the first year of the authorization period, estimates for all five years are included. In subsequent years of the authorization, the actual values replace the estimated values; the previous year's estimates are kept to compare with the actual values. The actual values are based on year-end reporting; thus, mid-year reporting in the current year does not occur in this report.

to as the "total carryover" or "BsUFA carryover." Maintaining an appropriate level of carryover enables FDA to mitigate financial risks to the program, including, for example, the risk of under collecting fees and the risk of a lapse in appropriations, so that FDA can continue program operations under such financial constraints. The unobligated BsUFA funds at the end of each fiscal year are referred to for purposes of this report as the "carryover" in **Table 1**.

H. User Fee Revenue

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

FDA assumes, for planning purposes, that cash collections will equal the target revenue amount. Cash 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.

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: Biosimilar Biological Product Revenue and Collections Statement for Fiscal Year 2018 through Fiscal Year 2022

Budgetary Resources	Notes	FY18	FY19	FY20	FY21	FY22
		Actual	Actual	Actual	Actual	Actual
Statutory Base		$45,000,000	$40,214,000	$40,947,463	$41,922,873	$42,493,066
Inflation Adjustment		$ -	$733,463	$975,410	$570,193	$883,856
Capacity Planning Adjustment		N/A	N/A	N/A	N/A	N/A
Operating Reserve Adjustment	Note 9	N/A	($2,100,000)	$0	$0	($3,336,686)
FY 2018 Adjustment	Note 6	($4,786,000)	N/A	N/A	N/A	N/A
Target Revenue Total	Note 1	**$ 40,214,000**	**$ 38,847,000**	**$ 41,923,000**	**$ 42,493,000**	**$ 40,040,000**

Target Revenue has been rounded to the nearest thousand dollars

Budgetary Resources	Notes	FY18	FY19	FY20	FY21	FY21	FY22
		Actual	Actual	Actual	Estimate	Actual	Estimate
Cash Collections		$29,238,601	$34,685,713	$37,971,967	$42,493,000	$42,705,959	$40,040,000
Recoveries	Note 2	$1,074,997	$456,236	$535,834	$600,000	$420,828	$600,000
Total Carryover, Beginning of Year		$48,723,308	$38,757,343	$31,840,903	$36,475,695	$36,475,695	$45,956,772
Total Budgetary Resources		**$ 79,036,906**	**$ 73,899,291**	**$ 70,348,704**	**$ 79,568,695**	**$ 79,602,481**	**$ 86,596,772**

Numbers have been rounded to the nearest dollar
N/A = Not Applicable

The base revenue for FY 2018 is specified in statute. The base revenue for each subsequent year is equal to the prior year's total target revenue amount, excluding any operating reserve adjustment for the prior year. See **Note 1** for a diagram of this process.

The process for setting of the annual target revenue is defined in statute. Each year's base revenue is adjusted for the following factors, as applicable:

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

  An inflation adjustment was not utilized in FY 2018; the actual inflation adjustment utilized in FY 2019, FY 2020, FY 2021, and FY 2022 was 1.8239, 2.3821, 1.3601, and 2.0800 (rounded) percent, respectively.

- **Capacity Planning Adjustment:** The capacity planning adjustment adjusts the inflation-adjusted base amount to reflect changes in the resource capacity needs of the BsUFA program.

  Section F above, as well as the references provided in that section, describe the implementation and mechanisms of the capacity planning adjustment.

- **Operating Reserve Adjustment:** The operating reserve adjustment was established in statute to provide a mechanism to support the management of the carryover balance from year to year.

  FDA is committed to reducing the BsUFA carryover balance to an amount that is no greater than 21 weeks of operating reserves by the end of FY 2022. The operating reserve adjustment provides a tool to help manage to this amount. Beginning in FY 2019, FDA may use the operating reserve adjustment to lower the annual target revenue in order to help manage to the committed carryover balance level. In support of this commitment, FDA determined that it would apply an operating reserve adjustment to lower the FY 2019 target revenue amount by $2,100,000. For FY 2020 and FY 2021, FDA did not apply an operating reserve adjustment. In FY 2022 FDA applied a downward operating reserve adjustment to lower the FY 2022 target revenue amount by $3,336,686 (rounded to the nearest dollar). This established an adjusted FY 2022 BsUFA fee revenue amount of $$40,040,000 (rounded to the nearest thousand dollars).

  Should FDA make an operating reserve adjustment, either up or down, FDA must explain its rationale in the annual fee-setting Federal Register notices.

- **FY 2018 Adjustment:** The FY 2018 adjustment enabled FDA to adjust the base revenue set for BsUFA II based on its best and most timely available workload estimates at the time the FY 2018 fees were to be set. Refer to **Note 6** for additional details.

