Five-Year Financial Plan

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

FOR THE

Generic Drug User Fee Amendments 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 Generic Drug User Fee Amendments (GDUFA) program over the current five-year authorization period (GDUFA III). This document addresses the plan for implementation and use of generic 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 GDUFA Reauthorization Performance Goals and Program Enhancements Fiscal Years 2023 Through 2027 (GDUFA III Commitment Letter),[1] section VIII.D.2, FDA published a GDUFA 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.

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 capability. FDA fulfills this responsibility by ensuring the security of the food supply and by fostering the development of medical products to respond to deliberate and naturally emerging public health threats.

[1] The GDUFA III Commitment Letter: https://www.fda.gov/media/153631/download

Program Organization

There are four major FDA components that support the GDUFA program: the Center for Drug Evaluation and Research (CDER), the Center for Biologics Evaluation and Research (CBER), 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.
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 GDUFA, FDA assesses and collects fees from human generic drug manufacturers to help fund human generic drug activities. The Federal Food, Drug, and Cosmetic (FD&C) Act, as amended by GDUFA, authorizes FDA to assess and collect fees from industry to supplement non-user fee appropriations that the Agency spends on human generic drug activities.

Originally authorized in 2012, the Generic Drug User Fee Amendments (GDUFA) to the FD&C Act were reauthorized by Congress in 2017 (GDUFA II) and most recently in 2022. The FDA User Fee Reauthorization Act of 2022 included the Generic Drug User Fee Amendments of 2022, also known as GDUFA III, which amended and extended the program from October 1, 2022, through September 30, 2027. This 5-year reauthorization helps ensure continued funding for FDA from FY 2023 through FY 2027 to support human generic drug activities. GDUFA III continues FDA's authority to assess user fees to help fund critical and measurable enhancements to the

performance of FDA's generic drugs program, and under the related GDUFA III commitment letter negotiated by FDA and industry, new enhancements to the program designed to maximize the efficiency and utility of each assessment cycle, with the intent to reduce the number of assessment cycles for abbreviated new drug applications (ANDAs) and facilitate timely access to quality, affordable, safe, and effective generic medicines. Also, GDUFA III provides enhancements relating to complex generic drug products and sets a sound financial foundation including through a new annual capacity planning adjustment as part of the statutory fee-setting calculations, beginning with FY 2024.

FDA spends GDUFA user fee collections and non-user fee appropriations to hire, support, and maintain personnel for the Agency's human generic drug activities to ensure that safe, effective, and high-quality generic drugs are available to the American public.

Exhibit 2 outlines the GDUFA III fee structure.

Exhibit 2: GDUFA III Fee Structure

Fee Type		Definition
Abbreviated New Drug Application (ANDA)		An ANDA filing fee is incurred upon submission of an abbreviated new drug application.
Type II Domestic and Foreign Active Pharmaceutical Ingredients (API) Drug Master File (DMF)		The one-time DMF fee is incurred on whichever of the following dates occurs earlier: (1) the first time a generic drug submission references that DMF by an initial letter of authorization on or after October 1, 2012, or (2) the date the DMF holder requests the initial completeness assessment.
Program	**Small, Medium, Large**	Each person (including its affiliates) will be assessed an annual fee depending on the number of approved ANDAs in the person's portfolio.
Facility	**Domestic and Foreign (API)**	An API facility fee is owed by each person who owns a facility that is identified in (1) at least one approved generic drug submission in which the facility is approved to produce one or more APIs or (2) in a Type II API drug master file referenced in at least one approved generic drug submission. An additional $15,000 is assessed for a facility located outside the United States and its territories and possessions.
	Domestic and Foreign Finished Dosage Form (FDF)	An FDF facility fee is owed by each person who owns a facility that is identified in at least one generic drug submission that is approved to produce one or more FDFs of a

Fee Type		Definition
		human generic drug. An additional $15,000 is assessed for a facility located outside the United States and its territories and possessions.
	Domestic and Foreign Contract Manufacturing Organization (CMO)	An annual CMO facility fee is owed by each person who owns an FDF facility that is identified in at least one approved ANDA, where the facility is not identified in an approved ANDA held by the owner of that facility or its affiliates. An additional $15,000 is assessed for a facility located outside the United States and its territories and possessions.

