Five-Year Financial Plan

Five Years
2023-2024-2025-2026-2027
FY 2026 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 the PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2023 Through 2027 (PDUFA VII Commitment Letter),[1] Title II, Section B, FDA published a PDUFA five-year financial plan in the second quarter of fiscal year (FY) 2023. FDA will publish updates to the five-year financial plan no later than the second quarter of each subsequent fiscal year. The purpose of this document is to meet these commitments.

C. Updates to the Five-Year Plan

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

[1] The PDUFA VII Commitment Letter: https://www.fda.gov/media/151712/download?attachment.

D. Organization Background

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

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

Exhibit 1: User Fee Program Components

Component	Mission
CDER	Protects and promotes public health by helping to ensure that human drugs are safe and effective, meet established quality standards, and are available to patients.
CBER	Protects and advances the public health by helping to ensure that biological products are safe, effective, and are available to patients.
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.
OII	Conducts rigorous, transparent, and science-based inspections and investigations, providing real-time evidence and insight essential in empowering fact-based regulatory decisions to protect public health.
HQ	Provides FDA-wide program direction and administrative services to ensure FDA's consumer and patient safety programs are effectively and efficiently managed.

User Fee Governance

Strong financial governance is needed because of the Agency's expanding level of user fees, the required reporting of FDA's performance commitments associated with these fees, and the need for FDA to convey how these user fee programs are executed. 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 program workload. The UFFMC advises the Executive Committee and other Center- and Office-level bodies on a variety of financial and performance-related topics.

Working Capital Fund/Cost Allocation

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

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

Internal Controls

The Department of Health and Human Services (HHS) provides guidance to its operating divisions (OpDivs) to implement The Federal Managers' Financial Integrity Act of 1982 (FMFIA) through its FMFIA Guidelines, which is intended to strengthen internal controls and accounting systems. OpDivs, including FDA, are responsible for developing and maintaining internal control and compliance programs that include programmatic and operational controls, as well as reporting controls to support sound financial management.

E. User Fee Background and Structure

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

PDUFA was enacted in 1992 and 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 included the seventh authorization of PDUFA, also known as PDUFA VII, which amended and authorizes continued funding for FDA from FY 2023 through FY 2027 to continue to build upon the successes of the existing review program and its performance goals while implementing enhancements as committed to under the PDUFA VII Commitment Letter. PDUFA has delivered 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 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.

Exhibit 2 outlines the PDUFA VII fee structure.

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 New Drug Application (NDA) or Biologics License Application (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.[2]

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.[3]

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

The PDUFA VII Commitment Letter continues many commitments from PDUFA VI and introduced additional enhancements to the program. PDUFA VII also made 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 continuing implementation of 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 Enhancements in PDUFA VII

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

The funding supports enhancements to:

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

- Regulatory science activities including 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 included changes to fee-setting mechanisms to provide predictable funding for the program and enhance flexibilities to sustain operations. Some of the changes included:

- 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 is added to the base revenue each fiscal year.

- Updating of the PDUFA Capacity Planning Adjustment (CPA), which is a mechanism to ensure that FDA is able to manage the resources needed for sustained increases in review workload submitted by sponsors, to clarify the workload categories used in the forecasting methodology. These workload categories will include only the activities described in the 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, 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 was 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).

Over the remainder of PDUFA VII, FDA will continue managing these changes to the fee-setting mechanisms to help FDA maintain a world-class workforce, manage sustained increases in workload, and mitigate financial risks to the 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 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 remainder of PDUFA VII, FDA will continue to build on the financial management enhancements achieved in PDUFA VI. 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,[4] hiring an independent contractor to evaluate 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.

- Convening a public meeting[5] 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 remainder of PDUFA VII, FDA will continue to promote transparency of the use of financial resources in support of the PDUFA program.

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

Financial Information

This section provides 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.