FDA adjusts the allocation of each fee type to the total target revenue each year to minimize variation in the fee amount from year to year. For FY 2021, fee rates were established to equal the following allocation: application fees provide 33 percent of the total revenue, biosimilar biological product program fees provide 39 percent of the total revenue, and BPD fees provide 28 percent of the total revenue. For FY 2022, fee rates were established to equal the following allocation: application fees provide 31 percent of the total revenue, biosimilar biological product program fees provide 51 percent of the total revenue, and BPD fees provide 19 percent of the total revenue. User fee collections are recognized and reported in the year the fee was originally due (referred to as the "cohort year"). Totals reported for each fiscal year are net of any refunds for the cohort year. **Table 3** presents the forecasted and actual total annual collections by fee type and cohort year.

Table 3: BsUFA II Collections by Cohort Year

Fee Type / Cohort Year / Cost Type	2018 Actual	2019 Actual	2020 Actual	2021 Estimate	2021 Actual	2022 Estimate
Application Fees	$9,170,411	$12,227,215	$14,410,646	$13,973,960	$15,720,705	$12,227,215
Program Fees	$2,433,296	$6,995,726	$12,470,642	$16,424,748	$16,120,586	$20,378,854
BPD Fees	$17,040,975	$16,130,583	$10,854,804	$12,094,292	$10,864,364	$7,433,931
Reactivation Fee	$0	$0	$235,975	$0	$0	$0
Total Cash Collections	**$28,644,682**	**$35,353,524**	**$37,972,067**	**$42,493,000**	**$42,705,655**	**$40,040,000**

Target Revenue has been rounded to the nearest thousand dollars
Numbers have been rounded to the nearest dollar

I. User Fee Obligations

Table 4 provides a breakout of planned user fee obligations by expense category for the 5 years represented in this plan. This plan will provide actual amounts for the preceding fiscal years, as well as updated planned amounts for the remaining fiscal year. The financial notes can be found in **Appendix C**

Biosimilar Biological Product User Fee Obligations by Expense Category for Fiscal Year 2018 through Fiscal Year

User Fee Obligations	Notes	FY18 Actual	FY19 Actual	FY20 Actual	FY21 Estimate	FY21 Actual	FY22 Estimate
Payroll & Operating	**Note 3**						
CBER		$0	$0	$46,149	$304,080	$20,173	$310,405
CDER		$31,113,433	$33,004,440	$25,932,156	$32,781,241	$26,244,410	$36,143,181
ORA		$1,128,256	$676,738	$1,092,113	$1,460,366	$1,094,666	$1,500,956
HQ		$2,293,521	$1,529,197	$1,297,005	$1,627,682	$1,303,454	$1,310,362
Total Rent	Note 4	$1,104,785	$1,382,811	$732,615	$1,551,504	$866,814	$1,567,019
Total Shared Services	Note 5	$4,639,568	$5,465,202	$4,772,972	$4,474,100	$4,116,192	$2,947,378
Total Obligations		**$40,279,564**	**$42,058,388**	**$33,873,010**	**$42,198,973**	**$33,645,709**	**$43,779,302**

Numbers have been rounded to the nearest dollar

Total obligations include payroll and operating, rent, and shared services costs. The details of each component of total obligations are as follows:

- **Payroll and Operating:** These obligations provide for all payroll and operating costs that support the allowable activities for which BsUFA fees may be expended, as set forth in statute. **Appendix A** provides additional information regarding allowable and excluded costs for the BsUFA program.

- **Rent:** This is paid to the General Services Administration (GSA) for the Federal buildings that FDA occupies, as well as to non-Federal sources for direct leases and services (see **Note 4**). Rent is charged at different rates depending on the type and location of the space provided. The future year amounts, for the purposes of this plan, are assumed to have an increase of 1 percent yearly.

- **Shared Services:** FDA has several shared service organizations that provide support across the user fee programs, such as human resources and IT. Shared services at FDA are located within the WCF. The future year amounts, for the purposes of this plan, are assumed to have an

increase of 1 percent yearly. Yearly costs are determined by the Cost Allocation and Recovery framework discussed previously. In FY 2020, the WCF absorbed several offices that were previously located within HQ. This change is responsible for the variance in HQ and Shared Services from the original plan, published in FY 2018, for FY 2020 and beyond. **Note 5** provides a full list of the what is contained in the WCF.

Variances occurred between the original FY 2021 plan and the actuals in some areas:

- **CBER Obligations:** Actual CBER obligations in FY 2021 were lower than estimated due to a lower amount of workload than anticipated. BsUFA funding will not be utilized other than for costs of the process for the review of biosimilar biological product applications (see **Appendix A** for additional information regarding allowable and excluded costs for the BsUFA program) and will depend on the workload at the Center.

- **CDER Obligations:** Actual CDER obligations in FY 2021 were lower than estimated due to slower than anticipated, dedicated growth in payroll and operating costs. BsUFA funding will not be utilized other than for costs of the process for the review of biosimilar biological product applications (see **Appendix A** for additional information regarding allowable and excluded costs for the BsUFA program) and will depend on the workload at the Center.

