FIVE-YEAR FINANCIAL PLAN

Fiscal Years
2018-2019-2020-2021-2022

2018 Version

FOR THE

BIOSIMILAR USER FEE ACT

PROGRAM

FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Five-Year Plan Overview

A. Scope

The purpose of the Five-Year Financial Plan is to communicate the anticipated financial position of the Biosimilar User Fee 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 build 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 will only cover the five-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 and advancing the public's 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 receive and manage BsUFA user fees: 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	Helps to ensure the safety, purity, and potency of biological products, including vaccines, blood and blood products, and gene therapies for the prevention, treatment, or cure of human diseases or conditions.
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 current user fee governance process leverages the User Fee Council (UFC) that consists of senior financial, business operations, and program experts across the agency that evaluate user fee resource needs, develop financial allocation plans, and forecast resource requirements – both programmatic and administrative – to support user fee financial decisions. The UFC is responsible for providing oversight support 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. In the near future, FDA expects to make enhancements to its existing governance structure based on recommendations from a third-party evaluation of BsUFA program resource management.

E. User Fee Background and Structure

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

BsUFA was reauthorized under BsUFA II from October 1, 2017 through September 30, 2022. The FDA Reauthorization Act of 2017 (FDARA) provided the second authorization of BsUFA. The five-year reauthorization ensures FDA continues to receive consistent funding from FY 2018 through FY 2022 to ensure the efficiency and effectiveness of the biosimilars 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 independent fee structure, decoupled from PDUFA, that is a simple and efficient user fee structure comprised of initial and annual (BPD) fees, reactivation fees, application fees, and

biosimilar biological product program fees. The new 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 wants 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 and 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 (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. Five-Year 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 Biosimilar Biological Product Development (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 budget authority (BA) 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 convert to original submissions early in BsUFA II, which would contribute to an increase in application review work relative to BsUFA I.

In the BsUFA II commitment letter, FDA committed a target of hiring 15 FTE in FY 2018, to enhance capacity for biosimilar guidance development, reviewer training, and timely communication. FDA is also working to improve the Agency's ability to attract, hire, and retain the top scientific talent that is required 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 as well as 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 Therapeutic Biologics and Biosimilars Staff (TBBS), launch the new scientific staffing capability, and to implement additional compensation given to current and new staff under Cures.

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

As mentioned in Section E, the changes to the BsUFA II fee structure 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 next five years is to build sufficient staff capacity to deliver on program performance and procedural goals, as outlined in the BsUFA II commitment letter, despite the uncertainty about the program workload.

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. While it will take several years to establish and mature the resource capacity planning capability, it will provide the ability to better forecast workload and to translate forecasts into human resource and financial requirements. 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.

[1] The Biosimilar User Fee Amendments of 2017 provide that 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% of the amount of such fee for FY 2018. (See section 744H(b)(3)(B) of the Food, Drug, and Cosmetic (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.

In addition, once the foundational resource capacity planning capability and the modernized time reporting approach are 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 required 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; the impact on fees and annual revenue amounts cannot be estimated at this time.

FDA also made commitments in BsUFA II to help enhance efficiency and transparency in the administration of BsUFA's financial resources. This includes a third-party evaluation of BsUFA program resource management during FY 2018 (currently in progress). It also includes the publishing of a five-year plan (this plan), to be updated annually. FDA also committed to holding an annual public meeting, the first to occur during FY 2019, to discuss this five-year financial plan, along with the Agency's progress in implementing resource capacity planning, modernized time reporting, and the modernized user fee structure.

Working Capital Fund/Cost Allocation

FDA has stood up a Cost Allocation and Recovery framework to improve financial management of resources, including BsUFA, the Prescription Drug User Fee Act (PDUFA) and the Generic Drug User Fee Amendments (GDUFA). Congress recently passed P.L. 115-141 which provides FDA with the authority to establish a Working Capital Fund (WCF) to finance Agency-wide centralized administrative services. Cost Allocation and Recovery and the WCF would benefit the financial management of Agency user fee funds by:

- Increasing transparency by defining administrative activities performed for Centers and Offices and allocating user fee costs based on Agency usage.
- Strengthening accountability by helping the Agency improve the tracking and management of administrative costs, including costs charged to user fees, relative to 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.

