Financial Report to Congress

Generic Drug User Fee Amendments

FY 2024

U.S. FOOD & DRUG ADMINISTRATION

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Executive Summary

The Generic Drug User Fee Amendments (GDUFA) to the Federal Food, Drug, and Cosmetic (FD&C) Act require the Food and Drug Administration (FDA) to report annually on the financial aspects of the GDUFA program implementation. This is the second report under the third authorization of GDUFA (GDUFA III) and covers fiscal year (FY) 2024.

The FD&C Act specifies that the following three legal conditions must be satisfied each year for FDA to collect and spend GDUFA user fees:

1. FDA's total appropriations for salaries and expenses (excluding user fees) must be equal to, or greater than, FDA's FY 2009 appropriations for salaries and expenses (excluding user fees) multiplied by the adjustment factor.
2. The fee amounts FDA may collect must be specified in appropriation acts.
3. FDA must allocate a minimum of $97,000,000 of appropriations (excluding user fees) multiplied by the adjustment factor for costs of human generic drug activities plus certain specified costs.

FDA met the three legal conditions in FY 2024, and this report explains how these legal conditions were satisfied. The statements and tables in the report provide data on human generic drug user fee collections, expenditures, and carryover, as well as comparative data from prior years.

In FY 2024, FDA had net collections of $569 million in human generic drug user fees, spent $613 million in user fees for human generic drug activities, and carried $89 million forward for future fiscal years.

GDUFA user fees and non-user fee appropriations in FY 2024 supported 2,317 full-time equivalents, including salaries and operational expenses, to support human generic drug activities. Detailed program accomplishments can be found in the GDUFA Performance Report.[1]

[1] The GDUFA Performance Report is available at https://www.fda.gov/about-fda/user-fee-performance-reports/gdufa-performance-reports.

Report Overview

A. Scope

This financial report addresses the implementation and use of human generic drug user fees by the Food and Drug Administration (FDA or Agency) during the period of October 1, 2023, through September 30, 2024. It presents the legal conditions that FDA must satisfy to collect and spend human generic drug user fees each fiscal year and documents how FDA determined that it had met those requirements. In addition, this report presents summary statements of fiscal year (FY) 2024 user fee program financials, revenue, obligations, carryover, total costs of human generic drug activities from both Generic Drug User Fee Amendments (GDUFA) fees and non-user fee appropriations, and full-time equivalents (FTEs).

B. Report Requirements

In accordance with section 744C(b) of the Federal Food, Drug, and Cosmetic (FD&C) Act, FDA will publish an annual financial report on the implementation of the authority for generic drug user fees during each fiscal year and the use by FDA of the fees collected for such fiscal year. The purpose of this report is to meet these requirements.

FDA is required to submit the financial report to Congress no later than 120 days after the end of each fiscal year (September 30).

C. 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 FD&C Act, as amended by GDUFA, authorizes FDA to assess and collect fees from industry to supplement the non-user fee appropriations that the Agency spends on human generic drug activities.

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 5-year reauthorization helps ensure continued funding for FDA from FY 2023 through FY 2027 to support program innovation, evaluation, and 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, and under the related GDUFA III commitment letter[2] 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.

[2] See https://www.fda.gov/media/153631/download.

Exhibit 1 outlines the GDUFA III fee structure.

Exhibit 1: 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 and affiliate 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 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 adjustments for inflation, capacity planning, and operating reserve, as applicable. The fee amounts are published in the *Federal Register* 60 days before the start of each fiscal year.[3]

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.

Legal Conditions

The FD&C Act, as amended by GDUFA, specifies that three legal conditions must be satisfied each fiscal year for FDA to collect and spend human generic drug user fees.

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

Exhibit 2 describes those legal conditions and provides a brief explanation as to how those legal conditions were met for FY 2024.