The statute specifies how the fees must be calculated each fiscal year, including annual adjustments that must be made for inflation. Starting with FY 2024, a capacity planning adjustment (CPA) calculation is also made, and the fee revenues and fees further adjusted, as needed, to reflect changes in resource capacity needs for human generic drug activities. In addition, adjustments may be made for the operating reserve, including a required decrease as applicable. These changes will be discussed in the following section. The fee amounts are to be published in the Federal Register each year, typically at the beginning of August.[2]

GDUFA 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

GDUFA III helps ensure continuity for FDA's generic drug review program by providing for stable and consistent funding during fiscal years 2023 to 2027 to support FDA's mission to provide the American public timely access to high-quality, affordable generic drugs. Specifically, these funds enable FDA to implement important program enhancements related to the assessment of ANDAs and to hire and retain the necessary scientific and technical talent needed to deliver GDUFA performance commitments and help achieve related public health priorities.

Highlights of the GDUFA III Commitment Letter

The GDUFA III Commitment Letter describes program enhancements agreed to by FDA and industry designed to improve the predictability and transparency of ANDA assessments and to minimize the number of assessment cycles necessary for approval. For example, FDA's discretion to take imminent actions (i.e., FDA continuing the assessment of an ANDA past the goal date if it may be possible to approve or

[2] See the GDUFA user fee rates at https://www.fda.gov/industry/fda-user-fee-programs/generic-drug-user-fee-amendments.

tentatively approve an ANDA within 60 days after the goal date), or to extend certain goal dates during its assessment of an ANDA (e.g., Information Requests and Discipline Review Letters classified as “major” may extend the goal date), increases opportunities for first cycle or current cycle approvals under GDUFA III. GDUFA III enhancements under the Commitment Letter related to the content, timing, and assessment of a pre-submission facility correspondence support FDA’s ability to meet related priority review goals.

The GDUFA III Commitment Letter continues to focus on the development of complex generic products which, because of their unique scientific and regulatory considerations, are harder to develop. Certain new program enhancements are specifically designed to facilitate the development, assessment, and approval of complex generic products. For example, the GDUFA III Commitment Letter includes enhanced pathways for discussions between FDA and prospective applicants before an ANDA for a complex product is submitted, and between FDA and applicants while an ANDA for a complex product is under assessment or after a complete response letter is issued. GDUFA III also continues to promote and advance scientific research around complex generic drug development. This research helps to ensure that regulatory standards, recommendations, and decisions are based on the most current scientific evidence and directly supports the FDA’s ability to meet new goal dates for issuing product specific guidances for complex products.

The GDUFA III Commitment Letter also provides more opportunities for timely regulatory and/or scientific advice on a specific element of generic drug product development or certain post-approval submission requirements through program enhancements to the controlled correspondence program. Similarly, GDUFA III’s new commitments to enhance FDA’s processes for reviewing and responding to suitability petitions will facilitate more timely responses to these submissions.

Changes to Fee Structure and Fee-Setting Mechanisms in GDUFA III

The following changes were made to the fee structure in the amendments to the FD&C Act as part of GDUFA III:

1. The proportion of fee revenues derived from API Facility fees decreased from seven percent in GDUFA II to six percent in GDUFA III.

2. Under the GDUFA II fee structure, CMOs paid one-third the annual fee paid by firms that manufacture under ANDAs which they or their affiliates own. Under GDUFA III, CMOs pay 24 percent of the annual fee paid by firms that manufacture under ANDAs which they or their affiliates own.

3. The proportion of fee revenues derived from the Generic Drug Applicant Program Fee increased from 35 percent in GDUFA II to 36 percent in GDUFA III.

There were several changes to the fee-setting mechanisms under GDUFA III amendments to the FD&C Act:

1. The base revenue amount for each fiscal year in GDUFA III is set using the general approach used in GDUFA II with some refinements. The total target revenue for FY 2023, as specified at section 744B(b)(1)(A) of the FD&C Act, was $582,500,000. The base revenue amount for subsequent fiscal years is based on the total target revenue amount for the prior fiscal year, excluding any operating reserve adjustment for that prior fiscal year.