- **HQ Obligations:** Actual HQ obligations were lower than anticipated in FY 2021 due to transfers into the WCF as well as returns from specific offices that were unable to hire. These offices continue to make efforts to bring new hires on board.

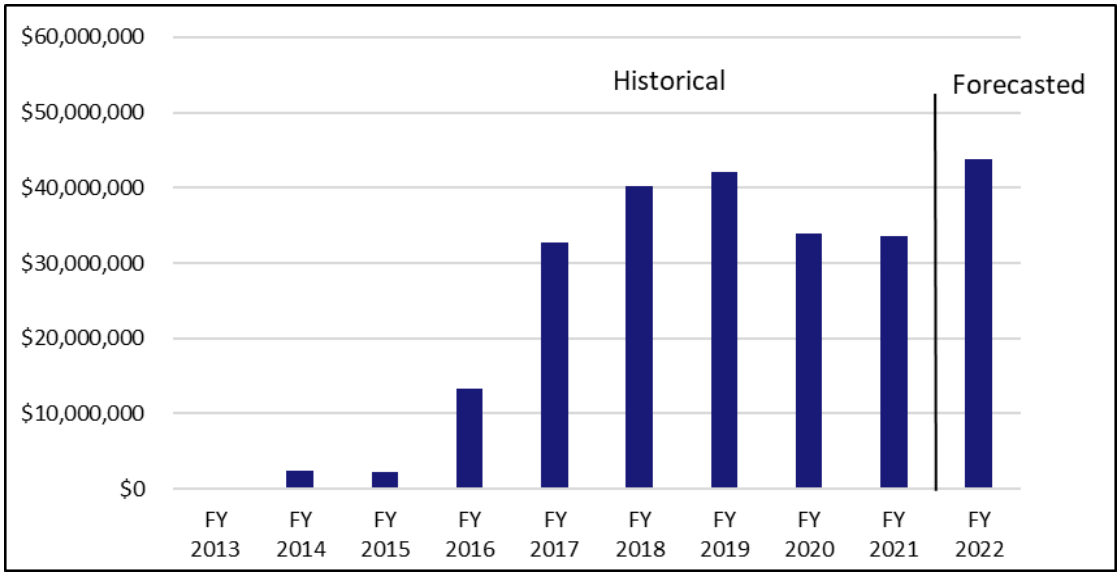
- **ORA Obligations:** Actual ORA obligations in FY 2021 were lower than anticipated due to the Agency reducing foreign travel out of safety concerns for employees related to the pandemic. This led to lower than planned spending on foreign inspectional travel.

- **Rent:** The variances in rent actuals for FY 2021 were due to a lower rent bill than anticipated. While small fluctuations are common, FDA does not anticipate large variances in the Rent account in future fiscal years.

- **Shared Services:** Shared Services obligations were adjusted to reflect a redistribution of costs by funding source, which caused an overall decrease of BsUFA user fee obligation in Shared Services in FY 2021.

Exhibit 3 below provides an illustration of historical BsUFA obligations and projected FY 2021 through FY 2022 needs.

Exhibit 3: Historical and Forecasted User Fee Obligations by Fiscal Year



As demonstrated by this graph, BsUFA user fee obligations from FY 2020 to FY 2021 occurred at a similar rate. Although payroll costs increased in FY 2021, these costs were offset by a decrease in operating costs.

FDA expects to continue to build staff and operational capacity to manage review workload and deliver on performance and procedural goals. This is subject, however, to fluctuations in the workload of the program.

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. In this report, such fee funds are referred to as the "total carryover" or "BsUFA carryover."

Maintaining an appropriate level of carryover enables FDA to mitigate financial risks to the program, including for example, the risk of under collecting fees and the risk of a lapse in appropriations. FDA considers the reasonable range of carryover for the BsUFA program to maintain in anticipation of these risks to be about 21 weeks. FDA notes that this reasonable range is higher for BsUFA than for the Prescription Drug User Fee Act (PDUFA) or Generic Drug User Fee Amendments (GDUFA). This is because BsUFA is a much smaller program, as measured by workload or planned expenditures, and small shifts in submissions could have a significant impact on workload and the requisite funding needed to maintain operations.

The net change in carryover balance each year is equal to cash collections minus net obligations. This is shown in **Table 1** above.

