Five-Year Financial Plan

Five Years
2023-2024-2025-2026-2027
FY 2024 Version

FOR THE

Prescription Drug 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 Prescription Drug User Fee Act (PDUFA) program. The PDUFA program was reauthorized by the FDA User Fee Reauthorization Act of 2022, which includes the Prescription Drug User Fee Amendments of 2022 (PDUFA VII). This document addresses the plan for implementation and use of prescription drug user fees by the Food and Drug Administration (FDA or the Agency) during the period of October 1, 2022, through September 30, 2027.

B. Five-Year Plan Commitments

In accordance with PDUFA Reauthorization Performance Goals and Procedures Fiscal Years FY 2023 Through 2027 (PDUFA VII Commitment Letter), Title 2, Section B, FDA will publish a PDUFA five-year financial plan no later than the second quarter of fiscal year (FY) 2023. FDA will publish updates to the five-year financial plan no later than the second quarter of each subsequent fiscal year. The purpose of this document is to meet these commitments.

C. Updates to the Five-Year Plan

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

Management Discussion

D. Organization Background

FDA is responsible for protecting public health by helping to ensure the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation. FDA also has responsibility for regulating the manufacturing, marketing, and distribution of tobacco products and advancing public health. FDA helps to speed innovations that make medical products more effective, safe, and affordable and helps the public get the accurate, science-based information needed to use medical products and to consume foods to maintain and improve their health. In addition, FDA plays a significant role in the nation's counterterrorism defense. FDA fulfills this responsibility by ensuring the security of the food supply and by fostering development of medical products to respond to deliberate and naturally emerging public health threats.

Program Organization

There are five major FDA components that support the PDUFA program: the Center for Drug Evaluation and Research (CDER), the Center for Biologics Evaluation and Research (CBER), the Center for Devices and Radiological Health (CDRH), the Office of Regulatory Affairs (ORA), and Headquarters (HQ). **Exhibit 1** provides an overview of the mission for each of these components.

Exhibit 1: User Fee Program Components

Component	Mission
CDER	Protects and promotes public health by helping to ensure that human drugs are safe and effective, meet established quality standards, and are available to patients.
CBER	Protects and advances the public health by helping to ensure that biological products are safe and effective and are available to patients.
CDRH	Protects and promotes public health by helping to ensure that patients and providers have timely and continued access to safe, effective, and high-quality medical devices and safe radiation-emitting products.
ORA	Protects consumers and enhances public health by maximizing compliance of FDA-regulated products and minimizing risk associated with those products. ORA inspects regulated products and manufacturers, conducts sample analyses of regulated products and reviews imported products offered for entry into the United States.
HQ	Provides FDA-wide program direction and administrative services to ensure FDA's consumer and patient safety programs are effectively and efficiently managed.

User Fee Governance

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

FDA's user fee governance process leverages the User Fee Financial Management Committee (UFFMC), which consists of senior financial, business operations, and program experts across the Agency that evaluate user fee resource needs, develop financial allocation plans, and forecast resource requirements—both programmatic and administrative—to support user fee financial decisions. The UFFMC is responsible for providing oversight and support of appropriate standards and policies to ensure FDA's compliance with sound financial management practices, as well as compliance with statutory provisions that authorize FDA to collect and spend user fees. The UFFMC receives policy guidance and strategic direction directly from FDA's Executive Committee relative to how the Agency will forecast and react to industry trends, plan and manage its research agenda in support of the user fee programs, and forecast its user fee workload. The UFFMC advises the Executive Committee and other Center- and Office-level bodies on a variety of financial and performance-related topics.

Working Capital Fund/Cost Allocation

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

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

Internal Controls

The Department of Health and Human Services (HHS) provides guidance to its operating divisions (OpDivs) to implement The Federal Managers' Financial Integrity Act of 1982 (FMFIA) through its FMFIA Guidelines, which is intended to strengthen internal controls and accounting systems. OpDivs, including FDA, are responsible for developing and maintaining internal control and compliance programs that include programmatic and operational controls, as well as reporting controls to support sound financial management. Additionally, FDA established an Enterprise Risk Management (ERM) Program, with an ERM Council as the governance body responsible for providing overall oversight and accountability. For further information regarding the Internal

Controls and Enterprise Risk Management, please refer to the User Fee Program's Financial Report.

E. User Fee Background and Structure

Under PDUFA, FDA assesses and collects fees from drug application holders to fund the human drug review process. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by PDUFA, authorizes FDA to collect fees from industry to supplement the non-user fee appropriations that the Agency spends on the process for the review of human drug applications.

PDUFA was enacted in 1992, reauthorized in 1997 (PDUFA II), 2002 (PDUFA III), 2007 (PDUFA IV), 2012 (PDUFA V), 2017 (PDUFA VI), and most recently in 2022 (PDUFA VII). The FDA User Fee Reauthorization Act of 2022 includes the seventh authorization of PDUFA, also known as PDUFA VII, and authorizes continued funding for FDA from FY 2023 through FY 2027 to support program operations, evaluation, and improvements. PDUFA VII will continue to deliver tremendous public health benefits by enhancing FDA's capacity to review novel drug products so that safe and effective products can come to the market more quickly.

FDA spends PDUFA user fee collections and non-user fee appropriations to hire, support, and maintain personnel for the review of human drug applications to help ensure that safe, effective, and high-quality prescription drugs are available to the American public.

The fee structure remains unchanged from PDUFA VI with two types of fees: application fees and program fees. The proportion of target revenue derived from program fees remains at 80 percent and the proportion derived from application fees remains at 20 percent.

Exhibit 2: PDUFA VII fee structure.

Fee Type	Definition
Application: With Clinical Data	A human drug application for which clinical data (other than bioavailability or bioequivalence studies) with respect to safety or effectiveness are required for approval is assessed **a full application fee** when the application is submitted.
Application: Without Clinical Data	A human drug application for which clinical data (other than bioavailability or bioequivalence studies) with respect to safety or effectiveness are not required for approval is assessed **one-half of a full fee** when the application is submitted.

Program	Prescription drug product program fees are assessed annually for eligible prescription products. The program fees are assessed annually for such drug product that is identified in an approved NDA or BLA as of October 1st of such fiscal year, or in some cases, when a drug is returned to marketing during the fiscal year.

The statute specifies how the fees must be calculated each fiscal year, including annual adjustments that must be made for inflation, strategic hiring and retention, capacity planning, additional dollar amounts, operating reserve, and additional direct costs. The fee amounts are published in the Federal Register each year, typically at the beginning of August.[1]

PDUFA user fees are not a fee for service. User fees are pooled and may be used for the allowable activities as defined in the FD&C Act. Refer to **Appendix A** for a detailed list of allowable and excluded activities.

F. Forward View

FDA developed the enhancements for PDUFA VII in consultation with drug industry representatives, patient and consumer advocates, health care professionals, and other public stakeholders in 2020 and 2021. Information on the PDUFA VII commitments can be found on FDA's website.[2]

The PDUFA VII Commitment Letter continues many commitments from PDUFA VI and introduces new enhancements to the program. PDUFA VII also makes changes to the fee-setting mechanisms and provides additional user fee funding for the program. Over the remaining fiscal years of PDUFA VII, FDA will focus on implementing the new commitments and changes to the program as well as new programs mandated by Congress in the Consolidated Appropriations Act, 2023. Below are some of the key highlights of what FDA will be focusing on during PDUFA VII.