Exhibit 2: GDUFA Legal Conditions

Legal Condition #	Details	
1	Description	The first condition requires that FDA's FY 2024 Salaries and Expenses Appropriation (excluding user fees) be greater than or equal to FDA's Salaries and Expenses Appropriation (excluding user fees) for FY 2009 multiplied by the adjustment factor for inflation.
	Met By	FDA's FY 2024 total appropriation for salaries and expenses was $3,522,150,000 (excluding user fees). FDA's FY 2009 Salaries and Expenses Appropriation (excluding user fees) was $2,683,653,832 after applying the FY 2024 adjustment factor. Therefore, the first legal condition was satisfied.
2	Description	The second condition requires that the fee amounts FDA may collect for each fiscal year must be specified in that year's user fee appropriation acts.
	Met By	The Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act (Division B of the Consolidated Appropriations Act, 2024, Public Law 118-42), which the President signed on March 9, 2024, specified that $613,538,000 shall be derived from human generic drug user fees and that human generic drug user fees collected in excess of this amount, if any, shall be appropriated for FDA. Therefore, the second legal condition was satisfied.
3	Description	The third condition requires a minimum spending from appropriations, excluding user fees, on human generic drug activities plus certain specified costs. The minimum spending from such appropriations is $97,000,000 multiplied by the adjustment factor.
	Met By	The specified minimum level for FY 2024 is $127,669,945. In FY 2024, FDA obligated $149,649,603 from appropriations (exclusive of user fees) for human generic drug activities plus certain specified costs. As FDA spent more than the specified minimum amount in FY 2024, the third legal condition was satisfied.

The legal conditions as stated in the FD&C Act and details on the adjustment factor are included in **Appendix B**.

Financial Information

This section provides an overview of the program financials for GDUFA for FY 2023 and FY 2024. These financials include user fee revenue, obligations, carryover, non-user fee appropriations, and FTEs.

D. User Fee Program Financials

Table 1 represents a summary of the GDUFA financial position for FY 2023 and FY 2024.

Table 1: Human Generic Drug User Fee Program Financials for FYs 2023 and 2024

Budgetary Resources	FY 2023	FY 2024
Total Carryover, Beginning of Year	$131,211,761	$120,195,906
Net Collections	$551,653,777	$569,359,591
Recoveries	$7,656,327	$12,580,852
Total Budgetary Resources	**$690,521,866**	**$702,136,349**
Obligations	**FY 2023**	**FY 2024**
Total Payroll	$359,048,484	$410,239,316
Total Operating	$113,234,967	$110,217,838
Total Rent	$15,134,245	$9,430,213
Total Shared Services	$82,908,264	$83,077,287
Total Obligations	**$570,325,960**	**$612,964,654**
Carryover	**FY 2023**	**FY 2024**
Total Carryover, End of Year	**$120,195,906**	**$89,171,695**

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 E** for more on user fee revenue.

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 GDUFA III. For more information on the allowable and excluded costs and activities, see **Appendix A**.

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. In this report, such fee funds are referred to as the "total carryover" or "GDUFA carryover." See **Section G** for more on carryover.

E. User Fee Revenue

User fees are set each year based on the target revenue amount. The process for setting the annual target revenue is defined in the statute and described below. **Table 2** outlines the annual target revenue amounts for FY 2023 and FY 2024.

Table 2: Human Generic Drug User Fee Revenue for FYs 2023 and 2024

Target Revenue	FY 2023	FY 2024
Base Revenue Amount	$582,500,000	$582,500,000
Inflation Adjustment	N/A	$22,631,290
Capacity Planning Adjustment	N/A	$8,406,725
Operating Reserve Adjustment	N/A	$0
Target Revenue Total	**$582,500,000**	**$613,538,000**

Target Revenue Total numbers have been rounded to the nearest thousand dollars.

Base Revenue Amount: The base amount for FY 2024 was the target revenue from FY 2023, not including any operating reserve adjustment.

Inflation Adjustment: The inflation adjustment maintains the purchasing power of fee funds in consideration of inflation. The adjustment is a composite measure that adjusts operating expenses by changes in the Consumer Price Index (CPI) and payroll-related expenses by changes in FDA's average personnel compensation and benefits amounts.

The inflation adjustment utilized in FY 2024 was 3.8852 percent.