Table 5 provides projections of BsUFA carryover balances at the end of the year. This is compared to calculations in **Table 1**, which cover beginning of the year carryover. The financial notes can be found in **Appendix C**

Table 4: BsUFA Carryover by Fiscal Year

Carryover	Notes	FY18 Actual	FY19 Actual	FY20 Actual	FY21 Estimate	FY21 Actual	FY22 Estimate
Total Carryover, End of Year		**$38,757,343**	**$31,840,903**	**$36,475,695**	**$37,369,722**	**$45,956,772**	**$42,817,470**
Future Year Refunds Allowance, Set Aside		($500,000)	($500,000)	($1,000,000)	($1,000,000)	($1,000,000)	($1,000,000)
Carryover Net of Set Aside, End of Year		**$38,257,343**	**$31,340,903**	**$35,475,695**	**$36,369,722**	**$44,956,772**	**$41,817,470**

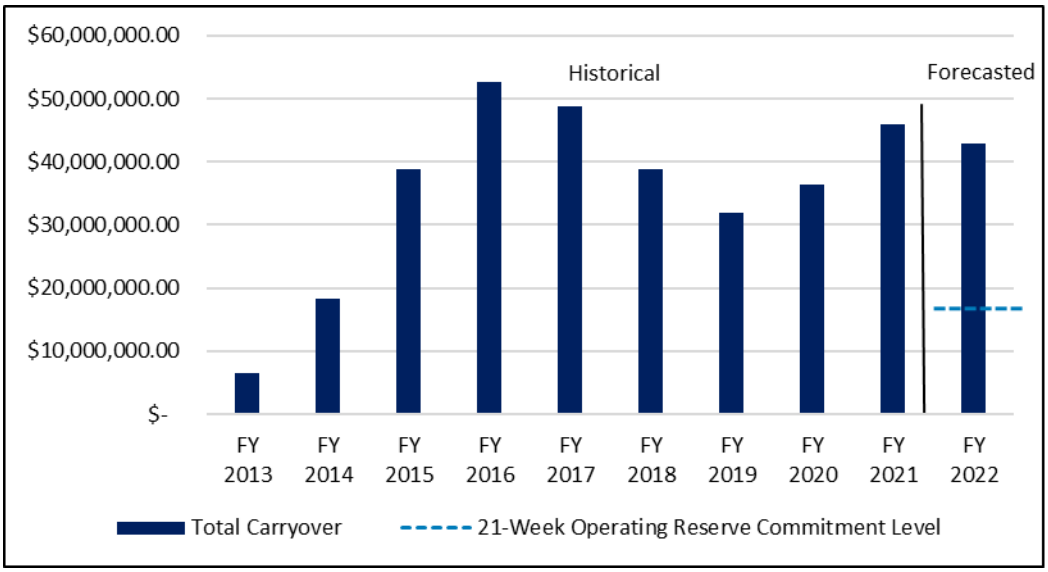
Numbers have been rounded to the nearest dollar

These terms are defined below:

- **Total Carryover, End of Year** – This is the total amount of unobligated funds at the end of the fiscal year.
- **Future Year Refunds Allowance, Set Aside** – FDA maintains a small amount to provide for future year refunds, as a matter of prudent operations. For that purpose, a total of $1,000,000 in fee funds available for obligation is being set aside annually. This amount has changed from prior years to provide a more accurate estimate based off a 3-year average. See **Note 7** 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 historic trend of carryover in BsUFA I and the forecasted carryover in BsUFA II.

Exhibit 4: Historical and Forecasted Carryover by Fiscal Year



The FY 2022 end of year carryover amount is expected to exceed the 21-week operating reserve commitment level. As detailed in the BsUFA II Commitment Letter, if FDA is unable to reduce the carryover to no greater than this 21-week level, it will outline its plan to do so in the FY 2022 BsUFA Financial Report and will update the five-year plan. FDA plans to use the carryover amounts in excess of the 21-week amount to support funding of certain program investments related to negotiated BsUFA III

initiatives. In addition, after these program investments, should additional excess carryover be anticipated, FDA would expect to reduce the excess carryover by offsetting fee amounts in a measured manner and in accordance with any commitments or requirements under BsUFA III. FDA notes that this plan is contingent on the final details of any reauthorization of the BsUFA program.

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 that fiscal year. This is often referred to as a "non-user fee spending trigger."[8] **Table 6** presents the actual non-user fee spending triggers for FY 2018, FY 2019, FY 2020, FY 2021, and FY 2022.

Table 5: Minimum Allocation of BsUFA Non-User Fee Appropriations by Fiscal Year

FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Actual	Actual	Actual	Actual	Actual
$21,711,380	$22,038,420	$22,243,160	$22,518,640	$23,536,120

Numbers have been rounded to the nearest dollar

FDA may not spend BsUFA fees in a fiscal year unless it allocates a minimum of $20 million in appropriated funds (excluding user fees), multiplied by the adjustment factor applicable to that fiscal year, for the BsUFA program. See **Note 8** for more details on the adjustment factor. The statute provides that FDA will be considered to have met this requirement in a fiscal year if an amount that is not more than 15 percent below the minimum level is spent. The specified minimum level for FY 2021 is $22,518,640. In FY 2021, FDA allocated and obligated $22,282,365 in appropriated funds (excluding user fees) for the BsUFA program, which is not more than 15 percent below the minimum level (see section 744H(f)(2)(C) of the FD&C Act). Thus, for FY 2021, the second legal condition was satisfied.