Highlights of New Enhancements in PDUFA VII

PDUFA VII provides additional funding to FDA to implement new enhancements to the program while sustaining existing commitments. This new funding is provided through the additional dollar amounts and additional direct cost adjustments outlined in statute, which will enable the program to hire 352 new employees and make critical investments in the program over the course of PDUFA VII.

The funding will support enhancements to:

[1] The PDUFA User Fee Rates Archive is available at https://www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-user-fee-rates-archive.
[2] https://www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-vii-fiscal-years-2023-2027

- Pre-market review processes and procedures including new formal meeting types and a new pilot program that seeks to expedite patient access to novel uses for existing therapies.

- Regulatory science activities including the launch of new pilot programs to advance rare disease development and enhance the quality and acceptability of real-world evidence.

- Regulatory decision tools to support drug development and review.

- FDA's drug safety system, including optimizing the Sentinel Initiative capabilities.

- Product quality reviews, chemistry, manufacturing, and control approaches, and advancing the utilization of innovative manufacturing technologies.

- Information technology and bioinformatics, including critical investments to accelerate CBER's data and technology modernization.

Changes to Fee-Setting Mechanisms in PDUFA VII

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

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

- Updating of the PDUFA Capacity Planning Adjustment, which is a mechanism to ensure that FDA is able to manage the resources needed for sustained increases in review workload submitted by sponsors, to clarify that the workload categories used in the forecasting methodology will include only the activities described in the PDUFA fee setting notice for FY 2021 and, as feasible, additional activities that are also directly related to the direct review of applications and supplements, including additional formal meeting types and the direct review of post marketing commitments and requirements, the direct review of risk evaluation and mitigation strategies, and the direct review of annual reports for approved prescription drug products.

- Modification of the Operating Reserve Adjustment to provide for a defined minimum required amount of operating reserves to be maintained each fiscal year to mitigate financial risks. This may require FDA to increase the annual revenue amount used to set fees to provide for the defined minimum required amount of operating reserves. To minimize impact on fee amounts from large

changes in any year, this defined minimum amount is phased in over three years (8 weeks of available operating reserves in FY 2023, 9 weeks of available operating reserves in FY 2024, and 10 weeks of available operating reserves in FY 2025 and subsequent fiscal years). If used, the funding will be used to adjust the fees and fee revenue.

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

Continued Efforts to Enhance Financial Management in PDUFA VII

Under PDUFA VI, FDA made numerous commitments to enhance the financial management of user fee resources in the program. This included establishing a resource capacity planning function and modernizing its time reporting to enable better forecasting of workload in the program and the ability to translate forecasts into more targeted human resource and financial needs. Upon establishing the foundational resource capacity planning capability, FDA implemented the new capacity planning adjustment (CPA) methodology that adjusts the annual target revenue amount to account for the resources required to respond to projected sustained changes in program workload. This helps ensure FDA has the resources it needs to deliver on its performance commitments in PDUFA.

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

Over the course of PDUFA VII, FDA will build on the financial improvements achieved in PDUFA VI to enhance financial management in the program. Some of the enhancements include:

- Publishing an implementation plan that will describe how resource capacity planning and time reporting will continue to be implemented during PDUFA VII,[3] hiring an independent contractor to evaluate of the resource capacity planning capability, and continuing to improve the resource capacity planning capability and CPA after reviewing the findings and recommendations of the evaluation.

- Publishing of a five-year financial plan with updates each year. The annual updates will include additional topics related to changes in personnel compensation and the managing of costs related to strategic hiring and retention after PDUFA VII.

[3] Published March 2023: https://www.fda.gov/media/166677/download?attachment

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

FDA is committed to ensuring the sustainability of PDUFA program resources and to enhancing the operational agility of the PDUFA program. The continued maturation of the resource capacity planning function and CPA over PDUFA VII will help ensure optimal use of user fee resources and is FDA's primary mechanism to acquire resources if there are sustained increases in workload in the program. Over the next four years, FDA will also continue activities to promote transparency of the use of financial resources in support of the PDUFA program.

Financial Information

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

G. User Fee Program Financial Summary

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

Table 1a: Prescription Drug Budgetary Resources for Fiscal Year 2023 through Fiscal Year 2027

Budgetary Resources	Notes	FY2023 Estimate	FY2023 Actual	FY2024 Estimate	FY2025 Estimate	FY2026 Estimate	FY2027 Estimate
Target Revenue	**Note 1**	**$1,310,319,000**	**$1,310,319,000**	**$1,422,104,000**	**$1,472,210,000**	**$1,541,682,000**	**$1,610,463,000**
Net Collections		$1,310,319,000	$1,222,888,088	$1,452,104,000	$1,472,210,000	$1,541,682,000	$1,610,463,000
Recoveries	Note 4	$12,000,000	$16,400,359	$12,567,000	$12,567,000	$12,567,000	$12,567,000
Total Carryover, Beginning of Year		$287,669,825	$287,669,825	$275,515,520	$351,685,404	$375,284,588	$402,087,721
Total Budgetary Resources		**$1,609,988,825**	**$1,526,958,272**	**$1,740,186,520**	**$1,836,462,404**	**$1,929,533,588**	**$2,025,117,721**

Table 1b: Prescription Drug Obligations for Fiscal Year 2023 through Fiscal Year 2027

Obligations	Notes	FY2023 Estimate	FY2023 Actual	FY2024 Estimate	FY2025 Estimate	FY2026 Estimate	FY2027 Estimate
Total Payroll & Operating	Note 5	$1,101,564,648	$1,051,761,127	$1,192,366,894	$1,256,286,769	$1,314,478,079	$1,370,683,912

Obligations	Notes	FY2023 Estimate	FY2023 Actual	FY2024 Estimate	FY2025 Estimate	FY2026 Estimate	FY2027 Estimate
Total Rent	Note 6	$59,306,768	$48,137,237	$28,672,907	$28,959,636	$29,249,233	$29,541,725
Total Shared Services	Note 7	$143,517,124	$151,544,388	$167,461,315	$175,931,410	$183,718,556	$191,428,874
Total Obligations		**$1,304,388,540**	**$1,251,442,752**	**$1,388,501,116**	**$1,461,177,816**	**$1,527,445,868**	**$1,591,654,511**

Table 1c: Prescription Drug Carryover for Fiscal Year 2023 through Fiscal Year 2027

Carryover	Notes	FY2023 Estimate	FY2023 Actual	FY2024 Estimate	FY2025 Estimate	FY2026 Estimate	FY2027 Estimate
Total Carryover, End of Year		$305,600,285	$275,515,520	$351,685,404	$375,284,588	$402,087,721	$433,463,210
Unappropriated Amounts	Note 11	($78,850,995)	($78,850,995)	($78,850,995)	($78,850,995)	($78,850,995)	($78,850,995)
Future Year Refunds Allowance, Set Aside		($20,000,000)	($20,000,000)	($25,229,000)	($25,229,000)	($25,229,000)	($25,229,000)
Carryover Net of Unavailable and Set Aside, End of Year		**$206,749,290**	**$176,664,525**	**$247,605,409**	**$271,204,593**	**$298,007,726**	**$329,383,215**

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

Budgetary Resources: The Total Budgetary Resources component of **Table 1a** illustrates the actual and previously estimated sum of total user fee funding for FY 2023 and estimates for FY 2024 through FY 2027. Budgetary resources include net collections, recoveries, and carryover amounts.