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.

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.[4]

FDA recognizes that the revenue provided by the capacity planning adjustment will be allocated to and used by organizational review components engaged in direct review work to enhance resources and expand staff capacity and capability. By the end of FY 2024, CDER had hired 23 of the 25 established reviewer positions in support of the generic drug program.

Operating Reserve Adjustment: The operating reserve adjustment 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

[4] For more information on the capacity planning adjustment, see slides 8-38 at https://www.fda.gov/media/158999/download.

remain below that maximum threshold amount of carryover for operating reserves. See **Appendix C.2** for additional details.

No operating reserve adjustment was made in the setting of FY 2024 fees.

Target Revenue Total: This is the summation of the base revenue and the adjustments described above, rounded to the nearest thousand dollars. This amount is the amount that is intended to be collected in fees for the respective fiscal year and serves as the basis for setting the fee amounts. Five percent of this amount is to be derived from drug master file (DMF) fees, 33 percent is to be derived from ANDA fees, 20 percent is to be derived from generic drug facility fees, six percent is to be derived from active pharmaceutical ingredient facility fees, and 36 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.

Collections

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. The net collections are reported in **Table 1** above.

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").[5] Totals reported are after any refunds for the cohort year. To ensure the quality of the information provided in this financial report, FDA annually updates prior years' numbers reported in the current report to account for any collections or refunds processed after publication of the prior year reports.

In FY 2024, cohort year collections from application fees, program fees, and DMF fees fell short of the target revenue. The result contributed to a net decrease in the available carryover. See **Section G** below.

Tables 3a and **3b** outline GDUFA collections by fee type and cohort year. **Table 3c** shows the outstanding amounts that are still owed for Cohort Years 2023 and 2024 (the "Fees Receivable"). Refer to **Section C** for more background and information on the GDUFA III fee structure.

Table 3a: Human Generic Drug User Fee Collections by Fee Source for Cohort Year 2023

Fees Collected	Estimated†	Actual	% Diff
Application Fees	$192,225,000	$166,465,635	(13%)
Generic Drug Program Fees	$209,700,000	$199,012,003	(5%)
Facility Fees	$151,450,000	$154,761,021	2%
DMF Fees	$29,125,000	$30,221,098	4%
Total Collections	**$582,500,000**	**$550,459,757**	**(6%)**

[5] For example, a fee originally due in FY 2023 but received in FY 2024 is attributed in FY 2023 cohort year collections.

Fees Collected	Estimated†	Actual	% Diff

† Estimated values were taken from the Generic Drug User Fee Rates for FY 2023.[6]

Table 3b: Human Generic Drug User Fee Collections by Fee Source for Cohort Year 2024

Fees Collected	Estimated†	Actual	% Diff
Application Fees	$202,467,540	$178,294,984	(12%)
Generic Drug Program Fees	$220,873,680	$203,216,529	(8%)
Facility Fees	$159,519,880	$164,121,487	3%
DMF Fees	$30,676,900	$24,996,048	(19%)
Total Collections	**$613,538,000**	**$570,629,048**	**(7%)**

† Estimated values were taken from the Generic Drug User Fee Rates for FY 2024.[7]

Table 3c: Human Generic Drug User Fees Receivable by Fee Source for Cohort Years 2023 and 2024

Fees Receivable	Cohort Year 2023 Actual	Cohort Year 2024 Actual
Application Fees	$481,164	$20
Generic Drug Program Fees	$5,988,399	$8,317,148
Facility Fees	$2,436,024	$1,697,228
DMF Fees	$234,879	$0
Total Receivables	**$9,140,466**	**$10,014,396**

F. User Fee Obligations

GDUFA fees may be expended only for 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**.

Obligations of GDUFA fees increased in FY 2024 from FY 2023. This increase in GDUFA user fee obligations can be attributed to a growth in payroll costs and shared services. In FY 2024, total rent-related obligations of GDUFA fees decreased from FY 2023 as, under the statute, certain expenses previously eligible for GDUFA fee funding were no longer eligible and had shifted to non-user fee appropriations.[8]

Table 4 provides a comparison of user fee obligations by expense category during the past 2 fiscal years.

