FIVE-YEAR FINANCIAL PLAN

Fiscal Years
2018-2019-2020-2021-2022
2020 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 enhances the public health through the regulation of biological and related products including blood, vaccines, allergenics, tissues, and cellular and gene therapies.
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, 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 User Fee Financial Management Committee 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 User Fee Financial Management Committee 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 User Fee Financial Management Committee 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 that must be made for inflation. 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

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. FDA anticipates that many of the development programs started in BsUFA I will continue to convert to original submissions in BsUFA II, contributing to an increase in application review work relative to BsUFA I. 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 a target of hiring 15 new hires in FY 2018 to enhance capacity for biosimilar guidance development, reviewer training, and timely communication. As the number of biosimilar biological products available on the market increases, outreach and education will be essential to facilitating acceptance among key stakeholders. Furthermore, with growth in the development of biosimilar biological products and the complexity of the scientific and regulatory issues in this space, opportunities exist to advance regulatory science to support the development and review of biosimilar biological product applications.

In FY 2018, there were eight total hires under BsUFA and in FY 2019 there were an additional five, for a total of 13 of the 15 targeted hires. 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 intends to utilize user fee resources, including the carryover balance, 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** are expected 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 continues to mature, FDA does 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 includes:

- The application of a capacity planning adjustment, which is discussed in greater detail later in this section, to adjust the target revenue to keep pace with sustained increases in program workload; the earliest the capacity planning adjustment is expected to be implemented is for the setting of BsUFA fees for FY 2021.
- 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.[1]

In addition to using the carryover balance to manage fluctuations in fee amounts and volatility in fee collections, FDA also intends to use it to sustain operations if there is a lapse in appropriations, and to build review capacity to manage a potential increase in workload in BsUFA II.

Because of the uncertainty in program workload and the flexible financial approach to mitigate that uncertainty, FDA acknowledges there are inherent challenges in estimating the target revenues, cash collections, obligations, and carryover balances for each fiscal year in this plan. FDA's focus over the remainder of BsUFA II is to continue building sufficient staff capacity to deliver on program performance and procedural goals, as outlined in the BsUFA II commitment letter.

[1] Until the first fiscal year for which the capacity planning adjustment is effective, the amount of any fee for a fiscal year after FY 2018 shall not exceed 125 percent of the amount of such fee for FY 2018. (See section 744H(b)(3)(B) of the FD&C Act.) If FDA receives less than the estimated number of industry submissions, there may be a deficit in targeted revenue. When FDA under collects user fees, it leverages its carryover balance to maintain continuity in operations.

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. While it will take several years to fully mature the resource capacity planning capability, it will provide the ability to better forecast workload and to translate forecasts into human resource and financial needs. This capability will help FDA ensure it has the resources it needs when it needs them to be able to deliver on its performance commitments.

In addition, once the foundational resource capacity planning capability is in place, FDA has the ability, through a process described in statute that includes a third-party evaluation and review of public comment, to implement a capacity planning adjustment methodology for BsUFA. This methodology would adjust the annual target revenue amount to account for the resources needed to respond to sustained changes in program workload. The earliest the new methodology is expected to be implemented would be in the setting of fees for FY 2021, therefore the impact on fees and annual revenue amounts cannot be estimated at this time.

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 resource management during FY 2018.[2] It also included the publishing of a five-year plan (this plan), to be updated annually. FDA also held an annual public meeting, the first occurred during FY 2019, to discuss this five-year financial plan, 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.[3]

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.

[2] https://www.fda.gov/drugs/development-resources/fiscal-year-2018-financial-management-evaluation-human-drug-user-fees-assessment-report

[3] https://www.fda.gov/drugs/news-events-human-drugs/financial-transparency-and-efficiency-prescription-drug-user-fee-act-biosimilar-user-fee-act-and

Financial Information

This section provides an overview of the projected financial outlook for BsUFA through the FY 2018 – FY 2022 reauthorization period. These projections include user fee revenue, 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. Refer to prior year BsUFA Five-Year Financial Plans for additional information on prior year estimates.[4]

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. Future updates to this plan will supplement the financial estimates with actual amounts received, obligated, and carried over for the past fiscal year. The financial notes can be found in **Appendix C**