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

Obligations: The Obligations component of **Table 1b** shows the actual and previously planned expenditures for FY 2023 and planned expenditures for FY 2024 through FY 2027 of PDUFA fee funds broken out into major expense categories. PDUFA fees may be expended only for costs to support the "process for the review of human drug applications," as defined in PDUFA VII. For more information on the allowable and excluded costs, see **Appendix A**.

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

Carryover: PDUFA fees collected, appropriated, and not obligated at the end of a fiscal year remain available to FDA for use in future fiscal years. In this report, such fee funds, plus certain user fee funds that FDA has collected that are considered unappropriated, are referred to as the "total carryover" or "PDUFA carryover."

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

H. Budgetary Resources

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

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

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

Table 2: Prescription Drug User Fee Target Revenue FY 2023 through FY 2027

Budgetary Resources	Notes	FY2023 Actual	FY2024 Actual	FY2025 Estimate	FY2026 Estimate	FY2027 Estimate
Statutory Base		$1,151,522,958	$1,256,844,387	$1,358,764,346	$1,432,854,767	$1,500,705,959
Inflation Adjustment		$18,889,583	$48,886,219	$55,936,252	$58,986,332	$61,779,562
Strategic Hiring and Retention Adjustment		$9,000,000	$4,000,000	$4,000,000	$4,000,000	$4,000,000
Capacity Planning Adjustment		$11,658,153	$23,936,069	TBD	TBD	TBD
Additional Dollar Amount Adjustment		$65,773,693	$25,097,671	$14,154,169	$4,864,860	$1,314,620
Operating Reserve Adjustment		$9,088,943	$0	TBD	TBD	TBD
Additional Direct Cost Adjustment		$44,386,150	$63,339,404	$39,355,553	$40,975,704	$42,662,550
Target Revenue Total	**Note 1**	**$1,310,319,480**	**$1,422,103,750**	**$1,472,210,320**	**$1,541,681,663**	**$1,610,462,691**
Target Revenue Total (Rounded)		**$1,310,319,000**	**$1,422,104,000**	**$1,472,210,000**	**$1,541,682,000**	**$1,610,463,000**

All numbers have been rounded to the nearest dollar.

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

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

- **Inflation Adjustment:** The inflation adjustment adjusts the base amount to maintain the purchasing power of fee funds in consideration of inflation. The adjustment is a composite measure that weights operating expenses by changes in the Consumer Price Index (CPI) and payroll-related expenses by changes in FDA's average personnel compensation and benefits amounts. The actual inflation adjustment utilized in FY 2024 was 3.8896 (rounded) percent. Inflation for FY 2025 is estimated to be 4.1167 and future years are set to match the estimated FY 2025 percent increase. See **Note 2** for more information.

- **Strategic Hiring and Retention Adjustment:** The strategic hiring and retention adjustment increases the inflation-adjusted base amount to cover the costs of hiring and retaining highly qualified scientific and technical staff for the process for the review of human drug applications. For FY 2023, this amount was $9,000,000. For FY 2024 and subsequent fiscal years, this amount is $4,000,000.

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

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

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

- FDA's plan for managing costs related to strategic hiring and retention after the adjustment required by section 736(b)(1)(C) of the FD&C Act expires at the end of FY 2027.

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

- **Capacity Planning Adjustment:** Adjusts for changes in the resource capacity needs of the PDUFA program; the revenue amounts generated by this adjustment support direct review functions of the program. See **Note 3** for more details.

  For FY 2024, the Capacity Planning Adjustment (CPA) was $23,936,069. These funds are being used to support 72 additional full-time equivalents.

  The intent of the CPA is to enable annual adjustments, if needed, to ensure that the Agency is appropriately resourced to be able to address sustained increases in the forecasted amount of direct review work. The CPA is a structured process utilizing validated forecasts models trained with the most recently available data and includes managerial decision points.[4] The CPA amount will fluctuate from year to year. FDA does not maintain expectations for future year CPA amounts as these are dependent on shifting industry activity. As such, FDA will not utilize placeholder estimates for the purposes of the financial plan. The actual CPA amounts will be updated each year.

- **Additional Dollar Amounts**: PDUFA VII provides an additional dollar amount for each of the five fiscal years for additional full-time equivalents to support enhancements outlined in the PDUFA VII commitment letter (see **Note 8**). For FY 2024, this amount was $25,097,671.

  PDUFA VII provided for the hiring of 352 new positions to support workload associated with initiatives established or expanded by PDUFA VII. These 352 new positions are scheduled to be hired over the five years of PDUFA VII. For details, see **Section L** – Planned Hiring.

- **Operating Reserve Adjustment**: PDUFA VII establishes a defined minimum threshold for the operating reserve adjustment. FDA is required to increase the fee revenue and fees, if needed, to provide for at least eight weeks of operating

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

reserves for FY 2023, nine weeks of operating reserves for FY 2024, and ten weeks of operating reserves for FY 2025 and subsequent years. For more information, see **Note 9**.

FDA is required to decrease fee revenue and fees to provide for not more than 14 weeks of operating reserves of carryover balance.

For the purposes of the operating reserve adjustment under PDUFA VII, the term "operating reserve" means the collected user-fee funds in the carryover balance that are available for obligation and does not include unappropriated collections of $78,850,995 (see **Note 11**).

In FY 2023, FDA applied an upward operating reserve adjustment of $9,088,943 because the estimated FY 2022 end-of-year operating reserves was below the eight-week minimum. For FY2024, there was no operating reserve adjustment applied. FDA is not currently estimating that for FY 2025 there will be an operating reserve adjustment. This amount may change when fees are set for FY 2025 based on more updated information on FY 2024 obligations and collections.

- **Additional Direct Cost Adjustment:** Additional direct costs provide for certain non-payroll costs associated with PDUFA VII initiatives (see **Table 2**). The amounts for each fiscal year are specified in statute; an inflation adjustment is applied to the amounts for FY 2024 through FY 2027. The additional direct cost amounts, being only operating and not payroll funds, use an inflation adjustment that is based only on changes in the CPI (see **Note 10**). The amount for FY 2024 is $63,339,404.

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

Table 3: Prescription Drug User Fee Budgetary Resources FY 2023 through FY 2027

Budgetary Resources	Notes	FY2023 Estimate	FY2023 Actual	FY2024 Estimate	FY2025 Estimate	FY2026 Estimate	FY2027 Estimate
Target Revenue	**Note 1**	**$1,310,319,000**	**$1,310,319,000**	**$1,422,104,000**	**$1,472,210,000**	**$1,541,682,000**	**$1,610,463,000**
Net Collections		$1,310,319,000	$1,222,888,088	$1,452,104,000[5]	$1,472,210,000	$1,541,682,000	$1,610,463,000
Recoveries	Note 4	$12,000,000	$16,400,359	$12,567,000	$12,567,000	$12,567,000	$12,567,000
Total Carryover, Beginning of Year		$287,669,825	$287,669,825	$275,515,520	$351,685,404	$375,284,588	$402,087,721
Total Budgetary Resources		**$1,609,988,825**	**$1,526,958,272**	**$1,740,186,520**	**$1,836,462,404**	**$1,929,533,588**	**$2,025,117,721**

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

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

[5] Current FY 2024 collections are trending to be above the target revenue amount.

