Five-Year Financial Plan

Five Years
2023-2024-2025-2026-2027
FY 2024 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), section VIII.D.2, FDA will publish a GDUFA five-year financial plan no later than the second quarter of fiscal year (FY) 2023. FDA will publish updates to the five-year financial plan no later than the second quarter of each subsequent fiscal year. The purpose of this document is to meet this commitment.

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 the 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.

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 Regulatory Affairs (ORA), and Headquarters (HQ).

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

Exhibit 1: User Fee Program Components

Component	Mission
CDER	Protects and promotes public health by helping to ensure that human drugs and therapeutic biological products 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.
ORA	Protects consumers and enhances public health by maximizing compliance of FDA-regulated products and by minimizing the risk(s) associated with those products. ORA inspects regulated products and manufacturers, conducts sample analyses of regulated products and reviews imported products offered for entry into the United States.
HQ	Provides FDA-wide program direction and administrative services to ensure FDAs 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 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-supported 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 program 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. Additionally, FDA established an Enterprise Risk Management (ERM) Program, with an ERM Council as the governance body responsible for providing overall oversight and accountability. For further information regarding the Internal Controls and Enterprise Risk Management, please refer to the GDUFA Financial Report. [1]

E. User Fee Background and Structure

The Federal Food, Drug, and Cosmetic Act (FD&C Act) authorizes FDA to assess and collect generic drug user 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

[1] 1 GDUFA Financial Reports https://www.fda.gov/about-fda/user-fee-financial-reports/gdufa-financial-reports

2022. The FDA User Fee Reauthorization Act of 2022 included the Generic Drug User Fee Amendments of 2022, also known as GDUFA III, which extended the program from October 1, 2022, through September 30, 2027. This five-year reauthorization helps ensure additional funding for FDA from FY 2023 through FY 2027 to support generic drug-related innovation, evaluation, and program improvement. 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, bringing greater predictability and timeliness to the review of generic drug applications. This delivers tremendous public health benefits by helping to provide the public access to safe, affordable, effective, and high-quality generic drugs.

FDA spends appropriated GDUFA user fee collections and non-user fee appropriations to hire, support, and maintain personnel for the review of generic drug product submissions to help ensure that safe, effective, and high-quality generic drug products are available to the American public.

Exhibit 2 outlines the GDUFA III user 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.
Facility: 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

Fee Type	Definition
	least one generic drug submission that is approved to produce one or more FDFs of a human generic drug. An additional $15,000 is assessed for a facility located outside the United States and its territories and possessions.
Facility: 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 collected are not a fee-for-service. The user fees that are collected 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 will 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

[2] See the GDUFA user fee rates archive at GDUFA User Fee Rates Archive.

assessment of an ANDA past the goal date if it may be possible to approve or 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 will decrease 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 will 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 will increase 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 will be 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 will be 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, will be conducted during GDUFA III that will include examining the ability of the CPA to forecast appropriate resource needs for the GDUFA Program, including 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 resulting report will be published for public comment and discussed at the FY 2026 GDUFA five-year

financial planning meeting. The findings and recommendations of the evaluation may inform future reauthorizations.

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.

Other Financial Impacts

Section 905(b) of the FDA Reauthorization Act of 2017 (FDARA) amended the FD&C Act to provide that the types of fee-coverable costs under the Prescription Drug User Fee Act (PDUFA) program, the GDUFA program, the Medical Devices User Fee Amendments (MDUFA) program, and the Biosimilar User Fee Act (BsUFA) program will narrow on October 1, 2023. The statutory definition of allowable cost categories, i.e., the "resources allocated for human generic drug activities" under GDUFA, is what determines the type of expenses related to human generic drug activities that GDUFA fees can be used for.

Due to a later provision in the Food and Drug Omnibus Reform Act (as included in the Consolidated Appropriations Act, 2023), section 744B of the FD&C Act was amended to clarify that while user fees may no longer be used to pay for certain costs as of fiscal year 2024, these costs as funded by budget authority will count toward the non-user fee spending trigger. For further information, see **Note 5**.

With this clarification, the provisions of FDARA section 905(b) are not expected to have an impact on the non-user fee spending trigger. The systems supporting these programs; however, are complex and multi-faceted. As such, FDA will continue to plan for and monitor the impacts of these changes to ensure minimal disruption to its user fee commitments and public health mission.

Financial Information

This section provides an overview of the financial outlook for GDUFA 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 Summaries

Table 1a, 1b, and 1c represent a summary of the estimated GDUFA financial position, as it relates to user fee budgetary resources. These tables also provide an overview of 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. The financial notes referenced in this table can be found in **Appendix B**.