In addition, the WCF authority would enhance efficient use of Agency user fees by specifying the collections that the Agency is authorized to credit to the fund and defining the fund's authorized uses, including which funds may be expended (i.e., scope of services).

Financial Information

This section provides an overview of the projected financial outlook for BsUFA through the fiscal year 2018 – 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 Five-Year Forward View section of this plan.

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
		Estimate	Estimate	Estimate	Estimate	Estimate
Target Revenue	**Note 1**	**$40,214,000†**	**$41,012,000**	**$41,826,000**	**$42,656,000**	**$43,503,000**
Cash Collections		$40,214,000	$41,012,000	$41,826,000	$42,656,000	$43,503,000
Carryover Available for Use, Beginning of Year		$48,223,308†	$47,972,011	$42,510,052	$33,863,487	$25,535,929
Total Cash Available for Obligation		**$88,437,308**	**$88,984,011**	**$84,336,052**	**$76,519,487**	**$69,038,929**

Obligations	Notes	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
		Estimate	Estimate	Estimate	Estimate	Estimate
Total Payroll & Operating	Note 2	$35,190,312	$41,146,224	$45,091,553	$45,548,736	$46,010,555
Total Rent	Note 3	$1,505,875	$1,520,934	$1,536,143	$1,551,504	$1,567,019
Total FDA Central	Note 4	$1,986,384	$2,006,248	$2,026,310	$2,046,573	$2,067,039
Total Shared Services	Note 5	$1,782,726	$1,800,553	$1,818,559	$1,836,744	$1,855,112
Total Obligations		**$40,465,297**	**$46,473,959**	**$50,472,565**	**$50,983,558**	**$51,499,725**

Carryover	Notes	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
		Estimate	Estimate	Estimate	Estimate	Estimate
Total Carryover, End of Year		$48,472,011	$43,010,052	$34,363,487	$26,035,929	$18,039,204
Carryover Unavailable for Use, End of Year		($500,000)	($500,000)	($500,000)	($500,000)	($500,000)
Carryover Available for Use, End of Year		**$47,972,011**	**$42,510,052**	**$33,863,487**	**$25,535,929**	**$17,539,204**

Target Revenue has been rounded to the nearest thousand dollars
†Indicates an actual amount

Budgetary Resources: The Budgetary Resources component of **Table 1** illustrates the forecast for the sum of available user fee funding (i.e., the existing available carryover balance and additional projected user fee collections) that are available to fund obligations. The target revenue is the annual revenue amount established when fees for the fiscal year are set. Cash collections is the actual amount collected during the fiscal year. Cash collections is forecasted to be equal to the target revenue, and will be updated with actuals each year. 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.

Obligations: The obligations component of **Table 1** shows the planned annual expenditure of BsUFA fee funds broken out into major expense categories.

BsUFA fees may be expended only for costs to support the "process for the review of biosimilar biological product applications," as defined in 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 fee funds at the end of each fiscal year are referred to as the "carryover

balance." Maintaining an appropriate level of carryover enables FDA to mitigate financial risks to the program, including for example, the risk of under collecting of fee amounts 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 target revenue amounts for the current fiscal year and the actual collections amount from the preceding fiscal year.