- **Net Collections:** FDA generally assumes, for planning purposes, that net collections will equal the target revenue amount. In practice, net collections may differ from the annual target revenue amount if the actual number of fee-paying units differ from the number of fee-paying units estimated when fees are set each year. The net collections estimate for FY 2024 has been increased above the target revenue amount as a result of the rate of collections thus far in FY 2024. This net collections estimate may be readjusted again depending on collections activity for the remainder of the fiscal year.

- **Recoveries:** For the purposes of this plan, future year recoveries are estimated using a three-year average of actual recoveries from the most recently completed prior fiscal years. Recoveries vary from year to year and the result could be either higher or lower that the current estimate. FDA estimates recoveries to be $12,567,000 annually. Additional details on recoveries are included in **Note 4.**

- **Total Carryover, Beginning of Year:** Total carryover represents the balance of unspent PDUFA fee funds at the beginning of the fiscal year. This includes funds considered available as well as funds considered unavailable. The total year carryover at the end of one fiscal year equals the total carryover at the beginning of the subsequent fiscal year. Carryover is discussed in more detail in **Section J.**

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

- **Net Collections:** Net collections are the actual dollar amounts collected in a fiscal year, regardless of the fiscal year the fee was due.

- **Table 1a** and **Table 3** report net collections.

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

- **Table 4** reports cohort year collections.

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

Table 4 presents actual and estimated total annual PDUFA fee collections by fee type and cohort year. Refer to **Section E** for more background and information on the PDUFA VII fee structure.

Table 4: PDUFA VII Fee Collections by Fee Type and Cohort Year

Fee Type	Cohort Year 2023 Estimate	Cohort Year 2023 Actuals	Cohort Year 2024 Estimate
Application Fees	$262,063,800	$183,579,697	$284,420,800

Fee Type	Cohort Year 2023 Estimate	Cohort Year 2023 Actuals	Cohort Year 2024 Estimate
Program Fees	$1,048,255,200	$1,077,266,228	$1,167,683,200[6]
Total Cohort Collections	**$1,310,319,000**	**$1,260,845,925**	**$1,452,104,000**

All numbers have been rounded to the nearest dollar.

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

I. User Fee Obligations

PDUFA fees may be expended only for certain costs to support the "process for the review of human drug applications," as defined in PDUFA VII. For more information on the allowable and excluded costs, see **Appendix A**.

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

Table 5: Prescription Drug User Fee Obligations by Expense Category for FYs 2023 through 2027

User Fee Obligations	Notes	FY2023 Estimate	FY2023 Actual	FY2024 Estimate	FY2025 Estimate	FY2026 Estimate	FY2027 Estimate
Payroll & Operating	**Note 5**						
CBER		$209,746,098	$195,551,429	$242,117,202	$270,255,052	$286,018,792	$299,438,447
CDER		$814,107,273	$782,635,425	$881,775,355	$915,783,660	$955,429,408	$996,697,448
CDRH		$4,372,971	$2,647,796	$3,682,045	$4,874,791	$5,075,471	$5,284,413
ORA		$9,482,846	$8,090,718	$10,181,990	$10,601,152	$11,037,570	$11,491,953
HQ		$63,855,459	$62,835,758	$54,610,302	$54,772,115	$56,916,838	$57,771,651
Total Rent	Note 6	$59,306,768	$48,137,237	$28,672,907	$28,959,636	$29,249,233	$29,541,725
Total Shared Services	Note 7	$143,517,124	$151,544,388	$167,461,315	$175,931,410	$183,718,556	$191,428,874
Total Obligations		**$1,304,388,539**	**$1,251,442,752**	**$1,388,501,116**	**$1,461,177,816**	**$1,527,445,868**	**$1,591,654,511**

All numbers have been rounded to the nearest dollar.

Total obligations include payroll and operating, rent, and shared services costs funded by PDUFA fee funds. Non-user fee funds supporting the PDUFA program are not included here. The details of each component of total obligations are as follows:

- **Payroll and Operating:** These obligations provide for all payroll and operating costs that support the allowable activities for which PDUFA fees may be expended, as set forth in the statute. Such payroll and operating activities include, for example, core regulatory review functions, pre-approval inspections, guidance and policy development activities, scientific activities, and management and administrative functions that support the PDUFA program. **Note 5** provides additional information regarding payroll and operating costs for the PDUFA program.

[6] Current FY 2024 collections are trending to be above the target revenue amount.

Payroll and operating are presented by each major organizational component relevant to the PDUFA program.

- **Rent:** This amount is paid to General Services Administration for federal buildings that FDA occupies, as well as to non-federal sources for direct leases and services (see **Note 6**). Rental rates vary based on the type and location of the space provided.

  Section 736(f)(3) of the FD&C Act provides that "beginning on October 1, 2023, the authorities under section 735(7)(C) shall include only leasing and necessary scientific equipment." The impact of the change means that certain costs related to facilities, fixtures, furniture, materials, and supplies are no longer funded by PDUFA user fee funds.

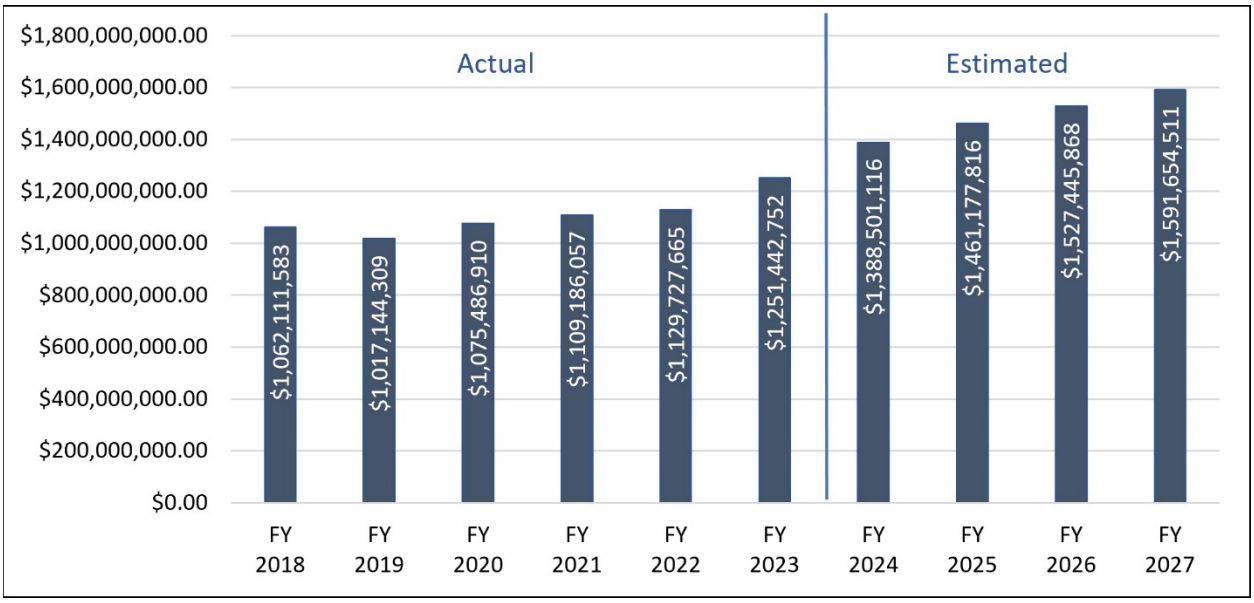
  The rent cost beginning in FY 2024 is adjusted for inflation using a flat inflation amount of 1 percent, which reflects recent trends in the FDA's rent cost. The reduction in user-fee funded costs due to the statutory change resulted in a lower FY 2024 rent cost than FY 2023.