Table 1a: Prescription Drug User Fee Budgetary Resources for FY 2023 through FY 2027

Budgetary Resources	FY2023 Actual	FY2024 Actual	FY2025 Estimate	FY2025 Actual	FY2026 Estimate	FY2027 Estimate
Total Carryover, Beginning of Year	$287,669,825	$275,515,520	$297,371,048	$297,371,048	$413,940,928	$619,012,442
Net Collections	$1,222,888,088	$1,381,243,203	$1,464,056,921	$1,457,945,602	$1,556,038,000	$1,633,772,000
Recoveries	$16,400,359	$17,785,244	$15,847,000	$18,301,186	$17,496,000	$17,496,000
Total Budgetary Resources	**$1,526,958,272**	**$1,674,543,967**	**$1,777,274,969**	**$1,773,617,836**	**$1,987,474,928**	**$2,270,280,442**

Table 1b: Prescription Drug User Fee Obligations for FY 2023 through FY 2027

Obligations	FY2023 Actual	FY2024 Actual	FY2025 Estimate	FY2025 Actual	FY2026 Estimate	FY2027 Estimate
Total Payroll	$813,591,182	$918,155,812	$966,967,735	$971,766,208	$910,030,649	$981,086,117
Total Operating	$238,169,945	$253,766,997	$227,668,663	$167,917,959	$229,931,374	$245,680,829
Total Rent	$48,137,237	$28,672,907	$31,793,381	$28,103,457	$34,053,116	$36,468,304
Total Shared Services	$151,544,388	$176,577,203	$172,371,010	$191,889,284	$212,189,804	$221,997,557
Total Obligations	**$1,251,442,752**	**$1,377,172,919**	**$1,398,800,789**	**$1,359,676,908**	**$1,386,204,943**	**$1,485,232,807**

Table 1c: Prescription Drug User Fee Carryover for FY 2023 through FY 2027

Carryover	FY2023 Actual	FY2024 Actual	FY2025 Estimate	FY2025 Actual	FY2026 Estimate	FY2027 Estimate
Total Carryover, End of Year	$275,515,520	$297,371,048	$378,474,180	$413,940,928	$601,269,985	$767,305,178
Unappropriated Amounts	($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)	($25,229,000)	($29,781,000)	($29,781,000)	($26,545,000)	($26,545,000)
Carryover Net of Unavailable and Set Aside, End of Year	**$176,664,525**	**$193,291,053**	**$269,842,185**	**$305,308,933**	**$495,873,990**	**$661,909,183**

Budgetary Resources: Total Budgetary Resources is the total user fee funding (i.e., the existing total carryover, user fee collections, and recoveries). Net Collections are the amounts collected during the fiscal year, net of refunds that have taken place.

Recoveries account for funds de-obligated from prior year obligations. For example, recoveries could include funding from a contract that ended in a prior year and was not expended. See **Section H** for more detail on budgetary resources.

Obligations: Total Obligations is the annual expenditure of PDUFA fee funds broken out by 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 the FD&C Act. For more information on the allowable and excluded costs and activities, see **Appendix A**. See **Section I** for more details on obligations.

Carryover: 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." See **Section J** for more details on carryover.

H. Budgetary Resources

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

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

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

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

Budgetary Resources	FY2023 Actual	FY2024 Actual	FY2025 Actual	FY2026 Actual	FY2027 Estimate
Annual Base Revenue	$1,151,522,958	$1,256,844,387	$1,358,764,346	$1,434,377,467	$1,515,410,160
Inflation Adjustment	$18,889,583	$48,886,219	$55,936,252	$72,167,833	$71,542,514
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	$1,522,700	$0	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	$5,007,412	$0	TBD
Additional Direct Cost Adjustment	$44,386,150	$63,339,404	$39,355,553	$40,627,674	$41,505,100
Target Revenue Total (Rounded)	**$1,310,319,000**	**$1,422,104,000**	**$1,478,740,000**	**$1,556,038,000**	**$1,633,772,000**

Annual Base Revenue Amount: The base amount for FY 2023 is specified in the statute. The statute also specifies that the base amount for fiscal years 2024 through 2027 is the target revenue from the prior fiscal year, not including any operating reserve or additional direct cost adjustment from the prior year.

Inflation Adjustment: The inflation adjustment adjusts the base amount to maintain the purchasing power of fee funds in consideration of inflation. The adjustment under

the statute is a composite measure that adjusts operating expenses by changes in the Consumer Price Index (CPI) and payroll-related expenses by changes in FDA's average personnel compensation and benefits amounts. The inflation adjustments for future years are projected using the most recent fiscal year percent increase. See **Appendix B.1.** for details on inflation adjustment rates.

The inflation adjustment utilized in FY 2026 was 5.0313 percent.

Strategic Hiring and Retention Adjustment: The strategic hiring and retention adjustment increases the inflation-adjusted base amount to cover the costs of hiring and retaining highly qualified scientific and technical staff for the process for the review of human drug applications. The amounts for each year are specified in statute.

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: The CPA, known prior to PDUFA VI as the workload adjustment, adjusts the annual target revenue amount to account for sustained increases in regulatory submissions. This adjustment helps ensure that FDA can expand its review capacity to meet additional workload demands.