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

Budgetary Resources	Notes	FY 2018	FY 2019		FY 2020	FY 2021	FY 2022
		Actual	Estimate	Actual	Estimate	Estimate	Estimate
Target Revenue	**Note 1**	**$40,214,000**	**$38,847,000**	**$38,847,000**	**$41,923,000**	**$42,943,000**	**$43,988,000**
Cash Collections		$29,238,601	$38,847,000	$34,685,713	$41,923,000	$42,943,000	$43,988,000
Recoveries	Note 2	$1,074,997	$500,000	$456,236	$400,000	$400,000	$400,000
Carryover Available for Use, Beginning of Year		$48,223,308	$38,257,343†	$38,257,343	$31,340,903†	$26,855,616	$22,338,762
Total Budgetary Resources		**$78,536,907**	**$77,604,343**	**$73,399,291**	**$73,663,903**	**$70,198,616**	**$66,726,762**

Obligations	Notes	FY 2018	FY 2019		FY 2020	FY 2021	FY 2022
		Actual	Estimate	Actual	Estimate	Estimate	Estimate
Total Payroll & Operating	Note 3	$34,535,211	$37,791,149	$35,210,375	$40,531,026	$41,519,820	$42,184,412
Total Rent	Note 4	$1,104,785	$1,520,934	$1,382,811	$1,536,143	$1,551,504	$1,567,019
Total Shared Services	Note 5	$4,639,568	$5,405,403	$5,465,202	$4,741,118	$4,788,529	$4,836,414
Total Obligations		**$40,279,564**	**$44,717,486**	**$42,058,388**	**$46,808,287**	**$47,859,854**	**$48,587,846**

Carryover	Notes	FY 2018	FY 2019		FY 2020	FY 2021	FY 2022
		Actual	Estimate	Actual	Estimate	Estimate	Estimate
Total Carryover, End of Year		$38,757,343	$33,386,857	$31,840,903	$27,355,616	$22,838,762	$18,638,917
Carryover Unavailable for Use, End of Year		($500,000)	($500,000)	($500,000)	($500,000)	($500,000)	($500,000)
Carryover Available for Use, End of Year		**$38,257,343**	**$32,886,857**	**$31,340,903**	**$26,855,616**	**$22,338,762**	**$18,138,917**

Target Revenue has been rounded to the nearest thousand dollars
All other numbers have been rounded to the nearest dollar
†Indicates an actual amount

Budgetary Resources: The budgetary resources component of **Table 1** illustrates the FY 2018 and FY 2019 actuals and the forecast for FY 2020 through FY 2022 for the sum of available user fee funding (i.e., the existing carryover balance available for use and additional projected user fee collections) that are available to fund obligations. The target revenue is the annual revenue amount established when fees

[4] https://www.fda.gov/about-fda/user-fee-reports/user-fee-five-year-financial-plans

for the fiscal year are set. Cash collections are the actual amount collected during the fiscal year and are forecasted to be equal to the target revenue. BsUFA II specifies how the fees must be calculated each fiscal year, including annual adjustments that must be made for inflation and changes in workload.

For the purposes of this plan, future year recoveries are estimated to be $400,000 annually. Additional details on recoveries are included in **Note 2**

Obligations: The obligations component of **Table 1** shows the FY 2018 and FY 2019 actual expenditure and planned annual expenditure for FY 2020 through 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 are available until expended. This means that the fees that are collected, appropriated, and not obligated at the end of the fiscal year remain available to FDA for use in future fiscal years. The unobligated BsUFA funds at the end of each fiscal year are referred to as the "carryover balance" of **Table 1**. 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.

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 **Appendix 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

Target Revenue	Notes	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
		Actual	Actual	Actual	Estimate	Estimate
Statutory Base		$45,000,000	$40,214,000	$40,947,463	$41,922,873	$42,943,234
Inflation Adjustment		$ -	$733,463	$975,410	$1,020,361	$1,045,195
Capacity Planning Adjustment		N/A	N/A	TBD	TBD	TBD
Operating Reserve Adjustment		N/A	($2,100,000)	TBD	TBD	TBD
FY 2018 Adjustment		($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**	**$42,943,000**	**$43,988,000**

Target Revenue has been rounded to the nearest thousand dollars

Budgetary Resources	Notes	FY 2018	FY 2019		FY 2020	FY 2021	FY 2022
		Actual	Estimate	Actual	Estimate	Estimate	Estimate
Cash Collections		$29,238,601	$38,847,000	$34,685,713	$41,923,000	$42,943,000	$43,988,000
Recoveries	Note 2	$1,074,997	$500,000	$456,236	$400,000	$400,000	$400,000
Carryover Available for Use, Beginning of Year		$48,223,308	$38,257,343†	$38,257,343	$31,340,903†	$26,855,616	$22,338,762
Total Budgetary Resources		**$78,536,907**	**$77,604,343**	**$73,399,291**	**$73,663,903**	**$70,198,616**	**$66,726,762**

Numbers have been rounded to the nearest dollar
N/A = Not Applicable, TBD = To Be Determined
†Indicates an actual amount

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.