- **Shared Services:** FDA has several shared services organizations that provide support across the user fee programs, such as human resources and information technology (IT). Shared services are located within the Working Capital Fund (WCF). **Note 7** provides a full list of what is contained in the WCF.

  FY 2024 Shared Service amounts use the inflation adjustment amount of 3.8896 percent, in addition to some one-time adjustments. All years also include small, proportionate increases to support the growth of the program.

Rent and Shared Services projections are informed by prior year actuals. Yearly costs are determined by the Cost Allocation and Recovery framework discussed previously. As stated in **Section H**, payroll and operating projections for future year amounts are assumed to have an increase of 4.1167 percent, which is currently the most recent inflation estimate available for FY 2025. **Exhibit 3** below provides an illustration of historical PDUFA VI obligations and projected PDUFA VII needs.

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



PDUFA VII obligations are expected to continue to grow to deliver on PDUFA VII enhancements. This growth is expected to be driven by the addition of new personnel costs, as well as inflationary pressures. This growth is primarily expected in the medical product Centers (CDER and CBER) as demonstrated in **Table 5** above.

J. User Fee Carryover

PDUFA fees collected, appropriated, and not obligated at the end of the fiscal year remain available to support the PDUFA program in future fiscal years.

Maintaining an appropriate level of carryover enables FDA to mitigate financial risks to the program, including, for example, the risk of under collecting fees and the risk of a lapse in appropriations, so that FDA can continue performing activities related to the process for the review of human drug applications under such financial constraints. FDA may set aside available user fee funds in the carryover for certain purposes, including, for example, for processing future year refunds.

The net change in PDUFA carryover each year is equal to net collections minus net obligations. This is demonstrated best in **Table 1c**.

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

Table 6: PDUFA Carryover by Fiscal Year

Carryover	Notes	FY2023 Estimate	FY2023 Actual	FY2024 Estimate	FY2025 Estimate	FY2026 Estimate	FY2027 Estimate
Total Carryover, End of Year		**$305,600,285**	**$275,515,520**	**$351,685,404**	**$375,284,588**	**$402,087,721**	**$433,463,210**
Unappropriated Amounts	Note 11	($78,850,995)	($78,850,995)	($78,850,995)	($78,850,995)	($78,850,995)	($78,850,995)
Total Available Carryover, End of Year		**$226,749,290**	**$196,664,525**	**$272,834,409**	**$296,433,593**	**$323,236,726**	**$354,612,215**
Future Year Refunds Allowance, Set Aside	Note 12	($20,000,000)	($20,000,000)	($25,229,000)	($25,229,000)	($25,229,000)	($25,229,000)
Carryover Net of Unavailable and Set Aside, End of Year		**$206,749,290**	**$176,664,525**	**$247,605,409**	**$271,204,593**	**$298,007,726**	**$329,383,215**

All numbers have been rounded to the nearest dollar.

These terms are defined below:

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

- **Unappropriated Amounts:** The PDUFA carryover includes $78,850,995 in fee collections that are considered unappropriated and therefore are currently unavailable for obligation. This amount is the cumulative total of fee collections that exceeded the annual level of PDUFA fees appropriated for a given year, prior to a technical fix that was added to the appropriations language to ensure that all fee collections would be considered appropriated. See **Note 11** for additional details.

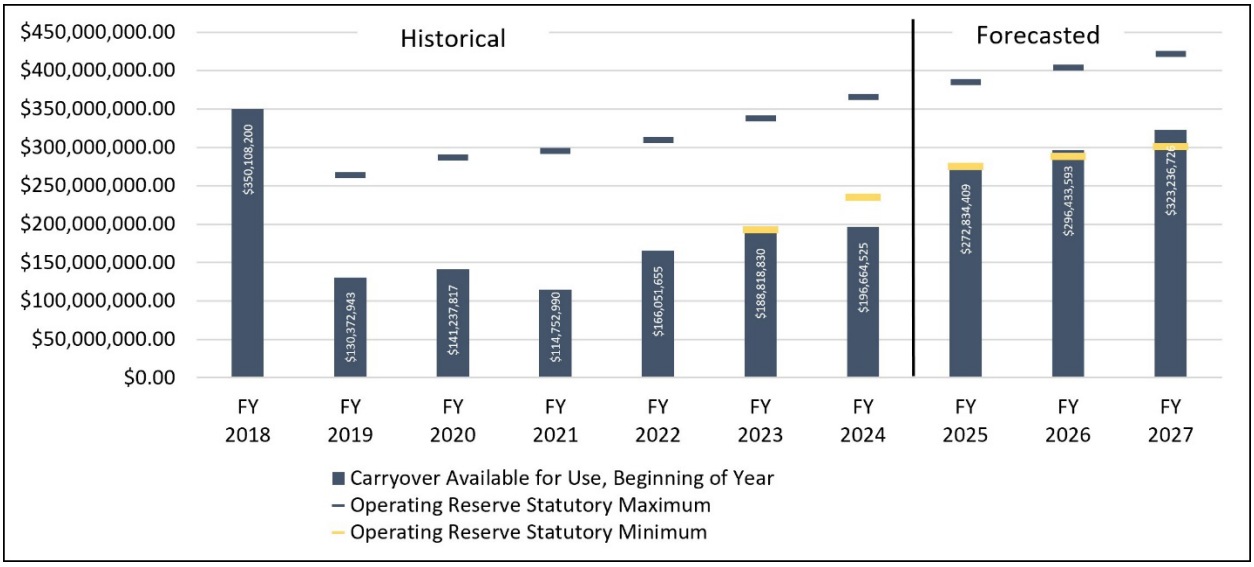
- **Total Available Carryover, End of Year**: This is the difference between the Total Carryover and the Unappropriated Amounts; this number is used in assessing the operating reserve adjustment.

- **Future Year Refunds Allowance, Set Aside:** FDA maintains a small amount to provide for any refunds, as a matter of prudent operations. In FY 2023 and prior FDA had used a flat amount for the set-aside allowance. In FY 2024 FDA estimated future year refund set-asides using a three-year average of actual refunds from the most recently completed prior fiscal years. This change was made for future years due to the uncertain nature of refunds, which could impact total year-end carryover. The estimated amount is $25,229,000 in fee funds that are available for obligation is being set aside annually. See **Note 12** for additional details.

- **Carryover Net of Unavailable and Set Aside, End of Year:** This is the total carryover less any carryover funds subject to set asides, or subject to any restrictions that currently preclude FDA from obligating the carryover funds.

Exhibit 4 below shows the historic trend of carryover in PDUFA and the forecasted carryover for the remainder of PDUFA VII.

Exhibit 4: Historical and Forecasted Carryover by Fiscal Year



Looking forward into PDUFA VII, the operating reserve adjustment will be a mitigation tool to ensure carryover remains within the minimum and maximum threshold.