2. Congress made a technical fix to the inflation adjustment used in GDUFA. The previous inflation adjustment language under GDUFA II referenced a Consumer Price Index (CPI) that the U.S. Bureau of Labor Statistics had discontinued (i.e., Washington-Baltimore, DC-MD-VA-WV; not seasonally adjusted; all items; annual index) and that it replaced with two separate indices (i.e., "Washington-Arlington-Alexandria, DC-VA-MD-WV" and "Baltimore-Columbia-Towson, MD"). In enacting GDUFA III, Congress updated the statutory CPI to the Washington-Arlington-Alexandria index. This results in use of a CPI which reflects the geographic region in which FDA is headquartered.

3. A capacity planning adjustment (CPA) was added, beginning with FY 2024, to increase annual revenue as needed to account for changes in program workload. The CPA has an annual cap of three percent of inflation-adjusted revenue except when certain circumstances are met (in which case the cap is increased to four percent). FDA will describe its application of the CPA methodology in the Federal Register notice publishing GDUFA fees each year.

4. The final year adjustment was replaced with an operating reserve adjustment that authorizes FDA to adjust fees for FY 2024 or subsequently during GDUFA III to maintain sufficient operating reserves of carryover user fees. FDA may increase fees to maintain up to eight weeks of reserve in FY 2024, nine weeks of reserve in FY 2025, and 10 weeks for FY 2026 and FY 2027. If the estimated carryover balance is in excess of 12 weeks of operating reserves, FDA is required to decrease fees for that fiscal year to reduce the operating reserve to not more than 12 weeks. FDA will provide the rationale for adjustments to the operating reserve in the annual Federal Register notice publishing fee rates for that fiscal year.

Efforts to Enhance Financial Management

Under the GDUFA III Commitment Letter, FDA continued its commitment to mature the Agency's resource capacity planning function, including utilization of modernized time reporting, to support enhanced management of GDUFA resources in GDUFA III and help ensure alignment of user fee resources to staff workload.

To further these efforts, an assessment of the resource capacity planning capability, including the CPA, was conducted that examined the ability of the CPA to forecast appropriate resource needs for the GDUFA Program, which included an assessment of the scope of the workload drivers in the CPA and their ability to represent the overall

workload of the GDUFA Program. The report was published on the FDA website in September 2025[3] and discussed at the FY 2025 GDUFA financial public meeting.[4]

FDA also made commitments under GDUFA III to enhance efficiency and transparency in the administration of GDUFA's financial resources. This includes publishing a five-year plan (this plan), to be updated annually. FDA will also hold an annual public meeting to discuss this five-year financial plan, along with the Agency's progress in implementing resource capacity planning, including the continual improvement of the capacity planning adjustment and time reporting, and the integration of resource capacity planning in resource and operational decision-making processes.

[3] https://www.fda.gov/media/188791/download?attachment
[4] 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 GDUFA financial outlook for the FY 2023 through FY 2027 reauthorization 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 GDUFA 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 GDUFA program in future fiscal years. Annual updates to this plan will provide actual amounts for the prior fiscal years.

Table 1a: Human Generic 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	$131,211,761	$120,195,906	$89,171,695	$89,171,695	$140,512,273	$209,423,308
Net Collections	$551,653,777	$569,359,591	$607,806,205	$620,713,654	$670,899,000	$702,146,000
Recoveries	$7,656,327	$12,580,852	$8,790,000	$8,683,062	$9,640,000	$9,640,000
Total Budgetary Resources	**$690,521,865**	**$702,136,349**	**$705,767,900**	**$718,568,411**	**$821,051,273**	**$921,209,308**

Table 1b: Human Generic 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	$359,048,484	$410,239,316	$388,090,916	$401,000,224	$401,529,461	$449,856,672
Total Operating	$113,234,967	$110,217,838	$104,925,737	$84,099,487	$103,633,653	$105,980,112
Total Rent	$15,134,245	$9,430,213	$10,456,504	$9,680,487	$11,533,680	$12,351,697
Total Shared Services	$82,908,264	$83,077,287	$75,865,018	$83,275,940	$94,931,171	$99,190,565
Total Obligations	**$570,325,960**	**$612,964,654**	**$579,338,175**	**$578,056,138**	**$611,627,965**	**$667,379,046**