  The inflation adjustment for future years, for the purposes of this plan, is estimated by using the Federal Reserve Bank of Cleveland's CPI projections, as well as historical averages of the changes in FDA's average salary and benefits amounts.

  An inflation adjustment was not utilized in FY 2018; the actual inflation adjustment utilized in FY 2019 and FY 2020 was 1.8239 and 2.3821 percent (rounded), respectively. The inflation adjustment for FY 2021 and FY 2022 is estimated at 2.4339 percent for each fiscal year.

- **Capacity Planning Adjustment:** The statute does not currently provide a method to adjust the BsUFA target revenue amount based on workload or the capacity needs of the program. The statute does, however, provide a procedure to develop a methodology to accurately assess changes in the resource and capacity needs of the biosimilar biological product review program.

  This procedure includes a third-party assessment of methodological options, resulting in a report published for public comment not later than September 30, 2020. Following review of the report and public comments, FDA will adopt a capacity planning methodology that will be effective beginning the first fiscal year for which fees are set after the methodology is established.

  For the purposes of this current plan, FDA does not estimate the capacity planning adjustment amount for FY 2021 and FY 2022.

- **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. This established an adjusted FY 2019 BsUFA fee revenue amount of $38,847,000 (rounded to the nearest thousand dollars). For FY 2020, FDA determined that it would not apply an operating reserve adjustment to lower the FY 2020 target revenue amount as FDA appears on track to reduce the carryover reserve to the committed level.

Once the capacity planning adjustment is implemented, which FDA expects to occur in FY 2021, FDA may also utilize the operating reserve adjustment to increase the annual target revenue amount. This upward adjustment may not be made to provide for an increase that would result in a carryover balance of more than 21 weeks. FDA does not foresee the need to utilize this upward adjustment in BsUFA II, however, this is an option that FDA expects will be available in FY 2021 and FY 2022 should the financial outlook change.

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 intends to adjust the allocation of each fee type to the total target revenue each year to minimize variation in the fee amount from year to year and to comply with fee rate caps established in statute. The fee amounts may not be set at more than 25 percent above the amounts set in FY 2018; however, once the capacity planning adjustment is effective, this rate restriction no longer applies. As the capacity planning adjustment is expected to be effective for FY 2021, FDA anticipates that this fee rate restriction will apply only through FY 2020.

For FY 2019, fee rates were established to equal the following allocation: application fees provide 40 percent of the total revenue, biosimilar biological product program fees provide 18 percent of the total revenue, and BPD fees provide 42 percent of the total revenue. For FY 2020, fee rates were established to equal the following allocation: application fees provide 42 percent of the total revenue, biosimilar biological product program fees provide 30 percent of the total revenue, and BPD fees provide 28 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 2018	Cohort Year 2019		Cohort Year 2020
	Actual	Estimate	Actual	Estimate
Application Fees	$9,170,411	$15,720,705	$12,227,215	$17,467,450
Program Fees	$2,433,296	$6,995,726	$6,995,726	$12,774,804
BPD Fees	$17,040,975	$16,130,569	$16,130,583	$11,680,746
Total Cash Collections	**$28,644,682**	**$38,847,000**	**$35,353,524**	**$41,923,000**

Estimated Total Cash Collections have been rounded to the nearest thousand dollars
All other 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. The annual updates to this plan will provide actual obligations for the preceding fiscal years, as well as updated planned amounts for the remaining fiscal years. The financial notes can be found in **Appendix C**.

Table 4: Biosimilar Biological Product User Fee Obligations by Expense Category for Fiscal Year 2018 through Fiscal Year 2022

User Fee Obligations	Notes	FY 2018	FY 2019		FY 2020	FY 2021	FY 2022
		Actual	Estimate	Actual	Estimate	Estimate	Estimate
Payroll & Operating	Note 3						
CBER		$-	$460,297	$-	$300,000	$307,302	$314,781
CDER		$31,113,433	$34,137,860	$33,004,440	$37,274,273	$38,181,492	$39,110,791
ORA		$1,128,256	$1,407,248	$676,738	$1,440,770	$1,475,837	$1,511,757
HQ		$2,293,521	$1,785,744	$1,529,197	$1,515,983	$1,555,190	$1,247,082
Total Rent	Note 4	$1,104,785	$1,520,934	$1,382,811	$1,536,143	$1,551,504	$1,567,019
Total Shared Services	Note 5	$4,639,568	$5,405,403	$5,465,202	$4,741,118	$4,788,529	$4,836,414
Total Obligations		**$40,279,564**	**$44,717,486**	**$42,058,388**	**$46,808,287**	**$47,859,854**	**$48,587,846**