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	Estimate	Estimate	Estimate	Estimate
Base Amount		$45,000,000	$40,214,000	$41,012,000	$41,826,000	$42,656,000
Inflation Adjustment		$ -	$798,000	$814,000	$830,000	$847,000
Capacity Planning Adjustment		N/A	N/A	N/A	TBD	TBD
Operating Reserve Adjustment		N/A	TBD	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**	**$41,012,000**	**$41,826,000**	**$42,656,000**	**$43,503,000**

Base Amount and Target Revenue numbers have been rounded to the nearest thousand dollars
N/A = Not Applicable

Budgetary Resources	Notes	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
		Estimate	Estimate	Estimate	Estimate	Estimate
Cash Collections		$40,214,000	$41,012,000	$41,826,000	$42,656,000	$43,503,000
Carryover Available for Use, Beginning of Year		$48,223,308†	$47,972,011	$42,510,052	$33,863,487	$25,535,929
Total Cash Available for Obligation		**$88,437,308**	**$88,984,011**	**$84,336,052**	**$76,519,487**	**$69,038,929**

†Indicates an actual amount

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

- **Inflation Adjustment:** The inflation adjustment adjusts the base amount to maintain the purchasing power of fee funds in consideration of inflation. The adjustment is a composite measure that weights operating expenses by changes in the 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 average inflation adjustment for FY 2019 – FY 2022 is estimated at 1.9853%.

- **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 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 a reasonable amount of fee funds carried over 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.

  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 FDA expects that 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 amount 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.

  FDA considered a range of factors including its best estimated level of submissions and activities (e.g., 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). FDA reduced the base amount by 10.636%.

The base amount for FY 2018 is specified in statute. The base amount for each subsequent year is equal to the prior year's base plus the prior year's inflation and capacity planning adjustments, if applicable. See **Note 1** for a diagram of this process.

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 statute says that the fee amounts may not be set at more than 25% above the amounts set in FY 2018. Once the capacity planning adjustment is effective, this rate restriction no longer applies. As the capacity planning adjustment is expected to be implemented in FY 2021, this fee rate restriction is likely to apply to FY 2019 and FY 2020.

For FY 2018, fee rates were established to equal the following allocation: application fees provide 56% of the total revenue, biosimilar biological product program fees provide 7% of the total revenue, and BPD fees provide 37% of the total revenue. **Table 3** presents the forecasted total annual collections by fee type for FY 2018.

Table 3: BsUFA II Collections

Fee Type	FY 2018
	Estimate
Application Fees	$22,707,685
Program Fees	$14,768,857
BPD Fee	$2,737,458
Total Cash Collections	**$40,214,000**

I. User Fee Obligations

Table 4 provides a breakout of planned user fee obligations by expense category for the five years represented in this plan. The annual updates to this plan will provide actual amounts for the preceding fiscal year, as well updated planned amounts for the remaining fiscal years. The financial notes can be found in **Appendix 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
		Estimate	Estimate	Estimate	Estimate	Estimate
Total Cash Available for Obligation		**$88,437,308**	**$88,984,011**	**$84,336,052**	**$76,519,487**	**$69,038,929**
Payroll & Operating	Note 2					
CBER		$208,018	$458,612	$716,717	$723,983	$731,324
CDER		$31,055,273	$36,720,837	$40,875,344	$41,289,779	$41,708,416
ORA		$1,382,041	$1,396,054	$1,410,208	$1,424,506	$1,438,949
HQ		$2,544,981	$2,570,722	$2,089,285	$2,110,468	$2,131,866
Total Rent	Note 3	$1,505,875	$1,520,934	$1,536,143	$1,551,504	$1,567,019
Total FDA Central	Note 4	$1,986,384	$2,006,248	$2,026,310	$2,046,573	$2,067,039
Total Shared Services	Note 5	$1,782,726	$1,800,553	$1,818,559	$1,836,744	$1,855,112
Total Obligations		**$40,465,297**	**$46,473,959**	**$50,472,565**	**$50,983,558**	**$51,499,725**