Table 1a: Human Generic Drug User Fee Budgetary Resources for Fiscal Year 2023 through Fiscal Year 2027

Budgetary Resources	Notes	FY2023 Estimate	FY2023 Actual	FY2024 Estimate	FY2025 Estimate	FY2026 Estimate	FY2027 Estimate
Target Revenue	**Note 1**	**$582,500,000**	**$582,500,000**	**$613,538,000**	**$638,962,000**	**$665,439,000**	**$693,014,000**
Cash Collections		$582,500,000	$551,653,777	$613,538,000	$638,962,000	$665,439,000	$693,014,000
Recoveries	Note 2	$10,000,000	$7,656,327	$10,000,000	$6,775,000	$6,775,000	$6,775,000
Carryover Available for Use, Beginning of Year		$131,211,761	$131,211,761	$120,195,906	$114,145,103	$117,306,853	$133,869,683
Total Budgetary Resources		**$723,711,761**	**$690,521,865**	**$743,733,906**	**$759,882,103**	**$789,520,853**	**$833,658,683**

Table 1b: Human Generic Drug User Fee Obligations for Fiscal Year 2023 through Fiscal Year 2027

Obligations	Notes	FY2023 Estimate	FY2023 Actual	FY2024 Estimate	FY2025 Estimate	FY2026 Estimate	FY2027 Estimate
Total Payroll & Operating	Note 3	$495,261,771	$472,283,451	$542,494,928	$553,672,510	$564,882,381	$574,769,419
Total Rent	Note 5	$21,595,013	$15,134,245	$9,430,213	$9,524,516	$9,619,761	$9,715,958
Total Shared Services	Note 6	$72,228,936	$82,908,264	$77,663,676	$79,377,917	$81,149,020	$82,928,287
Total Obligations		**$589,085,720**	**$570,325,960**	**$629,588,817**	**$642,574,943**	**$655,651,162**	**$667,413,664**

Table 1c: Human Generic Drug User Fee Carryover for Fiscal Year 2023 through Fiscal Year 2027

Carryover	FY2023 Estimate	FY2023 Actual	FY2024 Estimate	FY2025 Estimate	FY2026 Estimate	FY2027 Estimate
Total Carryover, End of Year	$134,626,041	$120,195,906	$114,145,103	$117,306,853	$133,869,683	$166,244,475
Future Year Refunds Allowance, Set Aside	($4,000,000)	($4,000,000)	($4,000,000)	($6,510,000)	($6,510,000)	($6,510,000)
Carryover Net of Unavailable and Set Aside, End of Year	**$130,626,041**	**$116,195,906**	**$110,145,103**	**$110,796,853**	**$127,359,683**	**$159,734,475**

Target Revenue, Refunds/Recoveries Estimates and Collections Estimates have been rounded to the nearest thousand dollars. All other numbers have been rounded to the nearest dollar.

Budgetary Resources: The Total Budgetary Resources component of **Table 1a** illustrates the actual and previously estimated sum of total user fee funding for FY 2023

and estimates for FY 2024 through FY 2027. Budgetary resources include net collections, recoveries, and carryover amounts.

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

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

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

Carryover: GDUFA fees collected, appropriated, and not obligated at the end of the fiscal year remain available to support the GDUFA program in future fiscal years. In this report, such fee funds are referred to as the "total carryover" or "GDUFA carryover."

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

H. Budgetary Resources

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

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

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

Table 2: Human Generic Drug User Fee Target Revenue for Fiscal Year 2023 through Fiscal Year 2027

Budgetary Resources	Notes	FY2023 Estimate	FY2023 Actual	FY2024 Actual	FY2025 Estimate	FY2026 Estimate	FY2027 Estimate
Base Amount		$582,500,000	$582,500,000	$582,500,000	$613,538,015	$638,961,803	$665,439,102
Inflation Adjustment	Note 4	$0	$0	$22,631,290	$25,423,788	$26,477,299	$27,574,466
Capacity Planning Adjustment		N/A	N/A	$8,406,725	TBD	TBD	TBD
Operating Reserve Adjustment		N/A	N/A	$0	TBD	TBD	TBD
Target Revenue T otal	**Note 1**	**$582,500,000**	**$582,500,000**	**$613,538,015**	**$638,961,803**	**$665,439,102**	**$693,013,568**
Target Revenue Total (Rounded)		**$582,500,000**	**$582,500,000**	**$613,538,000**	**$638,962,000**	**$665,439,000**	**$693,014,000**

Numbers have been rounded to the nearest dollar.
N/A = Not Applicable

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

- **Statutory Base:** Starting in 2024, the base amount is the total revenue amount (target revenue) for the prior fiscal year, not including any operating reserve adjustment for that prior year. This base amount is adjusted for inflation and by the CPA (as needed), and may be further adjusted for operating reserve, as described below. See **Note 1** for a diagram of this process.