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. The estimated payroll and operating obligations for future years have been revised downward between approximately $3.8 – $4.5 million each fiscal year since the publishing of the FY 2018 version of this plan to align more closely to the actual cost of program. This revision (FY 2020 Update) enables FDA to target an operating reserve equivalent to approximately 21 weeks of operations, or about $18 million, by the end of FY 2022. Given the uncertain nature of workload levels in the BsUFA program, exemplified in the $3.5 million under-collection in FY 2019 (see **Table 3**), FDA believes this is an optimal operating reserve target considering the uncertainty inherent to the 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 2019 plan and the actuals in some areas:

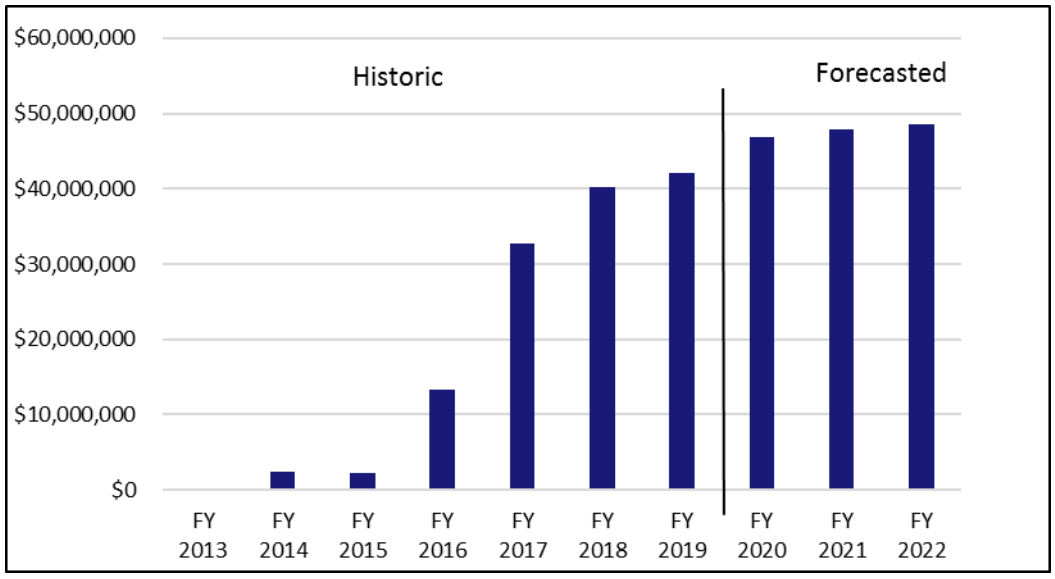
- **CBER Obligations:** Actual CBER obligations in FY 2019 were lower than estimated due to a lower amount of workload than anticipated. BsUFA funding will not be utilized other than for costs of the process for the review of biosimilar biological product applications (see **Appendix A** for additional information regarding allowable and excluded costs for the BsUFA program) and will depend on the workload at the Center. The planned obligations for CBER in FY 2020 through FY 2022 have been reduced to reflect lower workload.

- **ORA Obligations:** Actual ORA obligations in FY 2019 were lower than estimated due to a lower amount of inspectional workload than anticipated.

- **Rent:** The variances in rent actuals for FY 2019 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.

Exhibit 3 below provides an illustration of historical BsUFA obligations and projected FY 2019 through FY 2022 needs.

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



As noted in the Forward View section, early in BsUFA I (FY 2013 – FY 2017) FDA received fee collections from historically more volatile revenue sources (e.g., BPD fees), experienced challenges in hiring staff for the program, and faced uncertainty in meeting the non-user fee spending trigger[5] provisions, all of which contributed to limited spending of user fee funds. However, as workload increased during BsUFA

[5] BsUFA I established a non-user fee spending trigger amount of $20,000,000 (see Section K), to be adjusted for inflation each year. In the early years of BsUFA I, the total financial size of the program was relatively small and uncertain from year to year. For this reason, FDA took a conservative approach to spending user fee revenue. Since FY 2016, the BsUFA program workload has grown sufficient to confidently assure it will exceed the non-user fee spending trigger amount and, as such, FDA has increased the expenditure of fee dollars to the program.