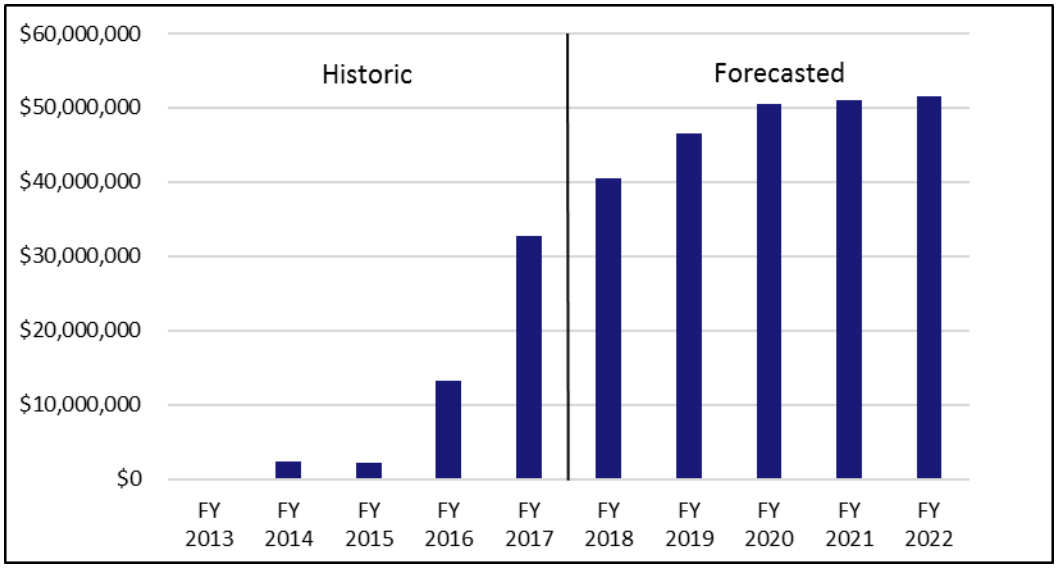
Total obligations include of payroll and operating, rent, central, and shared services costs. The details of each component of total obligations is as follows:

- **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. This includes, for example, core regulatory review functions, pre-approval inspections, guidance and policy development activities, science and research activities, and management and administrative functions that support the BsUFA program.
- **Rent:** This is paid to the General Services Administrations for the Federal buildings that FDA occupies, as well as directly to non-Federal sources for direct leases and services. This rent is charged at different rates depending on the type and location of the space provided.
- **Central:** The Central Account pays for Center-wide and Agency-wide services such as telecommunications, training, printing, mail and document management, information technology (IT) systems including maintenance, employee health units, and other support and miscellaneous services.
- **Shared Services:** FDA contains a number of shared service organizations that provide support across the user fee programs, such as human resources and IT.

Rent, FDA Central, and Shared Services projections are informed by prior year actuals. The future year amounts, for the purposes of this plan, are assumed to have an increase of 1% yearly. by the Cost Allocation and Recovery framework discussed previously.

For historical context, the **Exhibit 3** below provides an illustration of historical BsUFA I obligations and projected BsUFA II needs.

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



As demonstrated by this graph, there was a significant increase in BsUFA fee expenditures over the last two years of BsUFA I. This increase is largely driven by increases in the amount of application review work and of the increasing certainty of making the non-user fee BA spending trigger amount. Historically, FDA has experienced a ramp-up in early years of a new authorization period which has resulted in new carryover as hiring new staff tends to lag the availability of financial resources.

In FY 2017, FDA received 12 original biosimilar product applications; in the previous four years combined, it received a total of 10. The scale of this increase reflects the fact that BsUFA I represented a

new regulatory pathway and an emerging maturing industry sector. FDA assumes the workload will continue near or above the FY 2017 levels at least through the early years of BsUFA II.

BsUFA I established a non-user fee BA 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 BA spending trigger amount and, as such, FDA has increased the expenditure of fee dollars to the program.

As previously stated, in the first year of a new or reauthorized program, FDA often experiences some ramp up time. The result is that FDA may not reach the full anticipated operating level in the first year of a new or reauthorized program. It is forecasted that during BsUFA II, fee obligations will remain steady from 2020 to 2022.