Table 4: Human Generic Drug User Fee Obligations by Expense Category for FYs 2023 and 2024

User Fee Obligations	FY 2023	FY 2024
Payroll	**$359,048,484**	**$410,239,316**
CBER	$248,671	$0
CDER	$295,747,308	$340,158,030

[6] https://www.federalregister.gov/documents/2022/10/12/2022-22099/generic-drug-user-fee-rates-for-fiscal-year-2023.
[7] https://www.federalregister.gov/documents/2023/07/28/2023-16081/generic-drug-user-fee-rates-for-fiscal-year-2024
[8] See section 744B(e)(2) of the FD&C Act.

User Fee Obligations	FY 2023	FY 2024
ORA	$40,357,466	$50,904,789
HQ	$22,695,039	$19,176,497
Operating	**$113,234,967**	**$110,217,838**
CBER	$0	$0
CDER	$93,006,393	$92,558,409
ORA	$8,704,461	$7,791,673
HQ	$11,524,113	$9,867,756
Total Rent	**$15,134,245**	**$9,430,213**
Total Shared Services	**$82,908,264**	**$83,077,287**
Total Obligations	**$570,325,960**	**$612,964,654**

Payroll and Operating Costs: 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, scientific 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, ORA, and HQ.

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

For operating activities (e.g., certain contracting services), user fee funds are allocated based on the proportion to which those activities support human 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, located within the Working Capital Fund (WCF), that provide support for activities across the Agency, such as human resources and information technology (IT). **Appendix C.1** provides a full list of the offices that constitute the WCF.

Table 5 provides the total amount obligated by each FDA organization on human generic drug activities for the past 5 fiscal years, including both user fee and non-user fee appropriations. As illustrated by the table, costs have increased over time, and the percentage spent by each FDA organizational component has remained steady.

Table 5: GDUFA Program Historical Trend of Total Costs by Organization as of September 30 for FYs 2020 to 2024

Total Cost by Organization	FY 2020	FY 2021	FY 2022	FY 2023	FY 2024
CBER Spent($)	$869,426	$830,315	$881,356	$627,774	$543,146
CBER Percentage(%)	0%	0%	0%	0%	0%
CDER Spent($)	$564,114,473	$556,577,415	$547,764,711	$592,528,295	$604,289,275
CDER Percentage(%)	81%	82%	80%	80%	80%
ORA Spent($)	$88,292,430	$79,492,817	$88,908,847	$102,581,713	$106,570,940
ORA Percentage(%)	13%	12%	13%	14%	14%
HQ Spent($)	$44,808,856	$45,015,578	$43,847,098	$48,122,303	$46,953,723
HQ Percentage(%)	6%	7%	6%	6%	6%
Total Spent	**$698,085,185**	**$681,916,125**	**$681,402,012**	**$743,860,085**	**$758,357,084**

G. 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. This balance is referred to as the "total carryover" or "GDUFA carryover."

The net change in GDUFA carryover each year is equal to net collections minus net obligations. This is demonstrated best in **Table 6** below.

Table 6: Human Generic Drug User Fee Carryover for the Current Reauthorization Period (GDUFA III)

Current Carryover	FY 2023	FY 2024
Total Carryover, Beginning of Year	**$131,211,761**	**$120,195,906**
Net Collections	$551,653,777	$569,359,591
Recoveries	$7,656,327	$12,580,852
Total Obligations	($570,325,960)	($612,964,654)
Total Carryover, End of Year	**$120,195,906**	**$89,171,695**

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

GDUFA III adds an operating reserve adjustment, starting in FY 2024. This requires a downward adjustment if the carryover amount exceeds 12 weeks of operations. It also enables a discretionary upward adjustment to certain levels. These levels are not more than 8 weeks of operations in FY 2024, 9 weeks of operations in FY 2025, and 10 weeks of operations in FY 2026 and FY 2027.