Table 1c: Human Generic 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	$120,195,906	$89,171,695	$126,429,725	$140,512,273	$209,423,308	$253,830,262
Future Year Refunds Allowance, Set Aside	($4,000,000)	($4,000,000)	($6,002,000)	($6,002,000)	($5,604,000)	($5,604,000)
Carryover Net of Set Aside, End of Year	**$116,195,906**	**$85,171,695**	**$120,427,725**	**$134,510,273**	**$203,819,308**	**$248,226,262**

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 GDUFA fee funds broken out by major expense categories. GDUFA fees may be expended only for costs to support "human generic drug activities," 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: GDUFA fees collected, appropriated, and not obligated at the end of a fiscal year remain available to support human generic drug activities in future fiscal years. In this report, such fee funds are referred to as the "total carryover" or "GDUFA 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: Human Generic Drug User Fee Target Revenue for FY 2023 through FY 2027

Budgetary Resources	FY2023 Actual	FY2024 Actual	FY2025 Actual	FY2026 Actual	FY2027 Estimate
Base Revenue Amount	$582,500,000	$582,500,000	$613,538,015	$638,961,803	$670,899,031
Inflation Adjustment	$0	$22,631,290	$25,423,788	$31,937,228	$31,247,122
Capacity Planning Adjustment	N/A	$8,406,725	$0	$0	TBD
Operating Reserve Adjustment	N/A	$0	$0	$0	TBD
Target Revenue Total	**$582,500,000**	**$613,538,000**	**$638,962,000**	**$670,899,000**	**$702,146,000**

Target Revenue Total is rounded to the nearest thousand dollars.

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 adjustment from the prior year.

Inflation Adjustment: The inflation adjustment maintains 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 CPI and payroll-related

expenses by changes in FDA's average personnel compensation and benefits amounts. The inflation adjustment for future years is 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 4.9983 percent.

Capacity Planning Adjustment: Under section 744B(c)(2) of the FD&C Act, beginning with FY 2024, FDA shall use the capacity planning adjustment to further adjust, as needed, the fee revenue and fees to reflect changes in the resource capacity needs of FDA for human generic drug activities.

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

The capacity planning adjustment authorizes annual adjustments to ensure that the Agency is appropriately resourced to be able to address the forecasted amount of direct review work. The capacity planning methodology is a structured process utilizing validated forecast models trained with the most recently available data and includes managerial decision points.[5] The CPA amount will fluctuate from year to year. FDA does not maintain expectations for future year CPA amounts as these are largely 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.

Operating Reserve Adjustment: The operating reserve adjustment under section 744B(c)(3) of the FD&C Act provides for defined maximum amounts of carryover for operating reserves for human generic drug activities. This adjustment authorizes FDA to increase the annual revenue amount used to set fees, if needed, to provide not more than a specified number of weeks of carryover for such operating reserves. If the amount of such carryover is estimated to exceed a specified threshold, FDA is required to reduce the amount of fee revenues to remain below that maximum threshold amount of carryover for operating reserves. See **Appendix B.3.** for additional details.

No operating reserve adjustment was made in the setting of FY 2026 fees because estimated total available carryover at the end of FY 2025 provided for approximately 10 weeks of operating reserves in FY 2026. 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

[5] 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

Table 6.

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 total amount that, under the statute, is to be collected in fees for the respective fiscal year and serves as the basis for setting the fee amounts. Under section 744B(b)(2) of the FD&C Act, five percent of this amount is to be derived from drug master file (DMF) fees, thirty-three percent is to be derived from ANDA fees, twenty percent is to be derived from generic drug facility fees, six percent is to be derived from active pharmaceutical ingredient facility fees, and thirty-six percent is to be derived from generic drug applicant program 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 application fees, program fees, facility fees, and DMF fees paid in any given year.