The annual setting of fees for each fiscal year occurs at least three months prior to the fiscal year's end. For the FY 2024 PDUFA fee setting, FDA underestimated projected obligations, leading to an overestimation of available carryover for the operating reserve (see **Note 9**).

For FY 2025, FDA is not currently projecting that an operating reserve adjustment is needed to meet the statutory ten-week minimum amount. This amount may change when fees are set for FY 2025 based on more updated information on FY 2024 obligations and collections. The operating reserves for FY 2026 and FY 2027 are currently expected to be maintained within the minimum and maximum amount. Should that change, however, an operating reserve adjustment will be applied. See **Table 7** below.

Table 7: Operating Reserve Estimates by Fiscal Year

Operating Reserve	FY2023 Actual	FY2024 Actual	FY2025 Estimate	FY2026 Estimate	FY2027 Estimate
Operating Reserve Statutory Minimum(Weeks)	8	9	10	10	10
Operating Reserve Statutory Minimum($)	$193,360,675	$235,170,752	$275,548,994	$288,597,300	$301,500,027
Total Available Carryover, Beginning of Year	**$208,818,830**	**$196,664,525**	**$272,834,409**	**$296,433,593**	**$323,236,726**
Operating Reserve Statutory Maximum($)	$338,381,181	$365,821,170	$385,768,591	$404,036,220	$422,100,038

K. Non-User Fee Appropriations

For FDA to obligate user fees collected under PDUFA, a certain amount of non-user fee appropriations must be spent on the process for the review of human drug applications during that fiscal year. This is often referred to as a “non-user fee spending

trigger". **Table 8** presents the forecasted non-user fee spending triggers for FY 2023 through FY 2027.

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

FY2023 Actual	FY2024 Actual	FY2025 Estimate	FY2026 Estimate	FY2027 Estimate
$258,521,975	$278,545,507	$287,573,564	$293,325,035	$299,191,536

The non-user fee spending trigger amount is determined by multiplying the base amount spent on the human drug review process in FY 1997 (i.e., $147,959,689) times the adjustment factor for the applicable fiscal year. See **Note 13** for more details on the adjustment factor.

As a result of section 905(b) of FDARA, starting in FY 2024, certain costs associated with the process for the review of human drug applications will be shifted from user fee spending to non-user fee appropriations spending. Due to amendments to section 736(g)(2) of the FD&C Act made by Food and Drug Omnibus Reform Act of 2022, non-user fee appropriations spending on the shifted costs will be counted towards the spending trigger. See **Note 6** for more information.

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

L. Planned Hiring

PDUFA VII provides for the hiring of 352 new positions to support the workload associated with initiatives established or expanded by PDUFA VII. **Table 9** presents the hiring targets for these new positions each fiscal year of PDUFA VII.

Table 9: Target New Hires by Organization for PDUFA VII

Organization	FY2023 Actual	FY2023 Estimate	FY2024 Estimate	FY2025 Estimate	FY2026 Estimate	FY2027 Estimate
CBER	109	132	71	29	15	4
CDER	41	77	67	15	0	0
Other FDA	1	1	0	0	0	0
Total Hires	151	210	138	44	15	4

M. Additional Reporting Requirements

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

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

   The percentage change in the average personnel compensation and benefits costs (PC&B) per full-time equivalent for the process for the review of human drug applications (the PDUFA program) was 5 percent from FY 2022 to FY 2023. This is shown in Table 10a below.

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

PDUFA PC&B Costs	FY 2022	FY 2023	Change from FY 2022 to FY 2023
Total Process PC&B	$944,663,251	$1,040,590,183	10%
Process FTEs	4,583	4,807	5%
Average Total PC&B cost per Process FTE	**$206,123**	**$216,474**	**5%**

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

Table 10b. Change in Average Total PC&B Cost per Full-Time Equivalent for FDA used in the PDUFA Inflation Adjustment for FY 2023[7]

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

The changes in the personnel compensation and benefits costs for the process for the review of human drug applications (Table 10a) that exceed the amounts provided by the personnel compensation and benefit portion of the inflation adjustment (Table 10b) equals 3.6%.

The actual average cost of a PDUFA FTE increased by 3.6% more in FY 2023 than the amount provided by the PC&B portion of the PDUFA inflation adjustment in FY 2023.

2. FDA's plan for managing costs related to strategic hiring and retention after the adjustment required by section 736(b)(1)(C) of the FD&C Act expires at the end of FY 2027.

   The strategic hiring and retention adjustment provides resources to cover the costs of retaining and hiring highly qualified scientific and technical staff for

[7] See table 1: https://www.federalregister.gov/documents/2022/10/07/2022-21968/prescription-drug-user-fee-rates-for-fiscal-year-2023

the process for the review of human drug applications. FDA will continue to monitor payroll costs in the PDUFA program and, if growth of those costs continues to exceed funding provided by the inflation adjustment, leverage all available tools to manage those costs.

Challenges, Risk, and Mitigation

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

- **Under-Executing Planned Spend:** Historically, PDUFA budgetary resources have been under-spent because of the uncertainty around the timing of revenue (user fee and non-user fee) availability, non-user fee spending trigger requirements, and difficulties with hiring. To minimize this risk, FDA continues to enhance its planning and execution around the hiring of new staff and contract actions.

- **Uncertainty of Non-User Fee Appropriations Levels:** It is difficult to predict the amount of non-user fee appropriations that will be approved by Congress, which creates financial planning challenges for the program since non-user fee fund levels are often uncertain for a good portion of the fiscal year. With Continuing Resolutions (CRs) becoming more prevalent, FDA has had to spend at or slightly below levels from the prior authorized fiscal year during the CR period, thus limiting its ability to spend the non-user fee appropriations from the onset.

- **Lapse in Non-User Fee Appropriations:** FDA cannot control this risk; however, PDUFA VII grants the authority to maintain up to 14 weeks of an operating reserve, which can be utilized to continue program operations in the event of a lapse in appropriations.

- **Under collecting and Over collecting Fees:** If FDA does not receive the estimated number of industry submissions, there may be an excess or deficit in collections relative to the targeted revenue. When FDA under collects user fees, it leverages its available operating reserves to maintain continuity in operations. When FDA over collects, the carryover may increase without additional planned expenditures being identified to obligate those funds. The operating reserve adjustment mitigates these risks in PDUFA VII. In addition,

FDA monitors collections throughout the fiscal year, and the UFFMC and other FDA senior leaders determine how to mitigate any instances when user fee revenue deviates from forecasted estimates.

- **Section 736(f)(3) (amended by section 905(b) of FDARA):** FDA cannot use user fees on certain previously allowable expenses. Section 736(f)(3) of the FD&C Act provides that "beginning on October 1, 2023, the authorities under section 735(7)(C) shall include only leasing and necessary scientific equipment." The impact of the change means that certain costs related to facilities, fixtures, furniture, materials, and supplies are no longer funded by PDUFA user fee funds. This change will have an impact on the finances of the program. FDA is monitoring the impacts to the program's funding.