FDA is committed to spending 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

FDA will continue to hire additional dedicated staff as needed to address the program workload and achieve performance goals. In addition, FDA will review the financial status and workload demands of the program on a regular basis to ensure that funds are utilized to meet program commitments.

Management Assurance

M. Internal Controls

The Federal Managers' Financial Integrity Act of 1982 (FMFIA) is intended to strengthen internal controls and accounting systems. OMB Circular A-123, Management's Responsibility for Internal Control and

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

Enterprise Risk Management (OMB A-123), implements the FMFIA requirements. FMFIA requires that management establish and maintain effective internal control to achieve the following objectives:

1. Effective and efficient operations,
2. Reliable reporting, and
3. Compliance with applicable laws and regulations.

The Department of Health and Human Services (HHS) provides guidance to its operating divisions (OpDivs) to implement FMFIA through its FMFIA Guidelines. OpDivs, including FDA, are responsible for developing and maintaining internal control and compliance programs that include programmatic and operational controls, as well as reporting controls to support sound financial management. The Government Accountability Office's Standards for Internal Control in the Federal Government (Green Book) states: "Management is responsible for an effective internal control system. As part of this responsibility, management sets the entity's objectives, implements controls, and evaluates the internal control system." OMB A-123 requires an annual internal control assessment, and FMFIA requires the head of each executive agency to report annually on the effectiveness of the internal controls and any identified material weaknesses in those controls.

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

Additionally, FDA has an established Senior Assessment Team (SAT) to act as the governance body responsible for providing oversight and accountability for FDA's internal control over reporting, including overseeing the FMFIA and OMB A-123 assessments, and for fostering an environment that promotes strong internal control. The SAT is chaired by FDA's CFO and co-chaired by the Deputy CFO and Director of the Office of Financial Management, as well as a Program Co-Chair who is a Center Deputy Executive Officer appointed by the CFO. The SAT members are representatives from each FDA Center and Office.

FDA's internal control program includes integrated management controls covering the OMB A-123 appendices. Specifically, reporting controls are implemented in accordance with Appendix A, Management of Reporting and Data Integrity Risk; charge card controls are implemented in accordance with Appendix B, A Risk Management Framework for Government Charge Card Programs; controls over financial disbursements are implemented in accordance with Appendix C, Requirements for Payment Integrity Improvement; and financial system controls are implemented in accordance with Appendix D, Compliance with the Federal Financial Management Improvement Act of 1996. FDA's reimbursable activity cycle memo is specifically focused on the reporting controls related to the accounts receivable and payment processes associated with the user fee programs. This cycle memo describes the processes and controls performed by FDA to monitor the user fee cash receipts process and includes controls over reconciliation performance, aging, write-offs, and the interface between the User Fee System (UFS) and the Unified Financial Management System.

In FY 2021, FDA's annual assessment of internal controls included tests of 80 business, charge card, and IT controls across 18 transaction sub-cycles to identify recommendations to strengthen internal controls and compliance. This assessment included 27 IT controls related to the UFS. Annually, FDA conducts an improper payments risk assessment and performs improper payment testing. In March 2021, FDA completed this testing, which involved 100 payments related to user fee funding, including payments for vendors (64), purchase cards (16), grants (14), and travel (6). Any deficiencies identified during FDA's internal control testing are tracked under a Continuous Monitoring Program to facilitate timely remediation. UFS is compliant with HHS guidelines and with OMB Circular A-123 Appendix D, Compliance with the Federal Financial Management Improvement Act of 1996. FDA's Integrated Budget and Acquisition Planning System (IBAPS) not only is used to support FDA's budget formulation, budget execution, acquisition planning, and payroll planning but also meets FDA's and HHS's system requirements.

FDA has also implemented other internal control procedures, including the performance of Organizational Risk Reviews, which are reviews of targeted financial and non-financial management processes to identify potential recommendations to enhance internal controls. Also, FDA maintains a Continuous Monitoring Program to oversee the timely implementation of corrective action plans for any deficiencies identified through any of its control assessments.

As a component of HHS, FDA's financial data is presented in HHS's consolidated financial statements. The FY 2021 HHS audit found that FDA's financial statements fairly present, in all material respects, the consolidated financial position of HHS as of September 30, 2021, and 2020, and related notes are in accordance with generally accepted accounting principles in the United States. Further, FDA's FY 2021 Assurance Statement found no material weaknesses or financial system nonconformances.