I, along with greater certainty of making the non-user fee spending trigger amount, FDA increased user fee obligations to enhance staff and operational capacity for the program.

FDA plans to gradually increase user fee obligations each year through the end of BsUFA II to build staff and operational capacity to manage review workload and deliver on performance and procedural goals.

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. This balance is referred to as the 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 PDUFA or 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.

Carryover can be broken out into two categories:

- **Carryover Unavailable for Use** – This value represents carryover funds subject to claims or restrictions that precludes FDA from obligating the carryover funds.

- **Carryover Available for Use** – This value represents carryover funds that are not subject to any claims or restrictions and are therefore available for obligation.

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. Forecasted estimates will be supplemented with actual amounts in future Five-Year Financial Plan updates. The financial notes can be found in **Appendix C**.

Table 5: BsUFA Carryover by Fiscal Year

Carryover	Notes	FY 2018	FY 2019		FY 2020	FY 2021	FY 2022
		Actual	Estimate	Actual	Estimate	Estimate	Estimate
Total Carryover, End of Year		**$38,757,343**	**$33,386,857**	**$31,840,903**	**$27,355,616**	**$22,838,762**	**$18,638,917**
Refunds	Note 7	($500,000)	($500,000)	($500,000)	($500,000)	($500,000)	($500,000)
Carryover Available for Use, End of Year		**$38,257,343**	**$32,886,857**	**$31,340,903**	**$26,855,616**	**$22,338,762**	**$18,138,917**

Numbers have been rounded to the nearest dollar

To determine how much carryover is available for obligation at the end of a fiscal year, the following factors must be considered:

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

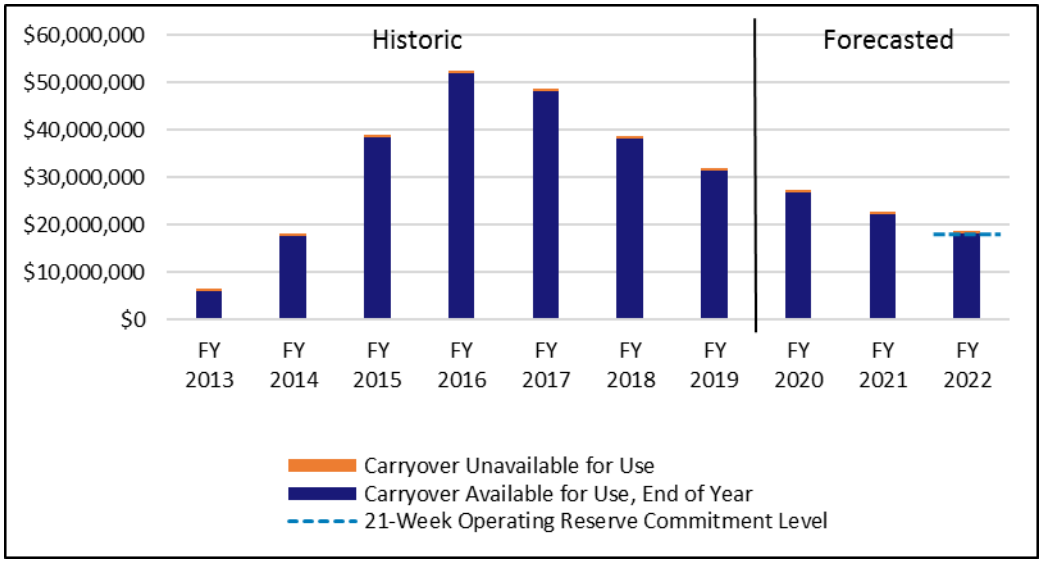
- **Carryover Unavailable for Use, End of Year** – As noted above, this value includes unobligated funds subject to any claims or restrictions on fees collected. This includes:

    - **Refunds** – FDA maintains a small amount to provide for any refunds, as a matter of prudent operations. For that purpose, a total of $500,000 is being set aside. See **Note 7** for additional details.

- **Carryover Available for Use, End of Year** – As noted above, this is the total carryover less any carryover unavailable for use. These funds become the carryover available for use at the beginning of the next fiscal year.

Exhibit 4 below shows the historic trend of carryover in BsUFA I and the forecasted carryover in BsUFA II.