J. User Fee Carryover

BsUFA fees collected, appropriated, and not obligated at the end of the fiscal year, and remain available to FDA 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 of fee amounts 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 is 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 net collections minus net obligations. This is demonstrated best 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
		Estimate	Estimate	Estimate	Estimate	Estimate
Total Carryover, End of Year		**$48,472,011**	**$43,010,052**	**$34,363,487**	**$26,035,929**	**$18,039,204**
Refunds	Note 7	($500,000)	($500,000)	($500,000)	($500,000)	($500,000)
Carryover Available for Use, End of Year		**$47,972,011**	**$42,510,052**	**$33,863,487**	**$25,535,929**	**$17,539,204**

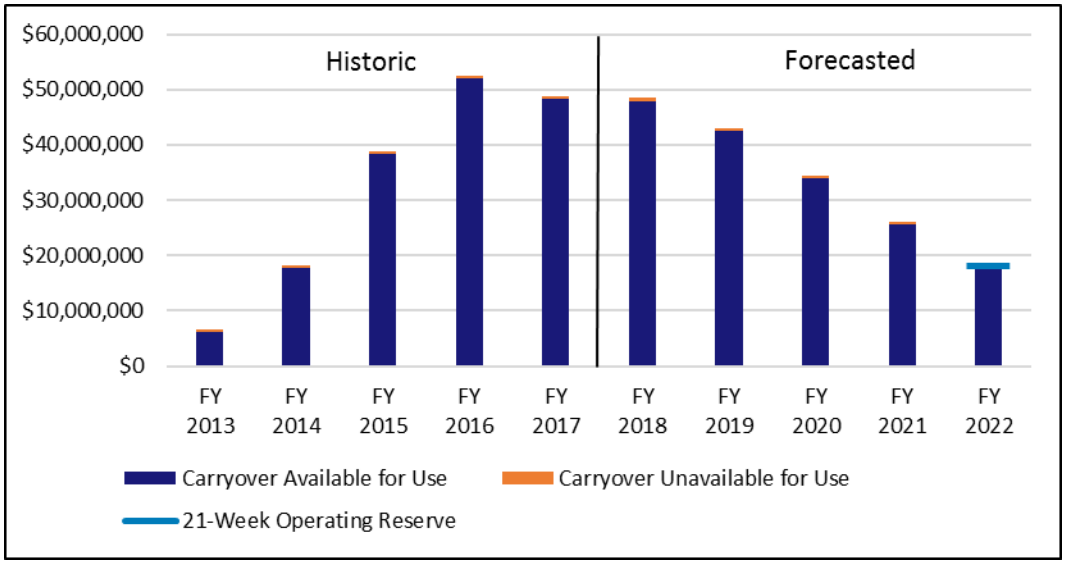
To determine how much carryover is available for obligation at the end of a fiscal year, the following factors must be considered:

- **Total Carryover, End of Year** – This is the total amount of unobligated fee funds at the end of the fiscal year.
- **Carryover Unavailable for Use, End of Year** – As noted above, this value includes unobligated fee 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.

For the purposes of this plan, future year recoveries have not been estimated. Additional details on recoveries are included in **Note 8**.

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



As illustrated, FDA plans to substantially reduce the amount of carryover in BsUFA II. The operating reserve adjustment will be a mitigation tool to ensure carryover is not greater than the 21-week operating levels. Looking forward into BsUFA II, FDA will have lowered the operating reserve to less than 21-weeks of carryover in FY 2022, as depicted in the graph above. As a result, carryover will be expended accordingly over the five-year period.

Carryover Reduction

Available carryover is expected to be reduced from $47,972,011 in FY 2018 to $17,539,204 in FY 2022. That is a reduction of 63% over the course of BsUFA II.

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 BA spending trigger". **Table 6** presents the forecasted non-user fee BA spending trigger for BsUFA II.

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

FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Actual	Estimate	Estimate	Estimate	Estimate
$21,711,380	$21,951,220	$22,190,140	$22,422,420	$22,682,280

The non-user fee BA 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 9** for more details on the adjustment factor.