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

Table 3: Human Generic 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	**$582,500,000**	**$613,538,000**	**$638,962,000**	**$638,962,000**	**$670,899,000**	**$702,146,000**
Total Carryover, Beginning of Year	$131,211,761	$120,195,906	$89,171,695	$89,171,695	$140,512,273	$209,423,308
Net Collections	$551,653,777	$569,359,591	$607,806,205	$620,713,654	$670,899,000	$702,146,000
Recoveries	$7,656,327	$12,580,852	$8,790,000	$8,683,062	$9,640,000	$9,640,000
Total Budgetary Resources	**$690,521,865**	**$702,136,349**	**$705,767,900**	**$718,568,411**	**$821,051,273**	**$921,209,308**

Target Revenue, Net Collections, and Recoveries Estimates have been rounded to the nearest thousand dollars.

Total Carryover, Beginning of year: Total carryover represents the balance of unspent GDUFA fee funds at the beginning of the fiscal year. 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 differs 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 $9,640,000 annually.

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

Table 4: GDUFA III 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	$166,465,635	$181,860,915	$210,857,460	$182,682,060	$221,396,670
Generic Drug Program Fees	$199,629,227	$203,722,347	$230,026,320	$222,837,962	$241,523,640
Facility Fees	$155,362,147	$164,326,956	$166,130,120	$173,158,660	$174,433,740
DMF Fees	$30,142,805	$24,901,366	$31,948,100	$35,656,465	$33,544,950
Total Cohort Collections	**$551,599,814**	**$574,811,584**	**$638,962,000**	**$614,335,147**	**$670,899,000**

Cohort Year Collections: User fee collections are generally recognized and reported in the fiscal year that the fee was originally due (referred to as the "cohort year").[6] 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 updated planned amount for the current year.

I. User Fee Obligations

GDUFA fees may be expended only for certain costs necessary to support "human generic drug activities," as defined in section 744A(9) of the FD&C Act. 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.

Table 5: Human Generic 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	**$359,048,484**	**$410,239,316**	**$388,090,916**	**$401,000,224**	**$401,529,461**	**$449,856,672**
CBER	$248,671	$0	$0	$0	$0	$0
CDER	$295,747,308	$340,158,030	$335,351,285	$345,359,305	$332,315,953	$374,946,841
OII	$40,357,466	$50,904,789	$35,217,057	$39,322,464	$51,350,810	$53,742,474
HQ	$22,695,039	$19,176,497	$17,522,574	$16,318,455	$17,862,698	$21,167,357

[6] 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.

User Fee Obligations	FY2023 Actual	FY2024 Actual	FY2025 Estimate	FY2025 Actual	FY2026 Estimate	FY2027 Estimate
Operating	**$113,234,967**	**$110,217,838**	**$104,925,737**	**$84,099,487**	**$103,633,653**	**$105,980,112**
CBER	$0	$0	$292,624	$88	$92	$96
CDER	$93,006,393	$92,558,409	$84,969,217	$64,547,687	$76,680,967	$83,645,135
OII	$8,704,461	$7,791,673	$11,922,467	$6,518,140	$5,703,241	$6,406,610
HQ	$11,524,113	$9,867,756	$7,741,429	$13,033,572	$21,249,353	$15,928,271
Total Rent	**$15,134,245**	**$9,430,213**	**$10,456,504**	**$9,680,487**	**$11,533,680**	**$12,351,697**
Total Shared Services	**$82,908,264**	**$83,077,287**	**$75,865,018**	**$83,275,940**	**$94,931,171**	**$99,190,565**
Total Obligations	**$570,325,960**	**$612,964,654**	**$579,338,175**	**$578,056,138**	**$611,627,965**	**$667,379,046**

Total obligations include payroll and operating, rent, and shared services costs funded by GDUFA fee funds. Non-user fee funds supporting human generic drug activities 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 GDUFA fees may be expended to support human generic drug activities, as defined in the statute. These allowable activities include, for example, core regulatory review functions, pre-approval and surveillance inspections, guidance and policy development activities, regulatory science activities, and management and administrative functions that support human generic drug activities. See **Appendix A** for a listing of those activities. The payroll and operating costs associated with human generic drug activities are based on obligations attributed to CBER, CDER, 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), GDUFA user fee funds are allocated based on the proportion to which those activities support human generic drug activities. If an operating activity solely supports human generic drug activities, it can be fully funded by GDUFA fees (and/or non-user fee appropriations). If the operating activity supports multiple user fee programs, GDUFA fees may fund the activity up to the appropriate proportion of the benefit from such activity that accrues to human generic 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 human generic drug activities, a portion of those charges is paid from non-user fee appropriations, and a portion is paid from GDUFA fees.