Exhibit 4: Historic and Forecasted Carryover Available by Fiscal Year



Carryover Reduction

Carryover available for use is expected to be reduced from $31,340,903 at the end of FY 2019 to $18,138,917 at the end of FY 2022.

As illustrated, the carryover decreased in FY 2019 but still remains above the targeted 21-week operating level. The greater than expected reduction (approximately $1.5 million more than forecasted for FY 2019) is the result of FDA spending to plan but collecting less user fee revenue than expected (see **Table 3**). Because of the volatility in fee collections FDA aims to maintain 21 weeks of operating reserves by the end of FY 2022 to mitigate collection shortfalls, manage fluctuations in fee amounts, and ensure it can sustain operations if there is a lapse in appropriations.

As discussed in **Section I**, FDA has lowered out-year spending in the plan to reflect the need to maintain 21-weeks of operating reserves.

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"[6]. **Table 6** presents the actual non-user fee spending triggers for FY 2018, FY 2019, and FY 2020, and the forecasted non-user fee spending triggers for FY 2021 and FY 2022.

Table 6: Minimum Allocation of BsUFA Non-User Fee Appropriations by Fiscal Year

FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Actual	Actual	Actual	Estimate	Estimate
$21,711,380	$22,038,420	$22,243,160	$22,501,380	$22,783,560

Numbers have been rounded to the nearest dollar

The non-user fee spending trigger amount is determined by multiplying the base amount of non-user fee appropriations spent on the biosimilar biological product review process ($20,000,000) times the adjustment factor for the fiscal year. See **Note 8** for more details on the adjustment factor.

FDA is committed to spend at least the required minimum from non-user fee appropriations each year. In years when FDA programs do not receive appropriations to cover costs of inflation and mandatory pay increases, FDA activities other than biosimilar biological product review may be reduced to assure that the allocation of non-user fee appropriations to the process for the review of biosimilar biological product applications meets the requirements of this trigger.

L. Planned Hiring

FDA hired 8 FTEs in FY 2018 and 5 FTEs in FY 2019, resulting in 13 of the 15 targeted hires to enhance capacity for biosimilar guidance development, reviewer training, and timely communication. FDA acknowledges there are systemic issues with the Agency's hiring process, as noted in the report, *Initial Assessment of FDA Hiring and Retention – A Path Forward*,[7] that impact BsUFA hiring. Addressing these systemic issues will take time, and FDA did not expect to see significant improvement in hiring early in BsUFA II.

FDA also notes FY 2019 was interrupted by the federal government shutdown (35 days). The shutdown slowed down FDA's business operations, including the hiring process. At the same time, FDA continued to compete in a very strong job market for medical and pharmaceutical fields. Government compensation lags behind private sector benefits for many of the occupations needed to support the BsUFA program. These factors, in addition to hiring system issues, contributed to FDA missing the targeted 15 new hires.

FDA will continue to strive to meet hiring goals and increase staff to address the increasing workload. 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.

[6] 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).

[7] https://www.fda.gov/media/108866/download

Management Assurance

M. Internal Controls

The Federal Managers' Financial Integrity Act (FMFIA) of 1982 is intended to strengthen internal controls and accounting systems. The Office of Management and Budget (OMB) Circular No. A-123, *Management's Responsibility for Enterprise Risk Management and Internal Control* (OMB A-123), implements the requirements of the FMFIA. The FMFIA requires that management establish and maintain effective internal control to achieve the objectives of:

1. Effective and efficient operations,
2. Reliable financial 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 a cost-effective internal control and compliance program that includes programmatic and operational controls, as well as controls over financial reporting, and supports sound financial management. The Government Accountability Office (GAO) *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 to the President and Congress on the effectiveness of the internal controls and any identified material weaknesses in those controls. FDA's FY 2019 Assurance Statement, already submitted to HHS, found no material weaknesses or financial system nonconformances.

Additionally, FDA has established a Senior Assessment Team (SAT) as the governance body responsible for providing oversight and accountability for FDA's internal control over financial reporting, including overseeing the FMFIA and A-123 assessments, to foster an environment that promotes strong internal control. The SAT is chaired by the FDA Chief Financial Officer (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 appointed by the CFO. The SAT members are representatives from each FDA Center and Office.