Table 7 details the GDUFA carryover at the end of FY 2023 and FY 2024.

Table 7: Human Generic Drug User Fee Carryover for FYs 2023 and 2024

Carryover	FY 2023	FY 2024
Total Carryover, End of Year	**$120,195,906**	**$89,171,695**
Future Year Refunds Allowance, Set Aside	($4,000,000)	($4,000,000)
Carryover Net of Set Aside, End of Year	**$116,195,906**	**$85,171,695**

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. For that purpose, a total of $4,000,000 in fee funds available for obligation was set aside for FY 2024. See **Appendix C.3** for additional details.

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

The operations in FY 2024 resulted in a net decrease of the carryover of $31,024,211, from $120,195,906 at the end of FY 2023 to $89,171,695 at the end of FY 2024. While fee collections were lower than estimated by seven percent overall (see **Table 3b**), obligations for the year (see **Table 4**) were nearly as much as the target revenue (see **Table 2**). The net impact was a decrease in the carryover balance in FY 2024 that was primarily driven by actual collections being less than estimated in FY 2024. The total available carryover at the end of FY 2024 provides for approximately 7 weeks of operating reserves in FY 2025 to mitigate the financial risks to the program.[9]

Table 8 reflects the historical amounts of fees collected, obligated, and carried over during the previous authorization periods.

Table 8: Historical Human Generic Drug User Fee Carryover by Reauthorization Period

Historical Carryover	GDUFA I (FY 2013 2017)	GDUFA II (FY 2018 2022)
Total Carryover, Beginning of Authorization Period	**$0**	**$142,412,048**
Net Collections	$1,581,961,651	$2,519,493,966
Recoveries	$6,688,743	$36,102,134
Total Obligations	($1,446,238,346)	($2,566,796,386)
Total Carryover, End of Authorization Period	**$142,412,048**	**$131,211,761**

H. Non-User Fee Appropriations

For FDA to obligate user fees collected under GDUFA, a certain amount of non-user fee appropriations must be spent on human generic drug activities plus certain specified costs during that fiscal year. This is often referred to as a "non-user fee spending trigger."[10] The spending trigger was $127,669,945 for FY 2024, less than the

[9] To calculate the available operating reserves by week, the FY 2025 target revenue amount is divided by 52 weeks in a year to generate the 1-week operating amount. The total available carryover is then divided by the 1-week operating amount.

[10] The statute provides that this requirement is met if an amount that is not more than 10 percent below the minimum level is spent (see sections 744B(i)(2)(A)(ii) and 744B(i)(2)(B) of the FD&C Act).

$149,649,603 for non-user fee appropriations obligated for FY 2024, meaning the trigger was met.

The non-user fee spending trigger amount is determined by multiplying a base amount ($97 million) times the adjustment factor for the applicable fiscal year. See **Appendix B.1** for more details on the adjustment factor.

Table 9 provides the total amounts spent on human generic drug activities for the past 5 fiscal years, as well as the dollar amounts and percentages derived from user fee and non-user fee appropriations.

Table 9: Historical Generic Drug User Fee Obligations by Funding Source as of September 30 for FYs 2020 to 2024

Obligations by Funding Source	FY 2020	FY 2021	FY 2022	FY 2023	FY 2024
Non-User Fee Appropriations Obligated: Total ($)	$157,391,163	$145,666,185	$133,415,075	$173,534,125	$145,392,430
Non-User Fee Appropriations Obligated: Percent (%)	23%	21%	20%	23%	19%
User Fee Funds Obligated: Total ($)	$540,694,021	$536,249,940	$547,986,937	$570,325,961	$612,964,654
User Fee Funds Obligated: Percent (%)	77%	79%	80%	77%	81%
Total Obligated	**$698,085,184**	**$681,916,125**	**$681,402,012**	**$743,860,085**	**$758,357,084**

I. Full-Time Equivalents

"FTE employment" (often referred to as "staff year"), as defined by section 85 of the Office of Management and Budget (OMB) Circular A-11, means the total number of regular straight-time hours—not including overtime or holiday hours—worked by employees, divided by the number of compensable hours applicable to each fiscal year. Annual leave, sick leave, compensatory time off, and other approved leave categories are considered "hours worked" for purposes of defining FTE employment.