Appendices

A. Allowable and Excluded Costs for the PDUFA Program

Section 735(6) of the FD&C Act defines in general terms, the activities that are included in the "process for the review of human drug applications." In summary, costs related to the following activities have been attributed to the "process for the review of human drug applications" under this definition:

Included Activities	
1.All investigational new drug review activities, including amendments 2.All review activities for new drug applications (NDAs) and biologic license applications (BLAs), including supplements and amendments 3.Regulation and policy development activities related to the review of human drug applications 4.Development of product standards for products subject to review and evaluation 5.Meetings between FDA and the sponsor of a covered application or supplement 6.Review of labeling prior to approval of a covered application or supplement and the review of the initial pre-launch advertising 7.Review of post-marketing studies and clinical trials that have been agreed to by sponsors as a condition for approval 8.Inspections of facilities undertaken as part of the review of pending applications or supplements 9.Lot release activities for covered biological	11.Monitoring of clinical and other research conducted in connection with the review of human drug applications 12.User Fee Act implementation activities 13.Research related to the human drug review process 14.Post-market safety activities with respect to drugs approved under human drug applications or supplements, including the following activities: collecting, developing, and reviewing safety information on approved drugs, including adverse event reports; developing and using improved adverse event data-collection systems, including information technology systems; developing and using improved analytical tools to assess potential safety problems, including access to external databases; implementing and enforcing section

products 10. Assay development and validation to ensure batch-to-batch consistency and reliability for covered biological products	505(o) (relating to post-approval studies and clinical trials and labeling changes) and section 505(p) (relating to risk evaluation and mitigation strategies); and carrying out section 505(k)(5) (relating to adverse event reports and post-market safety activities)

For FY 2023, section 735(7) of the FD&C Act defines the "costs of resources allocated for the process for the review of human drug applications" as the expenses incurred in connection with this process for the following:

Included Expenses
1.Officers and employees of FDA, contractors of FDA, advisory committees, and costs related to such officers, employees, committees, and contracts 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 4.Collecting user fees under section 736 of the FD&C Act and accounting for resources allocated for the review of human drug applications and supplements

The PDUFA program excludes costs related to the following:

Excluded Products	Excluded Activities
1.Generic drugs 2.Over-the-counter drugs not associated with an NDA or NDA supplement 3.Large-volume parenteral drug products approved before September 1, 1992 4.Certain allergenic extract products 5.Whole blood or a blood component for transfusion 6.In vitro diagnostic biologic products 7.Certain drugs derived from bovine blood 8.Biologic products for further manufacturing use 9.A drug that is not distributed commercially and is the subject of an application or supplement submitted by a State or Federal Government entity	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 5.Research unrelated to the human drug review process

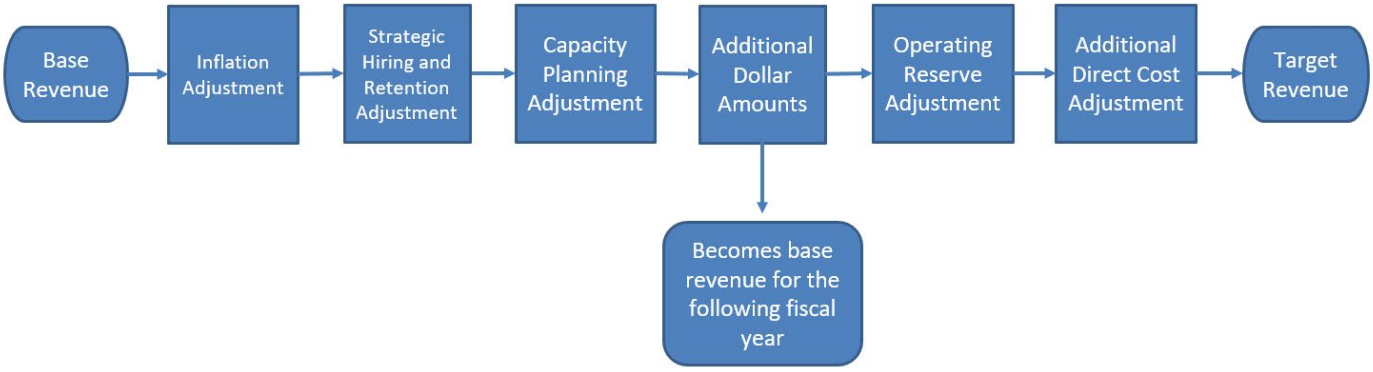
Section 736(f)(3) of the FD&C Act was amended by FDARA to limit the authorities of section 735(7)(C) to include only expenditures for leasing and necessary scientific equipment starting in FY 2024:

Included Expenses
1.Officers and employees of FDA, contractors of FDA, advisory committees, and costs related to such officers, employees, committees, and contracts 2.Management of information, and the acquisition, maintenance, and repair of computer resources 3.Leasing and necessary scientific equipment 4.Collecting user fees under section 736 of the FD&C Act and accounting for resources allocated for the review of human drug applications and supplements

B. Financial Notes

Note 1. Annual Target Revenue Methodology

Exhibit 5: PDUFA VII's Annual Target Revenue Methodology



Note 2. Inflation Adjustment

The inflation adjustment adjusts the base amount to maintain the purchasing power of fee funds in consideration of inflation. This adjustment is a composite measure that weights operating expenses by changes in the CPI and payroll-related expenses by changes in FDA's average personnel compensation and benefits amounts.

The inflation adjustment utilized in FY 2024 was 3.8896 percent. The inflation adjustment for FY 2025 is currently estimated to be 4.1167 percent. This is subject to change during the annual fee setting process.

Inflation estimates for future years shown in this five-year plan are set to match the most recent estimated inflation adjustment, which is currently FY 2025.

Inflation Rates:

- FY 2023: 1.6404 percent.
- FY 2024: 3.8896 percent.
- FY 2025: 4.1167 percent (estimated).
- FY 2026: 4.1167 percent (estimated).
- FY 2027: 4.1167 percent (estimated).

Note 3. Capacity Planning Adjustment

The capacity planning adjustment adjusts the annual target revenue amount to account for sustained increases in annual workload. This adjustment helps ensure that FDA is properly resourced to continue meeting its PDUFA performance goals.

Note 4. 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 5. Payroll and Operating Costs

Pay and operating costs associated with the PDUFA program are based on obligations attributed to CBER, CDER, CDRH, 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 PDUFA program. If an operating activity solely supports PDUFA, it will be fully funded by the program. If the operating activity is shared, PDUFA will fund the activity in proportion to how it is used by the program as compared to other programs.

Note 6. Rent Costs

The General Services Administration charges rent to FDA for the federal buildings that FDA occupies. This rent is charged at different rates depending on the type and location of the space provided. Because rent is an essential support cost for the process for the review of human drug applications, a portion of those charges is paid from non-user fee appropriations and a portion is paid from PDUFA 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 the rental of space and all recurring services for building operations such as overtime utilities, janitorial services, guards, and ground maintenance. The amount of rent and rent related costs each Center pays is directly related to the square footage occupied by that Center.

Section 905(b) of the FDA Reauthorization Act of 2017 (FDARA) amended the FD&C Act to provide that the types of fee-coverable costs under the PDUFA program, the Generic Drug User Fee Amendments program, the Medical Devices User Fee Amendments program, and the Biosimilar User Fee Act program will narrow on October 1, 2023.

Specifically, section 736(f)(3) of the FD&C Act was amended to limit the authorities of section 735(7)(C) to include only expenditures for leasing and necessary scientific equipment. The impact of the change means that certain costs related to facilities, equipment, materials, and supplies are no longer funded by PDUFA user fee funds.