FDA plans to spend at least the required minimum from appropriations each year. In years when FDA programs do not receive appropriations to cover costs of inflation and mandatory pay increases, other FDA activities other than biosimilar biological product review may have to be reduced to assure that appropriated spending for biosimilar biological product review meets the requirements of this trigger.

L. Planned Hiring

Fifteen new hires for CDER to be supported by fee funds are to support new or expanded initiatives on BsUFA II. In addition, FDA will review the financial status and the 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 (FMFIA) of 1982 is intended to strengthen internal controls and accounting systems. The Office of Management and Budget's Circular No. A-123, *Management's Responsibility for Internal Control and Enterprise Risk Management* (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.

DHHS 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) state, "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 the Congress on the effectiveness of the internal controls and any identified material weaknesses in those controls. FDA's FY 2017 Assurance Statement that was submitted to DHHS, 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, and 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 the HHS Guidelines, FDA has a robust internal control program, including integrated controls throughout processes, and conducts an annual assessment of its internal control activities. 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 5 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 piloted integration with internal controls. FDA's ERM program has facilitated cross-Center and Office collaboration to identify and manage risks.

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, 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 DHHS system requirements.

FDA is also a participant in the annual audit of the consolidated financial statements of DHHS, including the consolidated balance sheets, 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 2017 audit found that the financial statements present fairly, in all material respects, the consolidated financial position of DHHS as of September 30, 2017 and 2016, and its consolidated net cost, changes in net position, and budgetary resources for the years then ended 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 any Corrective Action Plans (CAPs) 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 annually, 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 BA 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 interest 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 much of the fiscal year. This is due to prolonged Continuing Resolutions (CRs), versus early in the fiscal year enactment of annual appropriations bills. 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 BA 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% range in which FDA can still comply with its non-user fee BA spending trigger requirements, without being forced to reduce fee revenue in the subsequent fiscal year. [2]

- **Lapse in Non-User Fee Appropriations:** FDA is mitigating this risk to the program by maintaining a certain level of carryover. In BsUFA II, FDA can maintain up to 21 weeks of an operating reserve so it can continue program operations in the event of a shutdown. See **Note 6** for additional details.

- **Under-Executing Planned Spend:** FDA historic experience with ramping up a new user fee program has resulted in new carryover as hiring new staff tends to lag the availability of financial resources. Comfort in FDA's ability to comply with the non-user fee BA spending trigger also impacts the program's ability to execute planned spend. To minimize this risk, FDA is enhancing their planning and execution around the hiring of new staff and contract actions. By putting more emphasis on the initial planning of initiatives in the first year of the five-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 industry submissions, 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

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

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 for FDA to adjust for sustained increases in workload. In addition, FDA monitors collections throughout the fiscal year, and the User Fee Council and other FDA senior leaders determine how to mitigate any instances when user fee revenue is off forecasted estimates.

In addition to these mitigation strategies, FDA implemented the 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. As initiatives associated with these commitments span the course of BsUFA II, the benefits expected from these initiatives will not be immediate, and, thus, FDA may experience delays in hiring staff for the BsUFA program. Thus, there may be an impact on the planned versus actual spending in the payroll and operating forecasts in this plan.

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 and accounting for resources.

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.