No capacity planning adjustment was made in the setting of FY 2026 fees.

The intent of the CPA is to enable annual adjustments, if needed, to ensure that the Agency is appropriately resourced to be able to address sustained increases in the forecasted amount of direct review work. The CPA is a structured process utilizing validated forecast models trained with the most recently available data and includes managerial decision points.[6] 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.

[6] 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.

Additional Dollar Amounts: PDUFA VII provides for the hiring of 352 new positions to support the workload associated with initiatives established or expanded by PDUFA VII. These 352 new positions are scheduled to be hired over the 5 fiscal years of PDUFA VII. The dollar amounts for the new positions committed to being hired each year are specified in the statute. See **Section L** for more details on 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 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 **Appendix B.3**.

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. For more information, see **Appendix B.5**.

In FY 2026, FDA did not apply an operating reserve adjustment because estimated FY 2025 end-of-year operating reserves were projected to be above the ten-week minimum and below the 14-week maximum. FDA does not maintain expectations for future year operating reserve adjustment amounts as these are dependent on uncertain collections, shifting industry activity, and obligations. As such, FDA will not utilize placeholder estimates for the purposes of the financial plan. The actual operating reserve adjustment amounts will be updated each year.

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

Additional Direct Cost Adjustment: Additional direct costs provide for certain non-payroll costs associated with PDUFA VII initiatives. 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. For more information, see **Appendix B.4.**

Target Revenue Total: This is the summation of the base revenue and the adjustments described above, rounded to the nearest thousand dollars. This is the amount that is intended to be collected in fees for the respective fiscal year and serves as the basis for setting the fee amounts. Eighty percent of this amount is allocated to be collected from program fees; twenty percent of this amount is allocated to be collected from application fees.

FDA does not automatically receive the target revenue amount. Fees are collected throughout the fiscal year and the actual amount of fee dollars collected will vary from the target revenue based on the number of fees paid in any given year.

Collections

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

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

Budgetary Resources	FY2023 Actual	FY2024 Actual	FY2025 Estimate	FY2025 Actual	FY2026 Estimate	FY2027 Estimate
Target Revenue Total (Rounded)	**$1,310,319,000**	**$1,422,104,000**	**$1,478,740,000**	**$1,478,740,000**	**$1,556,038,000**	**$1,633,772,000**
Total Carryover, Beginning of Year	$287,669,825	$275,515,520	$297,371,048	$297,371,048	$413,940,928	$601,269,985
Net Collections (Rounded)	$1,222,888,088	$1,381,243,203	$1,464,056,921	$1,457,945,602	$1,556,038,000	$1,633,772,000
Recoveries	$16,400,359	$17,785,244	$15,847,000	$18,301,186	$17,496,000	$17,496,000
Total Budgetary Resources	**$1,526,958,272**	**$1,674,543,967**	**$1,777,274,969**	**$1,773,617,836**	**$1,987,474,928**	**$2,252,537,985**

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: Although the amount of actual collections varies, FDA generally assumes, for planning purposes, that net collections will equal the target revenue amount. Net collections represent the total collections minus any refunds that occurred during the fiscal year, regardless of the year the fee was due. In practice, net collections may differ from the annual target revenue amount if the actual number of fee-paying units differ from the number of fee-paying units estimated when fees are set each year.

Recoveries: For the purposes of this plan, future year recoveries are estimated using a three-year average of actual recoveries from the most recently completed prior fiscal years. Recoveries vary from year to year and the result could be either higher or lower than the current estimate. FDA estimates recoveries to be $17,496,000 annually.

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 Actuals	Cohort Year 2024 Actuals	Cohort Year 2025 Estimate	Cohort Year 2025 Actuals	Cohort Year 2026 Estimate
Application Fees	$160,480,287	$214,074,761	$295,748,000	$293,080,106	$311,207,600
Program Fees	$1,101,002,208	$1,206,252,332	$1,182,992,000	$1,123,363,630	$1,244,830,400
Total Cohort Collections	**$1,261,482,495**	**$1,420,327,093**	**$1,478,740,000**	**$1,416,443,736**	**$1,556,038,000**

Cohort Year Collections: User fee collections are generally recognized and reported in the year that the fee was originally due (referred to as the "cohort year").[7] Totals reported are after any refunds for the cohort year. To ensure the quality of the information provided in this financial plan, FDA annually updates prior years' numbers to account for any new collections or refunds.