N. **Risks and Challenges**

Financial Risks and Mitigation

As is the case with all financial programs, there are certain financial risks and challenges that exist with FDA's user fee programs. These risks and challenges can vary from program to program, with some being in FDA's control and some out of FDA's control. An example of a shared financial risk across all user fee programs is that FDA cannot obligate funds in advance of receiving the funds, either through appropriated user fee collections or non-user fee appropriations. FDA can only assume what the Agency's total appropriation will be in any given year. As a result, FDA has some risk of missing important performance goals, or failing to meet the non-user fee spending trigger for the fiscal year, if that total appropriation comes in considerably lower than anticipated. Below is a listing of foreseeable risks associated with the collections and obligations of funds for which FDA has identified contingency plans in order to move forward in the best interests of the program.

- **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 (CR) becoming more prevalent, FDA has been spending at or slightly below levels from the prior authorized fiscal year during the CR period, thus limiting its ability to spend the non-user fee appropriations from the onset. Fluctuations in submissions from year to year can change the total program cost. This creates a situation where, due to extended CR periods, FDA is uncertain of its non-user fee appropriations for a significant portion of the year, yet it must still meet the non-user fee spending trigger. BsUFA I utilized a conservative approach in spending user fee revenue due the uncertain revenue levels, which

contributed to a relatively large carryover balance. BsUFA II provides for a 15 percent range in which FDA can comply with its non-user fee spending trigger requirements.[9]

- **Lapse in Non-User Fee Appropriations:** FDA is mitigating this risk to the program by maintaining a certain level of carryover so it can continue program operations in the event of a lapse of appropriations. FDA has committed to reducing the BsUFA carryover balance to no greater than 21 weeks. See **Note 9** for additional details.

- **Under-Executing Planned Spend:** BsUFA budgetary resources have been under-spent due to the uncertainty around the timing of revenue (user fee and non-user fee) availability, non-user fee spending trigger requirements, workload fluctuations, 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.

- **Under Collecting and Over Collecting Fees:** Since the BsUFA program experiences variation in workload, it is difficult to forecast the required revenue and set fees accordingly. If FDA does not receive the estimated number of fee-paying units, there may be an excess or deficit in targeted revenue. When FDA under collects user fees, it leverages its carryover balance to maintain continuity in operations. When FDA over collects, the carryover may increase without additional planned expenditures being identified to obligate those funds towards. The changes in the fee structure, minimization of clean-up billing, and the operating reserve are meant to mitigate these risks in BsUFA II. Resource capacity planning will help improve fee setting and allow FDA to adjust for sustained increases in workload. In addition, FDA monitors collections throughout the fiscal year, and the UFFMC and other FDA senior leaders determine how to mitigate any instances when user fee revenue deviates from forecasted estimates.

- **Global Health Pandemic:** There is currently some degree of uncertainty regarding the potential long term impact of COVID-19 on collections and application submissions. FDA is continually monitoring these impacts and will seek to address financial ramifications as warranted.

In addition to these mitigation strategies, FDA implemented IBAPS to enable greater and more timely insight into budget activity across the Agency. IBAPS improves the accuracy and availability of budget and acquisition information that enables FDA to better plan, forecast, track, and analyze the data to make better informed decisions about the best use of its resources.

Strategic Challenges

Given the relative size of the BsUFA program and demands from external factors such as COVID-19, FDA will continue to closely monitor the level of non-user fee obligations to ensure compliance with the non-user fee spending trigger requirements.

[9] 21 U.S.C 379j-52(f)(2)(C)

Appendices

A. Allowable and Excluded Costs for the BsUFA Program

Section 744G(13) of the FD&C Act defines the term "process for the review of biosimilar biological product applications" to mean the following activities of FDA with respect to the review of submissions in connection with biosimilar biological product development, biosimilar biological product applications, and supplements:

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

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

Included Expenses
1. Officers and employees of FDA, contractors of FDA, advisory committees, and the costs related to such officers, employees, and committees, and to contracts with such contractors; 2. Management of information and the acquisition, maintenance, and repair of computer resources; 3. Leasing, maintenance, renovation, and repair of facilities and acquisition, maintenance and repair of fixtures, furniture, scientific equipment, and other necessary materials and supplies; and 4. Collecting fees under section 744H of the FD&C Act and accounting for resources 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: • An allergenic extract product; • Whole blood or a blood component for transfusion; • An in vitro diagnostic biological product; or • A biological product for further manufacturing use only.	1. Enforcement policy development not related to sections 505(o) and (p) of the FD&C Act; 2. Post-approval compliance activities not related to the enforcement of sections 505(o) and (p) of the FD&C Act; 3. Advertising review activities once marketing of the product has begun; 4. Inspections unrelated to the review of covered applications, unless undertaken for the enforcement of sections 505(o) and (p) of the FD&C Act; and 5. Research unrelated to the BsUFA program.