- **Inflation Adjustment:** The inflation adjustment, which begins with FY 2024, adjusts the base amount to maintain the purchasing power of fee funds in consideration of inflation. The adjustment is a composite measure that weights operating expenses by changes in the applicable Consumer Price Index (CPI) and payroll-related expenses by changes in FDA's average personnel compensation and benefits amounts. The actual inflation adjustment utilized in FY 2024 was 3.8852 (rounded) percent. Inflation for FY 2025 is estimated to be 4.1438 (rounded) and future years are set to match the estimated percent increase. For more information, see **Note 4**.

- **Capacity Planning Adjustment:** 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. For FY 2024, the capacity planning adjustment was $8,406,725.

  The intent of the CPA is to enable annual adjustments if and as warranted to ensure that the Agency is appropriately resourced to be able to address the forecasted amount of direct review work. The CPA is a structured process utilizing validated forecasts models trained with the most recently available data and includes managerial decision points.[3] 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 was established to provide a mechanism to support the management of the carryover balance from year to year. The operating reserve adjustment would increase or decrease, if applicable, the fee revenue amount to set fees. Should FDA make an operating reserve adjustment, either up or down, FDA must explain its rationale in the annual GDUFA fee-setting Federal Register Notice. For more information, see **Note 7**.

  No operating reserve adjustment was made in the setting of FY 2024 fees. FDA does not currently anticipate an operating reserve adjustment for FY 2025. This

[3] For more information on the CPA process, see here: https://www.fda.gov/media/158999/download

may change when fees are set for FY2025 based on more updated information for FY 2024 obligations and collections.

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

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

Budgetary Resources	Notes	FY2023 Estimate	FY2023 Actual	FY2024 Estimate	FY2025 Estimate	FY2026 Estimate	FY2027 Estimate
Target Revenue	**Note 1**	**$582,500,000**	**$582,500,000**	**$613,538,000**	**$638,962,000**	**$665,439,000**	**$693,014,000**
Net Collections		$582,500,000	$551,653,777	$613,538,000	$638,962,000	$665,439,000	$693,014,000
Recoveries	Note 2	$10,000,000	$7,656,327	$10,000,000	$6,775,000	$6,775,000	$6,775,000
Total Carryover, Beginning of Year		$131,211,761	$131,211,761	$120,195,906	$114,145,103	$117,306,853	$133,869,683
Total Budgetary Resources		**$723,711,761**	**$690,521,865**	**$743,733,906**	**$759,882,103**	**$789,520,853**	**$833,658,683**

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

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

- **Net Collections:** FDA generally assumes, for planning purposes, that net collections will equal the target revenue amount. In practice, net collections may differ from the annual target revenue amount if the actual number of fee-paying units 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 actuals either higher or lower than the current estimate. FDA estimated this to be $6,775,000 (rounded) annually. Additional details on recoveries are included in **Note 2**.

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

- **Net Collections:** Net collections are the actual dollar amounts collected in a fiscal year, regardless of the fiscal year the fee was due. **Table 1a** and **Table 3** report net collections.

- **Cohort Year Collections:** Cohort year collections represent the fiscal year for which the fee was originally due. **Table 4** reports cohort year collections.

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

Table 4 presents actual and estimated total annual GDUFA 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 Collections by Cohort Year

Fee Type	Cohort Year 2023 Estimate	Cohort Year 2023 Actuals	Cohort Year 2024 Estimate
ANDA (Application) Fees	$192,225,000	$167,668,545	$202,467,540
DMF Fees	$29,125,000	$30,925,652	$30,676,900
Facility Fees (FDF, CMO, and API)	$151,450,000	$154,294,894	$159,519,880
Human Generic Drug Program Fees	$209,700,000	$198,174,450	$220,873,680
Total Cohort Collections	**$582,500,000**	**$551,063,540**	**$613,538,000**

Numbers have been rounded to the nearest dollar.

The annual updates to this plan will provide the actual net collections 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 5 years represented in this plan. The annual updates to this plan will provide actual amounts for the preceding fiscal year, as well as updated planned amounts for the remaining fiscal years. The financial notes can be found in **Appendix B.**

Table 5: Human Generic Drug User Fee Obligations by Expense Category for Fiscal Year 2023 through Fiscal Year 2027

User Fee Obligations	Notes	FY2023 Estimate	FY2023 Actual	FY2024 Estimate	FY2025 Estimate	FY2026 Estimate	FY2027 Estimate
Payroll & Operating	**Note 3**						
CBER		$1,040,390	$248,671	$1,110,810	$1,136,822	$1,163,137	$1,189,632
CDER		$403,639,923	$388,753,701	$449,387,722	$458,844,123	$468,227,809	$477,603,199
ORA		$53,494,587	$49,061,927	$60,069,858	$61,302,937	$62,545,705	$63,786,647