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

I. User Fee Obligations

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.

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

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

User Fee Obligations	FY2023 Actual	FY2024 Actual	FY2025 Estimate	FY2025 Actual	FY2026 Estimate	FY2027 Estimate
Payroll	**$813,591,182**	**$918,155,812**	**$966,967,735**	**$971,766,208**	**$910,030,649**	**$981,086,117**
CBER	$135,448,033	$159,563,624	$186,755,561	$185,178,088	$174,242,674	$190,092,588
CDER	$626,848,682	$711,497,874	$736,875,971	$740,906,189	$699,140,462	$752,914,836
CDRH	$2,646,738	$3,058,788	$2,321,151	$3,327,963	$2,097,367	$2,196,384
OII	$6,898,327	$7,653,639	$6,827,890	$7,682,014	$8,285,121	$8,676,262
HQ	$41,749,402	$36,381,887	$34,187,162	$34,671,954	$26,265,025	$27,206,047
Operating	**$238,169,945**	**$253,766,997**	**$227,668,663**	**$167,917,959**	**$229,931,374**	**$245,680,829**
CBER	$60,103,396	$73,196,127	$56,315,484	$42,164,463	$48,918,147	$59,225,500
CDER	$155,786,743	$160,904,091	$152,223,862	$106,538,311	$158,782,336	$164,267,292
CDRH	$1,058	$0	$1,339,733	$0	$116,846	$123,626
OII	$1,192,391	$1,419,359	$2,212,849	$1,187,684	$1,138,294	$1,194,864
HQ	$21,086,357	$18,247,420	$15,576,735	$18,027,501	$20,975,751	$20,869,547
Total Rent	**$48,137,237**	**$28,672,907**	**$31,793,381**	**$28,103,457**	**$34,053,116**	**$36,468,304**
Total Shared Services	**$151,544,388**	**$176,577,203**	**$172,371,010**	**$191,889,284**	**$212,189,804**	**$221,997,557**
Total Obligations	**$1,251,442,752**	**$1,377,172,919**	**$1,398,800,789**	**$1,359,676,908**	**$1,386,204,943**	**$1,485,232,807**

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 certain payroll and operating costs for which PDUFA fees may be expended to support the process for the review of human drug applications, as defined in the statute. These allowable activities include, for example, core regulatory review functions, pre-approval inspections, guidance and policy development activities, scientific activities, and management and administrative functions that support the PDUFA program. See **Appendix A** for a listing of those activities. The payroll and operating costs associated with the PDUFA program are based on obligations attributed to CBER, CDER, CDRH, OII, and HQ.

  Center employees are required to report their time in an activity-based reporting system. This allows FDA to ensure that user fee funds are only supporting payroll proportional to the time invested in allowable activities.

  For operating activities (e.g., certain contracting services), user fee funds are allocated based on the proportion to which those activities support human drug activities. If an operating activity solely supports the process for the review of human drug applications, it can be fully funded by PDUFA fees (and/or non-user fee appropriations). If the operating activity supports multiple user fee programs, PDUFA fees may fund the activity up to the appropriate proportion of the benefit from such activity that accrues to human drug activities.

- **Rent Costs:** The General Services Administration charges rent to FDA for the federal buildings that FDA occupies. This rent is charged at different rates depending on the type and location of the space provided. Since rent is an allowable support cost for the process for the review of human drug applications, a portion of those charges is paid from non-user fee appropriations and a portion is paid from PDUFA fees.

  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.

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

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

Future PDUFA VII obligations will reflect the cost of new personnel hired to deliver on negotiated enhancements and the effects of inflation.

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 PDUFA 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, to the extent of available carryover. FDA may set aside available user fee funds in the carryover for certain purposes, including, for example, for processing future year refunds.

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

Table 6 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.

Table 6: PDUFA Carryover by Fiscal Year

Carryover	FY2023 Actual	FY2024 Actual	FY2025 Estimate	FY2025 Actual	FY2026 Estimate	FY2027 Estimate
Total Carryover, End of Year	**$275,515,520**	**$297,371,048**	**$378,474,180**	**$413,940,928**	**$601,269,985**	**$767,305,178**
Unappropriated Amounts	($78,850,995)	($78,850,995)	($78,850,995)	($78,850,995)	($78,850,995)	($78,850,995)
Total Available Carryover, End of Year	**$196,664,525**	**$218,520,053**	**$299,623,185**	**$335,089,933**	**$522,418,990**	**$688,454,183**
Future Year Refunds Allowance, Set Aside	($20,000,000)	($25,229,000)	($29,781,000)	($25,229,000)	($26,545,000)	($26,545,000)
Carryover Net of Unavailable and Set Aside, End of Year	**$176,664,525**	**$193,291,053**	**$269,842,185**	**$309,860,933**	**$495,873,990**	**$661,909,183**