- **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 the offices that constitute 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 GDUFA III obligations will reflect inflation.

J. User Fee Carryover

GDUFA fees collected, appropriated, and not obligated at the end of the fiscal year remain available to support human generic drug activities in future fiscal years.

Maintaining an appropriate level of carryover enables FDA to mitigate financial risks to the generic drug review program, including, for example, the risk of under collecting fees and the risk of a lapse in appropriations, so that FDA can continue performing human generic drug activities 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 the carryover at the end of each year is equal to net collections minus net obligations. This is demonstrated best in **Table 1c** above.

Table 6 provides projections of GDUFA carryover balances at the end of each fiscal year. Forecasted estimates will be updated with actual amounts in future Five-Year Financial Plan annual updates.

Table 6: GDUFA Carryover by Fiscal Year

Carryover	FY2023 Actual	FY2024 Actual	FY2025 Estimate	FY2025 Actual	FY2026 Estimate	FY2027 Estimate
Total Carryover, End of Year	**$120,195,906**	**$89,171,695**	**$126,429,725**	**$140,512,273**	**$209,423,308**	**$253,830,262**
Future Year Refunds Allowance, Set Aside	($4,000,000)	($4,000,000)	($6,002,000)	($6,002,000)	($5,604,000)	($5,604,000)
Carryover Net of Set Aside, End of Year	**$116,195,906**	**$85,171,695**	**$120,427,725**	**$134,510,273**	**$203,819,308**	**$248,226,262**

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.
- **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. For FY 2026 and FY 2027, the amount is currently estimated to be $5,604,000 for each year. See **Appendix B.4.** for additional details.

- **Carryover Net of Set Aside, End of Year:** This is the total carryover less any carryover funds subject to set asides.

Looking forward in GDUFA III, the operating reserve adjustment will be used to ensure the operating reserve remains below the mandatory 12-week threshold and, per discretion afforded by the statute, may be applied to mitigate financial risks by increasing fee revenue, as needed, if the operating reserve falls below the discretionary increase threshold. Current estimates indicate the total carryover at the end of FY 2027 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 Thresholds

Operating Reserve	FY2023 Actual	FY2024 Actual	FY2025 Actual	FY2026 Actual	FY2027 Estimate
1-Week Operating Amount	N/A	$11,798,808	$12,287,727	$12,901,904	$13,502,811
Discretionary Operating Reserve Statutory Increase Threshold (weeks)	N/A	8	9	10	10
Discretionary Operating Reserve Statutory Increase Threshold ($)	N/A	$94,390,464	$110,589,543	$129,019,044	$135,028,106
Total Available Carryover, Beginning of Year	**$131,211,761**	**$120,195,906**	**$89,171,695**	**$140,512,273**	**$209,423,308**
Operating Reserve Statutory Decrease Threshold (weeks)	N/A	12	12	12	12
Operating Reserve Statutory Decrease Threshold ($)	N/A	$141,585,696	$147,452,724	$154,822,853	$162,033,728

K. Non-User Fee Appropriations

For FDA to obligate user fees collected under GDUFA, a certain amount of non-user fee appropriations must be allocated for human generic drug activities 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 Non-User Fee Appropriations under GDUFA by Fiscal Year

FY2023 Actual	FY2024 Actual	FY2025 Actual	FY2026 Actual	FY2027 Actual
$118,492,290	$127,669,945	$131,807,965	$135,232,162	$139,000,903

The non-user fee spending trigger amount is determined by multiplying the base amount of non-user fee appropriations spent on human generic drug activities ($97 million) times the adjustment factor for the fiscal year.