User Fee Obligations	Notes	FY2023 Estimate	FY2023 Actual	FY2024 Estimate	FY2025 Estimate	FY2026 Estimate	FY2027 Estimate
HQ		$37,086,872	$34,219,152	$31,926,538	$32,388,628	$32,945,730	$32,189,941
Total Rent	Note 5	$21,595,013	$15,134,245	$9,430,213	$9,524,516	$9,619,761	$9,715,958
Total Shared Services	Note 6	$72,228,936	$82,908,264	$77,663,676	$79,377,917	$81,149,020	$82,928,287
Total Obligations		**$589,085,720**	**$570,325,960**	**$629,588,817**	**$642,574,943**	**$655,651,162**	**$667,413,664**

Numbers have been rounded to the nearest dollar.

Total obligations include payroll and operating, rent, and shared services costs. 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 all payroll and operating costs that support the allowable activities for which GDUFA fees may be expended, as set forth in the statute. These allowable activities include, for example, core regulatory review functions, pre-approval inspections, guidance and policy development activities, regulatory science activities, and management and administrative functions that support human generic drug activities.

  As stated in **Section H**, payroll and operating projections for future year amounts are assumed to have an increase of 4.1438 percent, which is the most recent inflation estimate available for FY 2025, offset by some adjustments to better align spending with expected collections to improve operating reserve levels.

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

- **Rent:** This amount is paid to the General Services Administration (GSA) for the federal buildings that FDA occupies, as well as to non-federal sources for direct leases and services (see **Note 5**). Rental rates vary based on the type and location of the space provided.

  For FY 2023, rent includes all costs allowable under prior GDUFA authorizations. Due to amendments made by section 905 of FDARA, certain previously allowable costs will be excluded starting in FY 2024 (see **Note 5**). As a result, rent costs drop from FY 2023 to FY 2024.

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

- **Shared Services:** FDA has several shared service programs that provide support across the agency, such as human resources and information technology (IT). Shared services are supported by the Working Capital Fund (WCF), which is in turn supported in part by user fees (in proportion to the

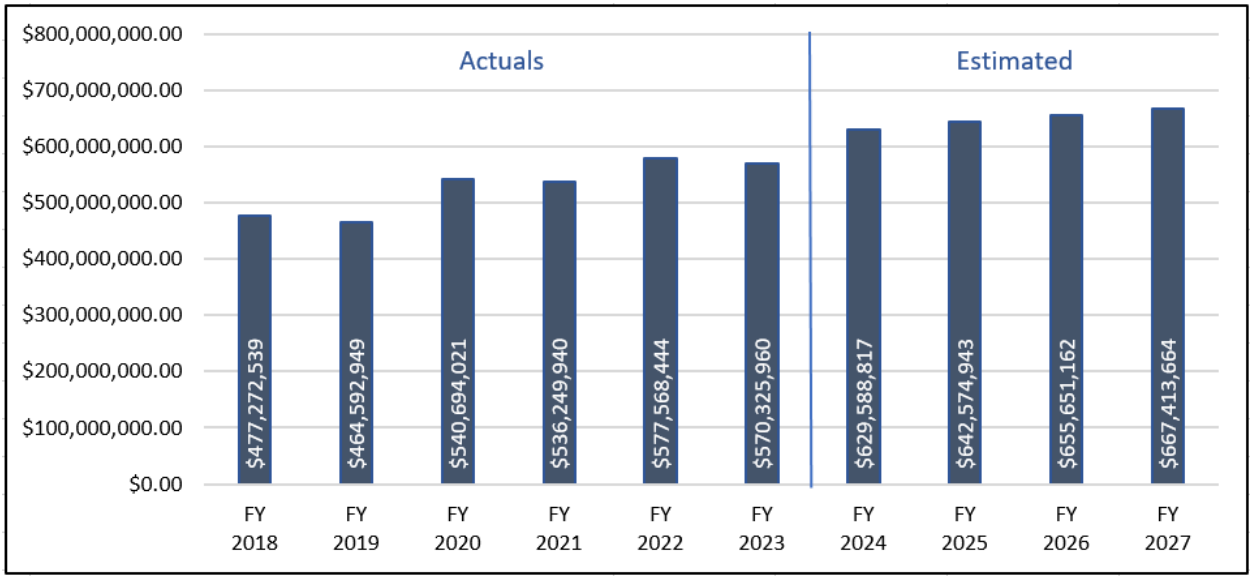
respective shared services provided). **Note 6** provides a full list of what is funded by the WCF.