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 **Appendix B.5.** 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. Starting in FY 2024 FDA estimated future year refund set-asides using a three-year average of actual refunds from the most recently completed prior fiscal years. This change was made for future years due to the uncertain nature of refunds, which could impact total year-end carryover. The FY 2026 and FY 2027 estimated amount is $26,545,000 in fee funds that are available for obligation being set aside annually. The actual refunds in the table above represent how much was set aside, not how much was actually refunded. For actual refunds, see the financial report. See **Appendix B.6.** 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.

Looking forward into the remainder of PDUFA VII, the operating reserve adjustment will be used, as needed, to ensure carryover remains between the minimum and maximum levels specified by statute. FDA will monitor the operating reserve levels and will apply the operating reserve adjustment, as needed, when setting PDUFA fees. Current

estimates indicate the total carryover at the end of FY 2026 will exceed the operating reserve decrease threshold. This will be assessed with the latest numbers at the time FY 2027 fees are set.

See **Table 7** below for the operating reserve threshold amounts and see **Appendix B.3.** for further details.

Table 7: Operating Reserve Estimates by Fiscal Year

Operating Reserve	FY2023 Actual	FY2024 Actual	FY2025 Actual	FY2026 Actual	FY2027 Estimate
Operating Reserve Statutory Minimum (Weeks)	8	9	10	10	10
Operating Reserve Statutory Minimum ($)	$193,360,675	$235,170,752	$275,841,821	$291,425,031	$306,205,250
Total Carryover Available for Use, Beginning of Year	**$208,818,830**	**$196,664,525**	**$218,520,053**	**$335,089,933**	**$522,418,990**
Operating Reserve Statutory Maximum (Weeks)	14	14	14	14	14
Operating Reserve Statutory Maximum ($)	$338,381,181	$365,821,170	$386,178,549	$407,995,043	$428,687,350

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 actual and 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 Actual	FY2026 Actual	FY2027 Actual
$258,521,975	$278,545,507	$287,573,564	$295,044,492	$303,266,908

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

The FD&C Act states (defined in section 735(8), "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."

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

FDA is committed to spending 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 ensure that the allocation of non-user fee appropriations for drug review meets the requirements of this trigger, under amendments made by the Food and Drug Omnibus Reform Act of 2022.

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 Commitments

Organization	FY2023 Actual	FY2024 Actual	FY2025 Estimate	FY2025 Actual	FY2026 Estimate	FY2027 Estimate
CBER	109	51	49	9	55	4
CDER	41	49	33	15	18	0
Other FDA	1	0	0	0	0	0
Total Hires	151	100	82	24	73	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 4 percent (rounded) from FY 2024 to FY 2025. This is shown in **Table 10a** below.

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

PDUFA PC&B Costs	FY 2024	FY 2025	Change from FY 2024 to FY 2025
Total Process PC&B	$1,139,962,844	$1,219,030,828	6.94%
Process FTEs	5,013	5,151	2.75%
Average Total PC&B cost per Process FTE	**$227,401**	**$236,659**	**4.07%**

   The change in the amounts provided by the PC&B portions of the inflation adjustment for FY 2025 is 3.85 percent. 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 2025[8]

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

The changes in the personnel compensation and benefits costs for the process for the review of human drug applications (**Table 10a**) that exceed the amounts provided by the personnel compensation and benefit portion of the inflation adjustment (**Table 10b**) equals 0.22 percent.

The actual average cost of a PDUFA FTE increased by 0.22 percent more in FY 2025 than the amount provided by the PC&B portion of the PDUFA inflation adjustment in FY 2025.

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 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.

[8] See table 1: https://www.federalregister.gov/documents/2024/07/31/2024-16875/prescription-drug-user-fee-rates-for-fiscal-year-2025.

Challenges, Risk, and Mitigation

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

- **Under-Executing Planned Spend:** Historically, 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 target revenue. When FDA under collects user fees, it leverages its available operating reserves of carryover to maintain continuity in operations. When FDA over collects, the carryover may increase without additional planned expenditures being identified to obligate those funds. The operating reserve adjustment mitigates these risks in 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.