B. User Fee Program History

The FD&C Act, as amended by BsUFA, authorizes FDA to collect user fees from the biosimilar biological product industry to supplement the non-user fee appropriations that the Agency spends on the process for the review of biosimilar biological product applications. FDA spends fee revenues and non-user fee appropriations to hire, support, and maintain personnel for the review of biosimilar biological product applications, and to help ensure that safe and effective biosimilar biological products reach the American public more quickly.

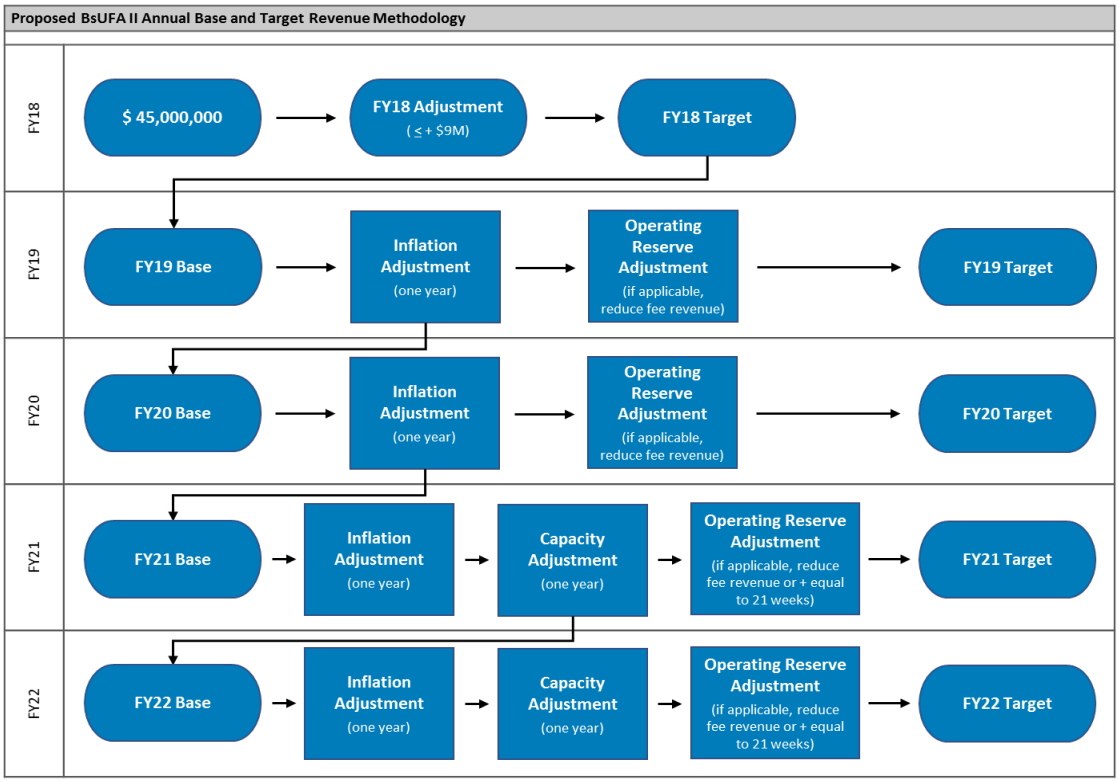
Originally authorized in 2012, BsUFA was reauthorized by FDARA in 2017 (BsUFA II) with the support of the biopharmaceutical industry, public stakeholders, Congress, and the Administration.

C. Financial Notes

Note 1. Annual Target Revenue Methodology

Exhibit 5 is a flow chart delineating the BsUFA II Annualized Base and Target Revenue Methodology.

Exhibit 5: BsUFA II Annualized Base and Target Revenue Methodology



Note 2. Recoveries

Recoveries account for funds returned to the Agency in the form of deobligations of prior year obligations. For example, recoveries could include funding from a contract that ended in a prior year and was not expended.

Note 3. Pay and Operating Costs

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

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 GSA charges rent to FDA for the Federal buildings that FDA occupies. This rent is charged at different rates depending on the type and location of the space provided. Since rent is an essential support cost for the process for the review of biosimilar biological product applications, a portion of those charges is paid from non-user fee appropriations and a portion is paid from BsUFA fees. Also included in this account are recurring costs that FDA pays to non-Federal sources under the delegation of direct lease and service authority. These services include rental of space, and all recurring services for building operations such as overtime utilities, janitorial services, guards, and ground maintenance. The

amount of rent and rent related costs each Center pays is directly related to the square footage occupied by that Center.