As a result of amendments under section 905(b) of the FDA Reauthorization Act of 2017, starting in FY 2024, certain costs shifted from user fee-coverable spending to non-user fee coverable appropriations spending. Even though these costs shifted, non-

user fee appropriations spending on the shifted costs counted towards the spending trigger, under amendments made by the Food and Drug Omnibus Reform Act of 2022.

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 generic drug activities may be reduced to ensure that the allocation of non-user fee appropriations for human generic drug activities meets the requirements of this trigger.

L. Planned Hiring

Under the GDUFA III Commitment Letter, FDA agreed to the hiring of 128 staff in FY 2023 to support the workload associated with initiatives established or expanded by GDUFA III (see section VIII.E.2. of the Commitment Letter). The Agency successfully hired 125 FTEs as of September 30th, 2025. **Table 9** presents the hiring activity for these new positions each fiscal year, with unfilled vacancies being targeted for the following fiscal year.

Table 9. Target New Hires by Organization for GDUFA III Commitments

Organization	FY2023 Actual	FY2024 Actual	FY2025 Estimate	FY2025 Actual	FY2026 Estimate	FY2027 Estimate
CDER	100	10	4	5	3	0
HQ	0	1	0	0	0	0
OII	5	4	4	0	0	0
Total	105	15	8	5	3	0

Note: In the FY25 FDA Re-Organization, 4 GDUFA vacancies (compliance officers) moved to CDER--when the compliance function moved out of OII.

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:** During GDUFA I and to a lesser extent in GDUFA II, budgetary resources had been under-spent due to the uncertainty

around the timing of resource (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, under GDUFA III, FDA has the authority to maintain up to a specified week-based level of an operating reserve of appropriated carryover fees, 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 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 GDUFA III. 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 GDUFA

Section 744A(9) of the FD&C Act defines the term "human generic drug activities," in general, as the activities associated with generic drugs and inspection of facilities associated with generic drugs, as further detailed in that definition and reflected in Exhibit 3. In summary, costs related to the following activities have been attributed to "human generic drug activities" under the FD&C Act's definition.

Exhibit 3: Included Activities

Included Activities
1. The activities necessary for the review of generic drug submissions, including review of DMFs referenced in such submissions. 2. The issuance of: a. Approval letters that approve ANDAs or prior approval supplements to such applications. b. Complete response letters that set forth in detail the specific deficiencies in such applications and, where appropriate, the actions necessary to place such applications in condition for approval. 3. The issuance of letters related to Type II API DMFs that: a. Set forth in detail the specific deficiencies in such submissions, and where appropriate, the actions necessary to resolve those deficiencies; or b. Document that no deficiencies need to be addressed. 4. Inspections related to generic drugs. 5. Monitoring of research conducted in connection with the review of generic drug submissions and DMFs. 6. Post-market safety activities with respect to drugs approved under ANDAs or supplements, including the following activities: a. Collecting, developing, and reviewing safety information on approved drugs including adverse event reports. b. Developing and using improved adverse-event data collection systems, including IT systems. c. Developing and using improved analytical tools to assess potential safety problems including access to external databases. d. Implementing and enforcing section 505(o) (relating to post-approval studies and clinical trials and labeling changes) and section 505(p) (relating to risk evaluation and mitigation strategies) insofar as those activities relate to ANDAs. e. Carrying out section 505(k)(5) (relating to adverse-event reports and post-market safety activities). 7. Regulatory science activities related to generic drugs.

Section 744A(12) of the FD&C Act defines the term "resources allocated for human generic drug activities" as expenses for the following:

Exhibit 4: Included Expenses

Included Expenses
1. Officers and employees of FDA, contractors of FDA, advisory committees, and the costs related to such officers, employees, and committees, and to contracts with such contractors. 2. Management of information and the acquisition, maintenance, and repair of computer resources. 3. Leasing and necessary scientific equipment.[7] 4. Collecting fees under section 744B and accounting for resources allocated for the review of ANDAs and supplements and inspection related to generic drugs.