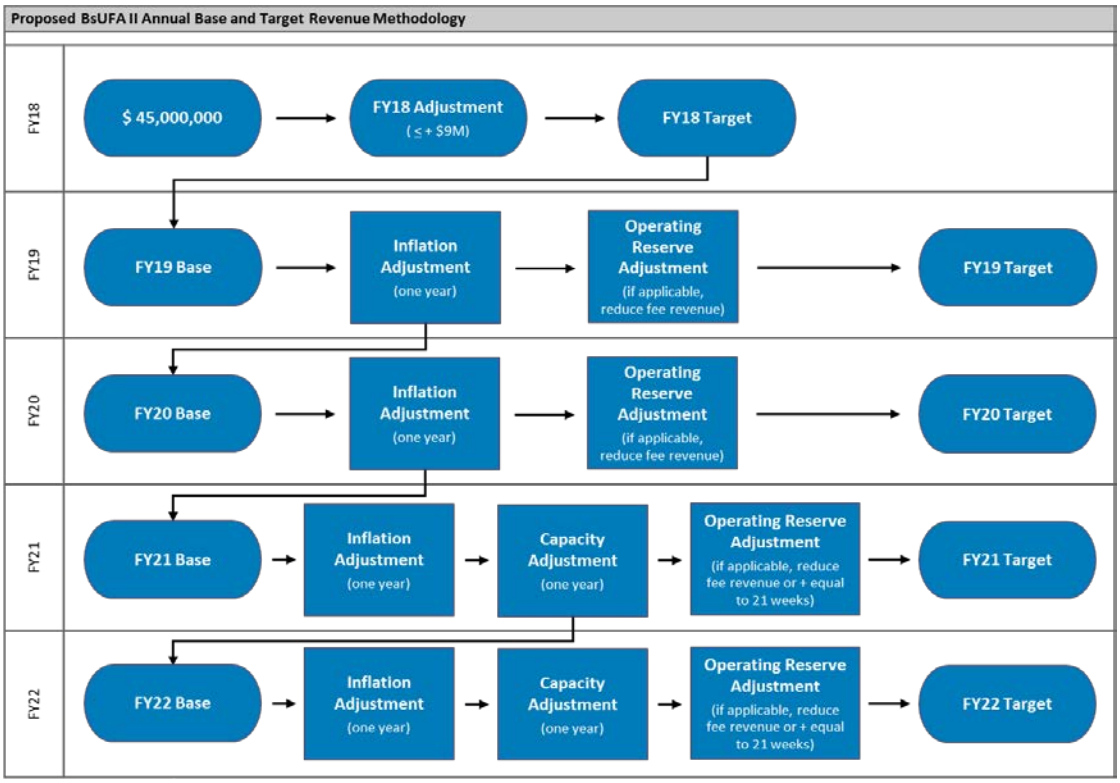
Originally authorized in 2012, BsUFA was reauthorized by FDARA in 2017 (BsUFA II) with the support of the biopharmaceutical industry, public stakeholders, Congress, and the Administration.

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. Pay and Operating Costs

Pay and operating costs associated with the BsUFA program are based on obligations attributed to CBER, CDER, ORA and HQ. These costs relate to how much of the BsUFA revenue is going toward payroll and operating expenses.

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 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 3. Rent Costs

The General Services Administration (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 directly 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 4. FDA Central Costs

The Central Account pays 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. Like rent, the amount of central account support FDA pays is directly related to the number of employees that must be serviced. Each Center pays its portion based on the number of employees working in the BsUFA program.

Note 5. Shared Service Costs

FDA contains a number of shared service organizations that provide support across the user fee programs. The shared service organizations include:

- **Employee Resource & Information Center (ERIC)**: Provides support to all FDA users requesting administrative, IT, facilities, human resources, and other employee services.
- **Employee Safety & Environmental Management (ESEM)**: Provides safety, health, and environmental compliance for all FDA employees.
- **Office of Acquisitions and Grants Services (OAGS)**: Manages contracts, grants, and other agreements.
- **Office of External Affairs (OEA)**: Provides the development, coordination, and dissemination of FDA communications and outreach to the news media and various stakeholders.
- **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 Human Resources (OHR)**: Supports workforce relations, client services, executive resources, accountability programs, policy and program development, and systems data and management.
- **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.

Note 6. Operating Reserve Adjustment

Until the capacity planning adjustment is effective, 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.

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 seventy-five percent of the application fee paid.

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

Note 8. Recoveries

Recoveries account for funds returned to the Agency in the form of deobligations of prior year obligations.

Note 9. Minimum Non-User Fee Appropriations Adjustment Factor

FDA must calculate and incorporate adjustment factors. For purposes of BsUFA II, the following definition is applied: "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) of the preceding fiscal year divided by such Index for September 2011."