Note 7. Shared Services Costs

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

- **FDA Central:** Provides for Center-wide and Agency-wide services such as telecommunications, training, printing, mail and document management, IT systems, employee health units, and other support and miscellaneous services.
- **Office of Digital Transformation**: Provides the vision and leadership in IT, data, and cybersecurity needed to advance FDA's mission and strategic priorities.
- **Office of Acquisitions and Grants Services:** Manages contracts, grants, and other agreements.
- **Office of Equal Employment Opportunity**: Promotes an inclusive work environment that ensures equal employment opportunity and fosters a culture that values diversity and empowers individuals.
- **Office of Facilities, Engineering, and Mission Support Services**: Provides FDA employees with office and laboratory facilities.
- **Office of Financial Management**: Provides financial managerial services and policy guidance.
- **Division of Budget Execution and Control**: Initiates, monitors, and analyzes FDA's budget resources.

- **Office of Finance, Budget, Acquisitions, and Planning**: Leads FDA's budget, acquisitions, and financial management functions while ensuring the financial integrity of FDA's resources.

- **Office of Security Operations**: Develops and implements the Agency-wide security policies and programs by providing leadership and guidance to managers and staff on all aspects of security. Administers vital security functions that contribute to the Agency's mission of protecting public health by enhancing the safety and security of all personnel, facilities, and information.

- **Office of Laboratory Safety**: Reinforces FDA's expectations for safety and laboratory security, enhances communications among FDA's safety staff, and provides program support.

- **Office of Ethics and Integrity:** Protects the integrity of FDA's programs and operations by promoting an ethical culture and ensuring compliance with applicable federal ethics laws.

- **Office of Enterprise Management Services:** Provides strategic and tactical enterprise-wide services through the development and implementation of administrative policies, programs, and initiatives.

- **Office of Human Capital Management:** Provides human resource services that promote collaboration and a work environment that is characterized by diversity, fairness, open communication, personal accountability, trust, and mutual respect.

- **Office of Talent Solutions:** Provides high quality and efficient human resource solutions that enable FDA to hire a talented and qualified workforce.

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

Note 8. Additional Dollar Amounts Adjustment

PDUFA VII specifies that additional direct costs be accounted for in target fee revenue amounts. Additional dollar amounts for each fiscal year are as follows:

- $65,773,693 for FY 2023.

- $25,097,671 for FY 2024.

- $14,154,169 for FY 2025.

- $4,864,860 for FY 2026.

- $1,314,620 for FY 2027.

Note 9. Operating Reserve Adjustment

PDUFA VII updates the operating reserve adjustment to provide for a defined minimum required amount of operating reserves. This requires FDA to increase the annual revenue amount used to set fees, if needed, to provide for the defined minimum required amount of operating reserves. To minimize impact on fee amounts from large changes in any year, this defined minimum amount is phased in: 8 weeks of available operating reserves in FY 2023, 9 weeks of available operating reserves in FY 2024, and 10 weeks of available operating reserves in FY 2025 and subsequent fiscal years. The statute also establishes a cap of 14 weeks of operating reserves of carryover user fees that can be maintained at the end of each fiscal year. Should FDA make an operating reserve adjustment, either up or down, FDA must explain its rationale in the annual PDUFA fee-setting Federal Register Notice.

To determine the dollar amounts for the 9-week and 14-week operating reserve thresholds for FY 2024, certain adjustments (inflation, strategic hiring and retention, capacity planning, and additional dollar amount) are applied to the FY 2024 base revenue resulting in $1,358,764,346. This amount is then divided by 52 to generate the 1-week operating amount of $26,130,083. The one-week operating amount is then multiplied by 9 and 14. This results in a 9-week threshold amount of $235,170,752 and a 14-week threshold amount of $365,821,170.

To determine the FY 2023 end-of-year operating reserves of carryover user fees, the Agency assessed the operating reserve of carryover fees at the end of July 2023 and forecast collections and obligations in the fourth quarter of FY 2023 combined. During this exercise the Agency underestimated the fourth quarter obligations by $94,899,220. This resulted in an estimated end-of-year FY 2023 operating reserve of carryover user fees, or $321,648,510, which equates to 12.3 weeks of operating reserves. Therefore, FDA didn’t increase the annual revenue amount used to set fees.

Had the correct fourth quarter obligations estimate been used, the estimated FY2023 end-of-year reserve of carryover calculation would have been $206,749,290, which equated to 7.9 weeks of operating reserve, which would be below the 9-week threshold and would have required an upward operating reserve adjustment.

Note 10. Additional Direct Cost Adjustment

PDUFA VII provides for an additional direct cost adjustment each year in PDUFA VII starting with FY 2023. For FY 2024 and forward, these amounts are adjusted for inflation.

- $44,386,150 for FY 2023.
- $60,967,993 for FY 2024.
- $35,799,314 for FY 2025.
- $35,799,314 for FY 2026.

- $35,799,314 for FY 2027.

The inflated values are:

- $44,386,150 for FY 2023.
- $63,339,404 for FY 2024.
- $39,355,553 (estimated) for FY 2025.
- $40,975,704 (estimated) for FY 2026.
- $42,662,550 (estimated) for FY 2027.

Note 11. Unappropriated Amounts

The unappropriated amount is the amount that FDA collected in user fees in excess of the amount specified in appropriation acts prior to FY 2010. FDA's ability to access and obligate these collections remains uncertain. **Table 10** outlines the excess user fees by fiscal year.

Table 11: Prescription Drug User Fees Collected, Collection Amounts Specified in Appropriation Acts, and Excess Amounts as of September 30, 2023

Fiscal Year	Collections Realized	Collection Amount Specified In Appropriation Acts	Amount In Excess Of Collection Amount Specified In Appropriation Acts
1998	$117,849,016	$117,122,000	$727,016
2004	$258,560,500	$249,825,000	$8,735,500
2005	$287,178,231	$284,394,000	$2,784,231
2006	$313,541,278	$305,332,000	$8,209,278
2007	$370,610,684	$352,200,000	$18,410,684
2008	$478,184,756	$459,412,000	$18,772,756
2009	$531,876,530	$510,665,000	$21,211,530
Total	**N/A**	**N/A**	**$78,850,995**

Note 12. Future Year Refunds Allowance, Set Aside

If an application is withdrawn after it is filed, FDA may refund the fee or a portion of the fee if no substantial work was performed on the application after the application was withdrawn. If an application is refused to file or withdrawn before it is filed, FDA refunds 75 percent of the fee. Additionally, if firms are granted waivers, exemptions, or refunds for program fees, FDA may refund fees that were already paid by the firm.

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

Table 12: Prescription Drug User Fees Estimated Future Year Refunds Allowance, Set Aside

Estimated Refunds Set aside	FY 2021	FY 2022	FY2023	3-Year Average
Actual Refunds	$14,608,529.88	$17,860,164.50	$43,218,203.25	$25,228,965.88

Note 13. Minimum Non-User Fee Appropriations Adjustment Factor

FDA must calculate and incorporate adjustment factors (defined in section 735(8) of the FD&C Act as amended). The FD&C Act states, "the term 'adjustment factor' applicable to a fiscal year is the Consumer Price Index for all urban consumers (all items, United States city average) for October of the preceding fiscal year divided by such Index for October 1996."

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