In accordance with FMFIA, OMB A-123, the Green Book, and HHS guidelines, FDA has a robust internal control program, including integrated controls throughout processes. The Agency also conducts an annual assessment of its internal control activities as well as operational risk reviews. In addition, FDA has an Enterprise Risk Management (ERM) Program, which began in earnest in FY 2016 and is integrated with FDA's FMFIA efforts. Under the ERM program, FDA has refreshed the enterprise risk profile and facilitated risk response planning for five priority enterprise risks. To accomplish this, Centers and Offices are engaged through senior leadership interviews, as well as working groups and problem-solving sessions. Further, FDA has established an ERM Community of Practice, and continues to align and integrate core ERM methodologies with those of internal controls. FDA's ERM program has facilitated cross-Center and Office collaboration to identify and manage risks. It is governed by the ERM Council, which is chaired by the Chief Operating Officer and the CDER Deputy Director for Operations.

FDA's internal control program includes an evaluation of controls over reporting, charge card compliance, improper payments, and financial systems compliance. One of the cycle memos included in the assessment scope includes internal controls over reporting for the reimbursable activity process,

specifically focused on the Accounts Receivable and Payment process associated with the user fee programs. This includes controls over reconciliation performance, aging, write-offs, and the interface between the User Fee System and the Unified Financial Management System. As an FDA-owned system, FDA's User Fee System is compliant with HHS requirements and requirements of the Federal Financial Management Improvement Act (FFMIA) of 1996. In addition, FDA's Integrated Budget and Acquisition Planning System (IBAPS) meets FDA and HHS system requirements.

FDA is also a participant in the annual audit of the consolidated financial statements of HHS, including the consolidated balance sheet, the related consolidated statement of net costs and changes in net position, the combined statement of budgetary resources, and the related notes to the financial statements. The FY 2019 audit found that the financial statements present fairly, in all material respects, the consolidated financial position of HHS as of September 30, 2019 and 2018, and its consolidated net cost, changes in net position, budgetary resources, and related notes are in accordance with U.S. generally accepted accounting principles.

FDA has also implemented other internal control procedures, including a continuous monitoring program to oversee the timely implementation of corrective action plans for deficiencies identified through any of its control assessments. This continuous monitoring program allows for management oversight of targeted remediation efforts and strengthening of internal controls. In addition, FDA offers annual internal control training sessions, which cover the importance of internal controls, timely deficiency remediation, and roles and responsibilities.

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 User Fees and Non-User Fee Appropriations Levels:** It is difficult to predict the amount of non-user fee appropriations that will be approved by Congress, which creates financial planning challenges for the program since non-user fee fund levels are often uncertain for a good portion of the fiscal year. With Continuing Resolutions (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.[8]

- **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, and difficulties with hiring. To minimize this risk, FDA continued to enhance its planning and execution around the hiring of new staff and contract actions in the second year of the authorization. By putting more emphasis on the initial planning of initiatives in the early years of the 5-year cycle, FDA predicts that there will be less variance while comparing planned allocations to actual expenditures than FDA has experienced in the past.

- **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 at appropriate levels. 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 User Fee Financial Management Committee and other FDA senior leaders determine how to mitigate any instances when user fee revenue deviates from forecasted estimates.

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

FDA has committed to improving hiring and retention of scientific staff as described in the BsUFA II commitment letter. Recent history with efforts to hire staff indicates that the Agency may experience challenges in meeting certain BsUFA II commitments. Thus, there may be an impact on the planned versus actual spending in the payroll and operating forecasts in this plan.

[8] 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. Post-market safety activities with respect to biologics approved under biosimilar biological product applications or supplements, including the following activities: a. Collecting, developing, and reviewing safety information on biosimilar biological products, including adverse-event reports. b. Developing and using improved adverse-event data-collection systems, including IT systems. c. Developing and using improved analytical tools to assess potential safety problems, including access to external databases. d. Implementing and enforcing section 505(o) of the FD&C Act (relating to post-approval studies and clinical trials and labeling changes) and section 505(p) of the FD&C Act (relating to risk evaluation and mitigation strategies). e. Carrying out section 505(k)(5) of the FD&C Act (relating to adverse-event reports and post-market safety activities).

Section 744G(9) of the FD&C Act defines the 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 Products	Excluded Activities
1. Applications that cite 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; 2. Allergenic extract products; 3. Whole blood or a blood component for transfusion; 4. In vitro diagnostic biological products; and 5. 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.