FY 2024 Shared Service amounts use an inflation adjustment of 3.8852 percent, in addition to some one-time adjustments. For FY 2025 through FY 2027, the outlays for Shared Services for these future years are assumed to increase by 4.1438 percent annually, including accounting for certain adjustments to user fee contributions to the WCF. These adjusted fee contributions help maintain appropriate levels of operating reserve carryover under each contributing user fee program.

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

Exhibit 3 provides an illustration of historical GDUFA II and GDUFA III FY 2023 obligations and projected FY 2024- FY2027 GDUFA III needs.

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



GDUFA III obligations are expected to continue to grow as the program hires new personnel to deliver on negotiated enhancements and as a result of inflationary pressures.

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 activities related to human generic drug activities under such financial constraints. FDA may set aside available user fee funds in the carryover for certain purposes, including, for example, for processing future year refunds.

The net change in 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. The financial notes can be found in **Appendix B**.

Table 6: GDUFA Carryover by Fiscal Year

Carryover	FY2023 Estimate	FY2023 Actual	FY2024 Estimate	FY2025 Estimate	FY2026 Estimate	FY2027 Estimate
Total Carryover, End of Year	**$134,626,041**	**$120,195,906**	**$114,145,103**	**$117,306,853**	**$133,869,683**	**$166,244,475**
Future Year Refunds Allowance, Set Aside	($4,000,000)	($4,000,000)	($4,000,000)	($6,510,000)	($6,510,000)	($6,510,000)
Carryover Net of Set Aside, End of Year	**$130,626,041**	**$116,195,906**	**$110,145,103**	**$110,796,853**	**$127,359,683**	**$159,734,475**

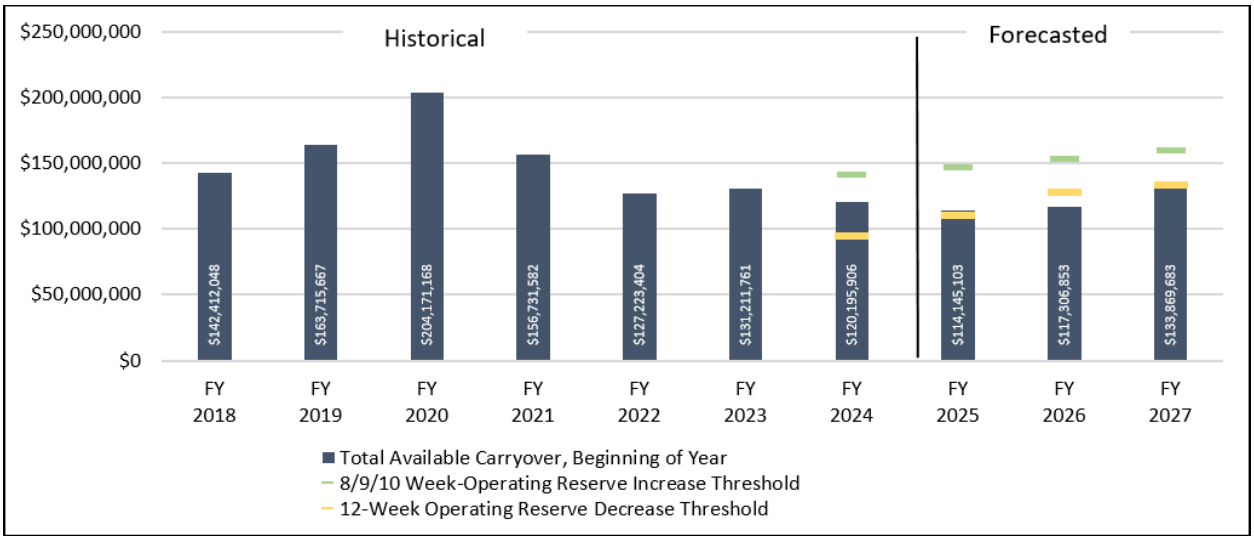
Refund Estimates have been rounded to nearest thousand and all other numbers have been rounded to the nearest dollar.

These terms are defined below:

- **Total Carryover, End of Year:** This is the total amount of unobligated fee funds at the end of the fiscal year.
- **Future Year Refunds Allowance, Set Aside:** FDA maintains a small amount to provide for any refunds, as a matter of prudent operations. In FY 2023 and prior FDA had used a flat amount for the set-aside allowance. In FY 2024 FDA decided for the purposes of this plan, that future year refunds set asides are to be estimated using a three-year average of actual refunds from the most recently completed fiscal years. This change was made for future years due to the uncertain nature of refunds which could impact total year-end carryover. The estimated amount of $4,000,000 was set aside for FY 2023 and FY 2024. For FY 2025-2027, the amount is currently estimated to be $6,510,000 for each year. See **Note 8** for additional details.
- **Carryover Net of Set Aside, End of Year:** This is the total carryover less any carryover funds subject to set asides.