As it specifically relates to GDUFA, FTEs are referred to as "Process FTEs," which are how FDA measures a paid staff year devoted to the GDUFA program. In the table below, an FTE does not represent an accounting of individual people but rather an estimate of labor hours expended on GDUFA-supported activities (i.e., human generic drug activities). Funding is distributed to FDA's Centers based on the workload to support payroll to accomplish the program goals.

Table 10 presents total Process FTE levels, paid from user fee and non-user fee appropriations, that support human generic drug activities. The data covers the past 5 fiscal years and is arranged by FDA's organizational components (CBER, CDER, ORA, and HQ). Staff in the consolidated shared services programs (e.g., procurement, IT services, etc.) are included in the FTE levels for various components.

Table 10: Historical Trend of Total Process FTEs Utilized by Organization as of September 30 for FYs 2020 to 2024

Total Process FTEs	FY 2020	FY 2021	FY 2022	FY 2023	FY 2024
CBER	2	2	2	2	1
CDER	1,689	1,692	1,668	1,754	1,832
ORA	288	298	305	324	362
HQ	127	117	123	129	122
TOTAL	**2,106**	**2,110**	**2,098**	**2,209**	**2,317**

Management Assurance

FDA maintains a strong internal control culture in order to support data-driven decision making, reliable financial forecasting, and accountability for resource use and to ensure compliance with laws, including:

- Federal Managers' Financial Integrity Act (FMFIA) – This act requires agencies to establish internal controls that provide a reasonable assurance of effective and efficient operations, compliance with applicable laws, and reliable financial reporting. This act requires agencies to comply with federal financial management systems requirements, ensuring that transactions are properly recorded, and financial reports are reliable.
- OMB Circular A-123 – This sets the standards for internal controls and requires agencies to implement internal control assessments, including managing risks and ensuring accountability.
- Government Accountability Office Standards for Internal Control (Green Book) – This provides the framework for designing, implementing, and operating an effective internal control system within the federal government.
- Improper Payments Elimination and Recovery Act – This requires agencies to identify and reduce improper payments and recover overpayments when they occur.
- Federal Information Security Modernization Act – This addresses internal controls related to information security, ensuring the protection of federal information systems.

Additionally, FDA established three councils to govern oversight and accountability:

- Office of Finance, Budget, Acquisitions, and Planning (OFBAP) Strategic Council: The OFBAP Strategic Council strengthens FDA's financial management processes, enhancing integrity, accountability, and compliance with federal regulations. Membership: Chief Financial Officer (CFO) serves as the Executive Sponsor and the Deputy Chief Financial Officer chairs the council, with OFBAP Directors and representatives from each FDA Center and Office.
- Enterprise Risk Management Council: The council oversees FDA's Enterprise Risk Management Program, managing the Agency's Enterprise Risk Profile and ensuring alignment with FMFIA, OMB Circular A-123, OMB Circular A-11, the Green Book, and Department of Health and Human Services guidelines. Membership: The council is chaired by the Chief Operating Officer, with a Center Director as Co-Chair and the CFO as President Pro Tempore. Senior executive representatives from each FDA Center and Office serve as members.
- User Fee Financial Management Committee: The committee oversees and ensures FDA's compliance with sound financial management practices and statutory provisions governing user fees, providing oversight for resource needs, financial planning, and forecasting. The CFO serves as the committee Chairman, a Program Representative serves as the Program Vice Chairman, and voting members include the Executive Officers from each FDA Center and Office.

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. 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.[11] 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. Conditions for Assessment and Use of Fees

B.1. Adjustment Factor

To determine whether the legal conditions are satisfied, FDA must calculate and incorporate an "adjustment factor" (defined in section 744A(3) of the FD&C Act as amended) in its assessments of the first and third conditions. The FD&C Act states:

> The term "adjustment factor" applicable to a fiscal year is the Consumer Price Index for all urban consumers (all items, United States city average) for October of the preceding fiscal year divided by such Index for October 2011.