Note 5. Shared Service Costs

FDA has several shared service organizations, located with the WCF, that provide support across the user fee programs. Several new organizations joined the WCF in FY 2020. The shared service organizations in FY 2021 include:

- **FDA Central**: Provides for Center-wide and Agency-wide services such as telecommunications, training, printing, mail and document management, IT systems, employee health units, and other support and miscellaneous services.
- **Employee Resource & Information Center**: Provides support to all FDA employees requesting administrative, IT, facilities, human resources, and other employee services.
- **Office of Acquisitions and Grants Services**: Manages contracts, grants, and other agreements.
- **Office of Equal Employment Opportunity**: Promotes an inclusive work environment that ensures equal employment opportunity, and fosters a culture that values diversity and empowers individuals.
- **Office of Facilities, Engineering, and Mission Support Services**: Provides FDA employees with office and laboratory facilities.
- **Office of Financial Management:** Provides financial managerial services and policy guidance.
- **Office of Information Management and Technology**: Provides the information, communication, and knowledge infrastructure and services that enhance, transform, and sustain the ability of FDA to protect and promote the public health.
- **Division of Budget Execution and Control:** Initiates, monitors and analyzes FDA budget resources. The agency budget is comprised of several appropriation accounts including: Salaries and Expenses, Revolving Fund for Color Certification and other Services, Cooperative Research and Development Agreement, Contingency Fund, Building and Facilities, and Royalties.
- **Office of Finance, Budget, Acquisitions, and Planning:** Leads FDA's budget, acquisitions, and financial management functions while ensuring the financial integrity of FDA's resources.
- **Office of Security Operations:** Develops and implements the Agency-wide security policies and programs by providing leadership and guidance to managers and staff on all aspects of security. Administers vital security functions that contribute to the Agency's mission of protecting the public health by enhancing the safety and security of all personnel, facilities, and information.
- **Office of Laboratory Safety:** Reinforces FDA's expectations for safety and laboratory security, enhances communications among FDA's safety staff, and provides program support.
- **Office of Ethics and Integrity:** Protects the integrity of FDA's programs and operations by promoting an ethical culture and ensuring compliance with applicable federal ethics laws.
- **Office of Enterprise Management Services:** Provides strategic and tactical enterprise-wide services through 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 resources 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. FY 2018 Adjustment

For FY 2018, the fee revenue amount was $45,000,000, adjusted as needed to reflect an updated assessment of the workload for the process for the review of biosimilar biological product applications. In considering the appropriate FY 2018 fee revenue adjustment, FDA considered a range of factors including its best estimated level of submissions and activities (including forecasts of new BPDs, new 351(k)s, resubmitted 351(k)s, advisory committee meetings, interchangeability supplements, industry meetings, inspection activity, science and research activities, policy work, and other activities). Considering the totality of work that was forecasted for FY 2018 (and recognizing the inherent uncertainty of any forecast), FDA determined the appropriate adjusted level of the FY 2018 BsUFA fee revenue amount to be $40,214,000 (rounded to the nearest thousand dollars). FDA used this amount as the target revenue amount for FY 2018.

Note 7. Future Year Refunds Allowance, Set Aside

If a person submits a biosimilar biological product application before October 1 of the fiscal year and the application is accepted for filing on or after October 1 of that fiscal year, the applicant may request a refund of the annual BPD fee paid by the applicant for such fiscal year. If an application is refused for filing or is withdrawn without a waiver before filing, FDA will refund 75 percent of the application fee paid.

Refunds impact net fee collections for each fiscal year. Cash collections reflect the amount of fees collected net any refunds or adjustments that occurred during that fiscal year.

Note 8. Adjustment Factors

FDA must calculate and incorporate adjustment factors in establishing fees. For purposes of calculating BsUFA fees for FY 2019 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-Baltimore, DC–MD–VA–WV; Not Seasonally Adjusted; All items; Annual Index) for the first 3 years of the preceding 4 years of available data".

For the purposes of calculating the “non-user fee spending trigger” amount for FY 2018 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 that is the Consumer Price Index for urban consumers (Washington-Baltimore, DC-MD-VA-WV; Not Seasonally Adjusted; All items) for October of the preceding fiscal year divided by such Index for October 2011.” Since the data in this index for October is unavailable, FDA utilizes the most recent data, which is September.

As a result of a geographical revision made by the Bureau of Labor and Statistics in January 2018, the Washington, DC-Baltimore index was discontinued and replaced with two separate indices (i.e., "Washington-Arlington-Alexandria" and "Baltimore-Columbia-Towson"). In order to continue applying a CPI which best reflects the geographic region in which FDA is located and which provides the most current data available, the Washington-Arlington-Alexandria index is now used in calculating these BsUFA II adjustment factors.

Note 9. Operating Reserve Adjustment

Beginning in FY 2019, the target revenue may be reduced for long-term financial planning purposes. Beginning with the first fiscal year for which fees are set after the capacity planning adjustment is

effective, FDA may reduce the fee revenue for long-term financial planning purposes or increase the fee revenue to provide for not more than 21 weeks of operating reserves of carryover user fees for the process for the review of biosimilar biological product applications. Should operating reserves be increased or decreased in a given fiscal year, the rationale for the adjustment will be provided in the fee-setting notice in the Federal Register.