Exhibit 4 below shows the historic trend of carryover in GDUFA and the forecasted carryover for the remainder of GDUFA III.

Exhibit 4: Historical and Forecasted Carryover by Fiscal Year



Looking forward in GDUFA III, the operating reserve adjustment will be used to ensure the operating reserve remains below the 12-week threshold and, with appropriate discretion, to mitigate risks if the operating reserve falls below the discretionary increase threshold. See **Table 7** below for the operating reserve threshold amounts.

Table 7: Operating Reserve Thresholds

Operating Reserve	FY2023 Actual	FY2024 Actual	FY2025 Estimate	FY2026 Estimate	FY2027 Estimate
1-Week Operating Amount	N/A	$11,798,808	$12,287,727	$12,796,906	$13,327,184
Discretionary Operating Reserve Statutory Increase Threshold (weeks)	N/A	8	9	10	10
Discretionary Operating Reserve Statutory Increase Threshold ($)	N/A	$94,390,464	$110,589,543	$127,969,060	$133,271,840
Total Available Carryover, Beginning of Year	**$131,211,761**	**$120,195,906**	**$114,145,103**	**$117,306,853**	**$133,869,683**
Operating Reserve Statutory Decrease Threshold (weeks)	N/A	12	12	12	12
Operating Reserve Statutory Decrease Threshold ($)	N/A	$141,585,696	$147,452,724	$153,562,872	$159,926,208

Numbers have been rounded to the nearest dollar.

Beginning with FY 2024, should the operating reserves of carryover user fees drop below a statutorily-specified, week-based level, 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 so specified: 8 weeks in FY 2024; 9 weeks in FY 2025; and 10 weeks in FY 2026 and FY 2027. Based on projections, FY 2026 and 2027 are currently estimated to be below the discretionary increase threshold. FDA will monitor the operating reserve levels and will apply appropriate discretion with the utilization of any increase, should it be needed, at the time fee amounts are published each year.

For any fiscal year FDA has carryover balances for human generic drug activities in excess of 12 weeks of operating reserves, FDA shall decrease the fee revenue and fees to provide for not more than 12 weeks of such operating reserves.

To calculate the dollar amounts of these week-based thresholds, applicable 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 the threshold number of weeks.

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 on 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 Estimate	FY2026 Estimate	FY2027 Estimate
$118,492,290	$127,669,945	$131,807,965	$134,444,124	$137,133,007

Numbers have been rounded to the nearest dollar.

The non-user fee spending trigger amount is determined by multiplying the base amount of non-user fee appropriations spent on human generic drug activities ($97 million) times the adjustment factor for the fiscal year. See **Note 9** for more details on the adjustment factor.

As a result of amendments under section 905(b) of FDARA, starting in FY 2024, certain costs will be shifted from user fee spending to non-user fee appropriations spending. Even though these costs will be shifted, non-user fee appropriations spending on the shifted costs will be counted towards the spending trigger. See **Note 5** for more information.

FDA is committed to spend at least the required minimum from non-user fee appropriations 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 assure 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). FDA will provide additional information on the progress of the hiring of GDUFA III staff in the GDUFA annual reports.

Changes in the Number of Individuals Hired as Agreed in the GDUFA Commitment Letter, the Number of remaining vacancies, the Number of Full-time Equivalents (FTEs) Funded by Fees Collected Pursuant to Section 744B, and the Number of FTEs Funded by Budget Authority (BAs) by Division Within CDER, CBER, ORA, and OC.

This section addresses the requirement to provide data, analysis, and discussion of the changes in the number of individuals hired as agreed upon in the letters described in section 301(b) of FDA User Fee Reauthorization Act of 2022 and the number of remaining vacancies as well as the number of FTEs funded by fees and budget authority at FDA by each division within CDER, CBER, ORA, and OC. See **table 9** below for changes in the number of individuals hired.

Table 9. Number of Individuals Hired to Meet GDUFA III Commitments

Center	Number Hired in FY 2022*	Number Hired in FY 2023	Changes in Number Hired	Remaining Vacancies in FY 2022*	Remaining Vacancies in FY 2023	Change in Number of Remaining Vacancies
CDER	0	100	100	0	14	14
CBER	0	0	0	0	0	0
OC	0	0	0	0	0	0
ORA	0	5	5	0	8	8
Total	0	105	105	0	22	22

*GDUFA III became effective in FY 2023 therefore there are no GDUFA III hires in FY 2022

FDA committed to hiring 128 individuals between FY 2023 and FY 2027. The Agency successfully hired 105 FTEs as of September 30th, 2023.

Challenges, Risk and Mitigation

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

- **Under-Executing Planned Spend:** 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 resources (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 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. Resource capacity planning helps improve fee setting and allows FDA to adjust for sustained increases in workload. In addition, FDA monitors collections throughout the fiscal year, and the UFFMC and other FDA senior leaders determine how to mitigate any instances when user fee revenue deviates from forecasted estimates.