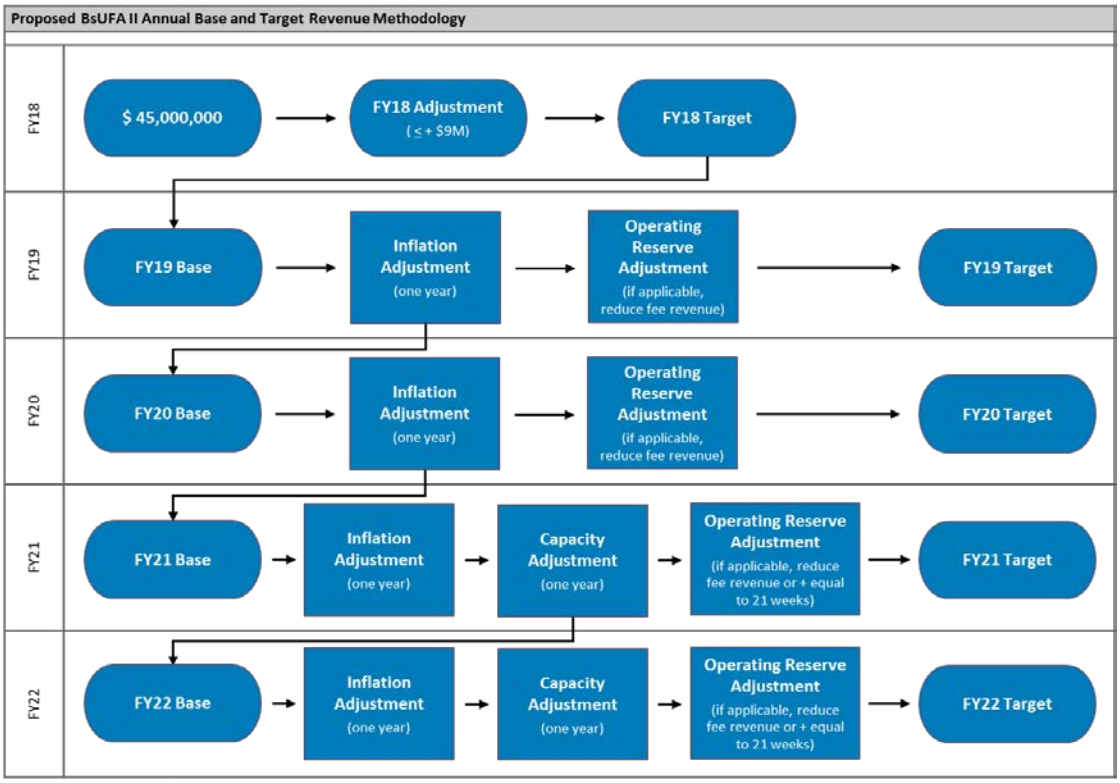
Originally authorized in 2012, BsUFA was reauthorized by FDARA in 2017 (BsUFA II) with the support of the biopharmaceutical industry, public stakeholders, Congress, and the Administration.

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 number of employees that must be housed.

Note 5. Shared Service Costs

FDA 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 2020 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 (ERIC)**: Provides support to all FDA employees requesting administrative, IT, facilities, human resources, and other employee services.
- **Office of Acquisitions and Grants Services (OAGS)**: Manages contracts, grants, and other agreements.
- **Office of Equal Employment Opportunity (OEEO)**: 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 (OFEMS)**: Provides FDA employees with office and laboratory facilities.
- **Office of Financial Management (OFM):** Provides financial managerial services and policy guidance.
- **Office of Information Management and Technology (OIMT)**: 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 (DBEC):** 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 External Affairs – History:** Provides research, documentation, and preservation of significant FDA historical resources, as well as serving as historian for the Agency.
- **Office of Security Operations (OSO):** 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.
- **Paperwork Reduction Act (PRA):** Acts as the liaison between FDA Centers, HHS, and OMB on all information collection matters.
- **Office of Laboratory Science and Safety (OLSS):** OLSS reinforces FDA's expectations for safety and laboratory security, enhances communications among FDA safety staff, and provides program support.
- **Office of Ethics and Integrity (OEI):** 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 (OEMS):** Informs operational objectives and guides strategic management planning to facilitate increased Agency effectiveness and efficiency.
- **Program Alignment Team (PAT):** Provides advice and guidance on reorganizations and delegations of authority.

- **Office of Human Capital Management (OHCM):** Provides Human Resource services which promote collaboration and a work environment that is characterized by diversity, fairness, open communication, personal accountability, trust and mutual respect.
- **Office of Talent Solutions (OTS):** To provide high quality and efficient Human Resource solutions that enable the FDA to hire a talented and qualified workforce.

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. Refunds

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 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.