The GDUFA program excludes costs related to the following:

Exhibit 5: Excluded Activities

Excluded Activities
1. All activities necessary for the review of new drug applications, biologic license applications, and investigational new drugs for drugs that will not be approved under ANDAs. 2. The issuance of controlled correspondence unrelated to abbreviated new drug submissions, pre-ANDAs, or prior approval supplements. 3. Inspections unrelated to human generic drugs. 4. Monitoring of research unrelated to human generic drug submissions and DMFs. 5. Post-market safety activities apart from those drugs approved under ANDAs or supplements.

B. Supplemental Financial Information

B.1. Inflation Adjustment

Inflation Adjustment Rates:

- FY 2023: Not applicable.
- FY 2024: 3.8852 percent.

[7] Section 905(b) of the FDA Reauthorization Act of 2017 amended the FD&C Act to provide under section 744B(e)(2) that, beginning on October 1,2023, the authorities under section 744A(12)(C) shall include only 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."

- FY 2025: 4.1438 percent.
- FY 2026: 4.9983 percent.
- FY 2027: 4.6575 percent.

B.2. Shared Service 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

GDUFA III amendments to the FD&C Act established an operating reserve adjustment that authorizes FDA to adjust fees for FY 2024 or subsequently during GDUFA III to maintain sufficient operating reserves of carryover user fees. To determine the dollar amounts for the operating reserve thresholds, adjustments for inflation and capacity planning are applied to the base revenue. This amount is then divided by 52 to generate the one-week operating amount. The one-week operating amount is then multiplied by threshold amounts (in terms of weeks of operation) specified in the statute.

FDA may use the operating reserve adjustment to further increase the fee revenue and fees to provide operating reserves of carryover user fees for human generic drug activities for not more than the number of weeks specified: 8 weeks in FY 2024; 9 weeks in FY 2025; and 10 weeks in FY 2026 and FY 2027.

If the estimated carryover balance is in excess of 12 weeks of operating reserves, FDA is required to decrease fees for that fiscal year to reduce the operating reserve to not more than 12 weeks.

Should FDA make an operating reserve adjustment, either up or down, FDA must explain its rationale in the annual Federal Register notices publishing the GDUFA fees.

For FY 2026 fee setting, the base revenue amount of $638,961,803, along with the inflation adjustment of $31,937,228, resulted a target revenue of $670,899,031. No capacity planning adjustment was made in the setting of FY 2026 fees. This amount was divided by 52 to calculate the estimated 1-week operating amount of $12,901,904.

Taking the 1-week operating amount and multiplying it by 10 produced the estimated 10-week operating reserve discretionary increase threshold amount of $129,019,044. At the time the FY 2026 fees were set, the estimated total carryover amount at the end of FY 2025 (which is also the beginning of FY 2026) was $126,429,724, which did not exceed this 10-week increase threshold. Per its statutory discretion, FDA did not increase GDUFA fee rates using the operating reserve adjustment.

Multiplying the 1-week operating amount by 12 resulted in a 12-week decrease threshold amount of $154,822,853. The estimated total carryover amount at the end of FY 2025 (which is also the beginning of FY 2026) was below this threshold; therefore,

FDA was not required to use the operating reserve adjustment to decrease GDUFA fee rates.

B.4. Future Year Refunds Allowance, Set Aside

If an ANDA is considered not to have been received within the meaning of section 505(j)(5)(A) of the FD&C Act for a cause other than failure to pay user fees, or if the ANDA is withdrawn prior to be being received within the meaning of section 505(j)(5)(A), the applicant is eligible for a 75-percent refund of the ANDA filing fee. If an ANDA is initially received under section 505(j)(5)(A), but FDA subsequently determines that the exclusivity period for a listed drug should have prevented the ANDA from being received, the ANDA is no longer considered received under section 505(j)(5)(A), and the applicant is eligible for a full refund of the ANDA filing fee paid.

Table 10 outlines the actual refunds by fiscal year that are used to calculate the currently estimated refunds set aside to be implemented in FY 2026.

Table 10: Human Generic Drug User Fee Estimated Future Year Refunds Allowance, Set Aside

Estimated Refunds Set Aside	FY 2023	FY 2024	FY 2025	3-Year Average*
Actual Refunds	$7,471,831	$5,053,995	$4,285,283	$5,604,000

**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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