- **Section 744B(e) (amended by section 905(b) of FDARA):** FDA cannot use user fees on certain previously allowable types of expenses. Section 744B(e)(2) of the FD&C Act provides that "beginning on October 1, 2023, the authorities under section 744A(12)(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 will no longer be able to be funded by GDUFA user fee funds. This change will have an impact on the finances of the program. FDA is monitoring the impacts to the program's funding.

Appendices

A. Allowable and Excluded Costs for the GDUFA Program

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. In summary, costs related to the following have been attributed to human generic drug 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:

Included Expenses
1. Officers and employees of FDA, contractors of FDA, advisory committees, and the costs related to such officers, employees, and committees, and to contracts with such contractors. 2. Management of information and the acquisition, maintenance, and repair of computer resources. 3. Leasing, maintenance, renovation, and repair of facilities and acquisition, maintenance and repair of fixtures, furniture, scientific equipment, and other

necessary materials and supplies (subject to section 744B(e)(2), as noted above).
4. Collecting fees under section 744B and accounting for resources allocated for the review of ANDAs and supplements and inspections related to generic drugs.

The GDUFA program excludes costs related to the following:

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 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.

Section 744B(e) of the FD&C Act was amended by section 905 of FDARA to limit the definition of certain "resources allocated for human generic drug activities" under section 744A(12)(C), i.e., the types of expenses related to human generic drug activities that fees can cover. Thus, the category of expenses described in section 744A(12)(C) is applied as shown in no. 3 below, to include only expenditures for leasing and necessary scientific equipment starting with FY 2024:

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. 4. Collecting fees under section 744B and accounting for resources allocated for the review of ANDAs and supplements and inspection related to generic drugs.

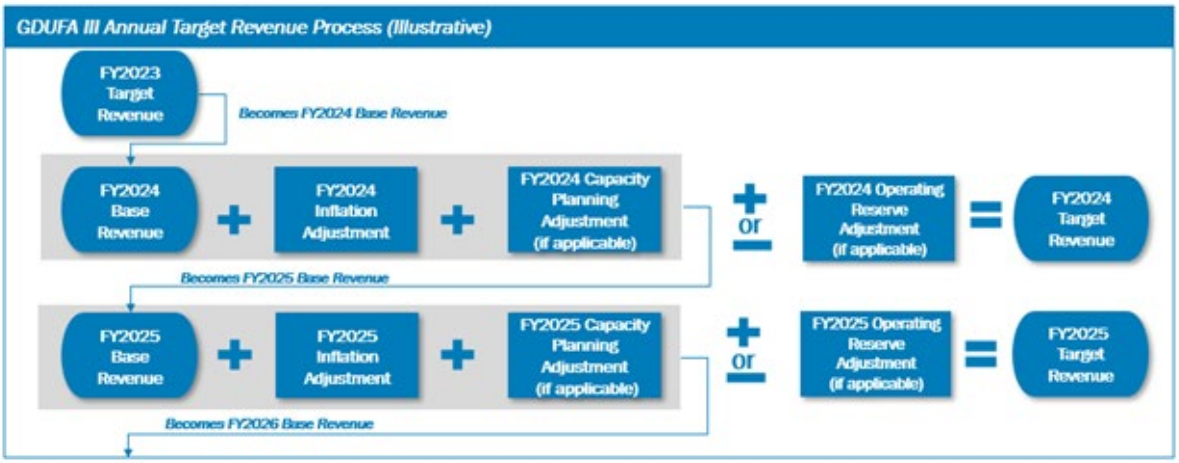
Beginning with FY 2024, in addition to costs excluded under the FDARA section 905 amendments, the GDUFA program will continue to exclude costs as outlined above.

B. Financial Notes

Note 1. Annual Target Revenue Methodology

Exhibit 5 is a flowchart that outlines GDUFA III's Annual Target Revenue Methodology.

Exhibit 5: GDUFA III Annualized Base and Target Revenue Methodology



Note 2. Recoveries

Recoveries account for funds returned to the Agency in the form of deobligations of prior year obligations. For example, recoveries could include funding from a contract that ended in a prior year and was not expended.

Note 3. Pay and Operating Costs

For payroll, most employees are required to report their time in an activity-based reporting system, which allows FDA to identify activities that user fees can be used to support. See **Appendix A** for a listing of those activities. For operating activities (e.g., contracting services), funds are allocated based on the proportion to which those activities support human generic drug activities. If an operating activity solely supports human generic drug activities, it will be fully funded by the GDUFA program. If the operating activity is shared, GDUFA will fund the activity in proportion to how it is used by the generic drug review program (i.e., for human generic drug activities) as compared to other programs.