Appendices

A. Allowable and Excluded Costs and Activities 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 the FD&C Act's definition.

Exhibit 3: Included Activities

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 products
10. Assay development and validation to ensure batch-to-batch consistency and reliability for covered biological products
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

Included Activities
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 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)

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:

Exhibit 4: Included Expenses

Included Expenses
• Officers and employees of FDA, contractors of FDA, advisory committees, and costs related to such officers, employees, committees, and contracts • Management of information, and the acquisition, maintenance, and repair of computer resources • Leasing and necessary scientific equipment[9] • 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 also excludes costs related to the following products and activities:

[9] Section 905(b) of the FDA Reauthorization Act of 2017 (FDARA) amended the FD&C Act to provide under section 736(f)(3) that beginning on October 1, 2023, the authorities under section 735(7)(C) shall include only expenditures for leasing and necessary scientific equipment. The referenced authorities had otherwise listed expenses for "leasing, maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, scientific equipment, and other necessary materials and supplies;"

Exhibit 5: Excluded Products and Activities

Excluded Products	Excluded Activities
• Generic drugs • Over-the-counter drugs not associated with an NDA or NDA supplement • Large-volume parenteral drug products approved before September 1, 1992 • Certain allergenic extract products • Whole blood or a blood component for transfusion • In vitro diagnostic biologic products • Certain drugs derived from bovine blood • Biological products for further manufacturing use only • A drug that is not distributed commercially and is the subject of an application or supplement submitted by a State or Federal Government entity	• Enforcement policy development not related to sections 505(o) and (p) of the FD&C Act • Post-approval compliance activities not related to the enforcement of sections 505(o) and (p) of the FD&C Act • Advertising review activities once marketing of the product has begun • Inspections unrelated to the review of covered applications, unless undertaken for the enforcement of sections 505(o) and (p) of the FD&C Act • Research unrelated to the human drug review process

B. Supplemental Financial Information

B.1. Inflation Adjustment

Inflation Adjustment Rates:

- FY 2023: 1.6404 percent.
- FY 2024: 3.8896 percent.
- FY 2025: 4.1167 percent.
- FY 2026: 5.0313 percent.
- FY 2027: 4.7210 percent.

B.2. Shared Services Costs

FDA has several shared service programs, supported by the WCF, that provide support for activities across the Agency. The shared service programs in FY 2026 include:

- **Office of Digital Transformation:** Provides the vision and leadership in IT, data, and cybersecurity needed to advance FDA's mission and strategic priorities.

- **Office of Equal Employment Opportunity:** Promotes a work environment that ensures equal employment opportunity and fosters a professional culture that values and empowers individuals so they can participate and contribute to their fullest potential.

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

- **Office of Facilities, Engineering, and Mission Support Services:** Provides FDA employees with office and laboratory facilities.

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

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

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

- **Office of Occupational Safety and Health:** Reinforces FDA's expectations for workplace health and safety, laboratory safety and security, laboratory quality and efficiency, enhances communications among FDA safety staff, and provides program support.

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

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

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

B.3. 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 10-week and 14-week operating reserve thresholds for FY 2026, certain adjustments (inflation, strategic hiring and retention, capacity planning, and additional dollar amount) are applied to the FY 2026 base revenue, resulting in $1,515,410,160. This amount is then divided by 52 to generate the 1-week operating amount of $29,142,503. The one-week operating amount is then multiplied by 10 and 14. This results in a 10-week threshold amount of $291,425,031 and a 14-week threshold amount of $407,995,043.

To determine the FY 2025 end-of-year operating reserves of carryover user fees, the Agency assessed the operating reserve of carryover fees at the end of June 2025 and forecasted collections and obligations in the fourth quarter of FY 2025 combined. This provided an estimated end-of-year FY 2025 operating reserve of carryover user fees of $299,623,185, which equates to 10.28 weeks of operations.

Because the estimated FY 2025 end-of-year operating reserves of carryover user fees were within the 10-week and 14-week thresholds, FDA did not increase or reduce the FY 2026 fees or fee revenue under the statutory provision for operating reserve adjustments.

B.4. 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 for FY 2025.
- $40,627,674 for FY 2026.
- $41,505,100 for FY 2027.

B.5. 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 11** 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**

B.6. 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 filed. 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 or application fees, FDA may refund fees that were already paid by the firm.

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

Estimated Refunds	FY 2023	FY 2024	FY 2025	3-Year Average*
Actual Refunds	$43,218,203	$28,265,814	$8,150,358	$26,545,000

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

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