The Consumer Price Index (CPI) for October 2022, the October of the fiscal year preceding FY 2024, was 298.012. The CPI for October 2011 was 226.421. Dividing the CPI of October 2022 by the CPI of October 2011 yields an adjustment factor of 1.316185 (rounded to the sixth decimal place) for FY 2024.

[11] 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."

B.2. Legal Conditions

Exhibit 6 below provides the details regarding each legal condition, as quoted from the FD&C Act.

Exhibit 6: Legal Conditions

Legal Condition #	FD&C Act Section	Details
1	744B(h)(1)	Fees under subsection (a) shall be refunded for a fiscal year beginning after fiscal year 2012, unless appropriations for salaries and expenses of the Food and Drug Administration for such fiscal year (excluding the amount of fees appropriated for such fiscal year) are equal to or greater than the amount of appropriations for the salaries and expenses of the Food and Drug Administration for fiscal year 2009 (excluding the amount of fees appropriated for such fiscal year) multiplied by the adjustment factor (as defined in section 744A) applicable to the fiscal year involved.
2	744B(i)(2)(A)(i)	The fees authorized by this section—(i) subject to subparagraph (C), shall be collected and available in each fiscal year in an amount not to exceed the amount specified in appropriation Acts, or otherwise made available for obligation, for such fiscal year.
3	744B(i)(2)(A)(ii)	The fees authorized by this section— (ii) shall be available…(II) for fiscal year 2024 and each subsequent fiscal year, to defray the costs of human generic drug activities (including such costs for an additional number of full-time equivalent positions in the Department of Health and Human Services to be engaged in such activities), only if the sum of the amounts allocated by the Secretary for such costs, excluding costs paid from fees collected under this section, plus other costs for the maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, and other necessary materials and supplies in connection with human generic drug activities, is no less than $97,000,000 multiplied by the adjustment factor defined in section 744A(3) applicable to the fiscal year involved.

C. Supplemental Financial Information

C.1. Shared Services Costs

FDA has several shared service programs, located within the WCF, that provide support across the user fee programs. The shared service programs in FY 2024 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 Enterprise Management Services:** Provides strategic and tactical enterprise-wide services through development and implementation of administrative policies, programs, and initiatives.
- **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 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, Acquisitions, and Planning:** 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 diversity, fairness, open communication, personal accountability, trust, and mutual respect.
- **Office of Laboratory Safety:** Reinforces FDA's expectations for safety and laboratory security, enhances communications among FDA safety staff, and provides program support.
- **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 Talent Solutions:** Provides high quality and efficient solutions that enable FDA to hire a talented and qualified workforce.

C.2. Operating Reserve Adjustment

In GDUFA III, Congress established authority for the operating reserve adjustment to provide a mechanism to support the management of the carryover balance from year to year. 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 such operating reserves, FDA is required to decrease fees for that fiscal year to reduce the operating reserve to not more than 12 weeks.

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 *Federal Register* notice publishing GDUFA 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 1-week operating amount. The 1-week operating amount is then multiplied by the applicable threshold amounts noted above (i.e., for FY 2024,

the increase threshold is for not more than 8 weeks, and the decrease threshold is 12 weeks).

C.3. 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.

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 the 5-year plan, that future year refunds set asides are to be estimated using a 3-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 that 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 to FY 2027, the amount is currently estimated to be $6,510,000 for each year.

Table 11 outlines the actual refunds by fiscal year that are used to calculate the currently estimated refunds set aside to be implemented starting in FY 2025.

Table 11: Human Generic Drug User Fee Estimated Future Year Refunds Allowance, Set Aside

Estimated Refunds Set Aside	FY 2021	FY 2022	FY 2023	3 Year Average*
Actual Refunds	($6,577,461)	($5,479,546)	($7,471,831)	($6,510,000)

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

The FY 2024 actual refunds for GDUFA were $5,053,995.

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