Note 4. Inflation Adjustment

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

For FY 2023, the first program year of the current five-year GDUFA authorization (enacted under the FDA User Fee Reauthorization Act of 2022), there is no inflation adjustment, as the target revenue is set by the statute. The inflation adjustment utilized in FY 2024 was 3.8852 percent. For FY 2025, the inflation adjustment is currently estimated to be 4.1438 percent for GDUFA. This is subject to change during the annual fee setting process.

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

Inflation Rates:

- FY 2023: Not applicable.
- FY 2024: 3.8852 percent.
- FY 2025: 4.1438 percent (estimated).
- FY 2026: 4.1438 percent (estimated).
- FY 2027: 4.1438 percent (estimated).

Note 5. Rent Costs

The General Services Administration (GSA) charges rent to FDA for the federal buildings that FDA occupies. This rent is charged at different rates depending on the type and location of the space provided. Because rent is an essential 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.

Also included in this account are recurring costs that FDA pays directly to non-federal sources under the delegation of direct lease and service authority. These services include rental of space, and all recurring services for building operations such as overtime utilities, janitorial services, guards, and ground maintenance. The amount of rent and rent related costs each Center pays is directly related to the square footage occupied by that Center.

Section 905(b) of FDARA amended the FD&C Act to provide that the types of fee-coverable costs for the PDUFA, GDUFA, MDUFA, and BSUFA user fee programs will change on October 1, 2023. The statutory definition of allowable cost categories, i.e.,

the “resources allocated for human generic drug activities” under GDUFA, is what determines the type of expenses related to human generic drug activities that GDUFA fees can be spent on.

Specifically, section 744B(e) of the FD&C Act was amended by FDARA section 905(b) to narrow the “resources allocated for human generic drug activities”, as detailed in section 744A(12)(C) of the FD&C Act, to include only expenditures for leasing and necessary scientific equipment. The impact of the change means that certain costs related to facilities, equipment, materials, and supplies will no longer be able to be funded by GDUFA user fee funds.

Note 6. Shared Service Costs

FDA has several shared service programs, supported by the WCF, that provide support across the agency. The shared service programs in FY 2024 include:

- **FDA Central:** Provides for Center-wide and Agency-wide services such as telecommunications, training, printing, mail and document management, IT systems, employee health units, and other support and miscellaneous services.

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

- **Office of Acquisitions and Grants Services:** Manages contracts, grants, and other agreements.

- **Office of Equal Employment Opportunity**: Promotes an inclusive work environment that ensures equal employment opportunity and fosters a culture that values diversity and empowers individuals.

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

- **Office of Financial Management:** Provides financial managerial services and policy guidance.

- **Division of Budget Execution and Control:** Initiates, monitors, and analyzes FDA’s budget resources.

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

- **Office of Security Operations:** Develops and implements the Agency-wide security policies and programs by providing leadership and guidance to managers and staff on all aspects of security. Administers vital security functions

that contribute to the Agency's mission of protecting public health by enhancing the safety and security of all personnel, facilities, and information.

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

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

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

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

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

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

Note 7. 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 (For FY 2024, the increase threshold is 8 weeks and the decrease threshold is 12 weeks).

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 2024 fee setting, the base revenue amount of $582,500,000, along with the inflation adjustment of $22,631,290, and CPA of $8,406,725, resulted a target revenue of $613,538,015. This amount was divided by 52 to calculate the estimated 1-week operating amount of $11,798,808.

Taking the 1-week operating amount and multiplying it by 8 produced the estimated 8-week operating reserve discretionary increase threshold amount of $94,390,464. The estimated total carryover amount at the end of FY 2023 (which is also the beginning of FY 2024), at the time that fees were set, was $120,195,906, which exceeded this 8-week increase threshold. As a result, 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 $141,585,696. The estimated total carryover amount at the end of FY 2023 (which is also the beginning of FY 2024) was below this threshold; therefore, FDA was not required to use the operating reserve adjustment to decrease GDUFA fee rates.

Note 8. 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.

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

Note 9. Calculating the Minimum Non-User Fee Spending Trigger Amount

In determining the applicable amount of the non-user fee spending trigger for a fiscal year (which must be met in order to use fees), FDA must calculate and apply an adjustment factor (defined in section 744A(3) of the FD&C Act). This FD&C Act provision states, “the term ‘adjustment factor’ means a factor applicable to a fiscal year that 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 2011.”

Note 10. Capacity Planning Adjustment

GDUFA III amendments to the FD&C Act established a capacity planning adjustment that authorizes FDA to adjust the annual target revenue amount, within certain

parameters, to account for sustained increases in workload. This adjustment helps ensure that FDA can expand its review capacity to meet additional workload demands and maintain performance on its review timelines.

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