Financial Report to Congress

Prescription Drug User Fee Amendments

FY 2024

Table of Contents

Executive Summary

The Prescription Drug User Fee Amendments (PDUFA) to the Federal Food, Drug, and Cosmetic (FD&C) Act require the Food and Drug Administration (FDA or Agency) to report annually on the financial aspects of the PDUFA program implementation. This is the second report under the seventh authorization of PDUFA (PDUFA VII) 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 PDUFA user fees:

1. FDA's overall Salaries and Expenses Appropriation (excluding user fees) must be equal to, or greater than, FDA's FY 1997 Salaries and Expenses Appropriation (excluding user fees), multiplied by the adjustment factor.

2. The fee amounts FDA may collect must be specified in appropriation acts.

3. FDA must spend at least as much from appropriated funds (excluding user fees) for the review of human drug applications, plus certain specified costs, as FDA spent in FY 1997 for the review of human drug applications, multiplied by the adjustment factor.

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 prescription drug user fee collections, expenditures, and carryover, as well as comparative data from prior years.

In FY 2024, FDA had net collections of $1.381 billion in prescription drug user fees, spent $1.377 billion in user fees for the human drug review process, and carried $297 million forward for future fiscal years.

PDUFA user fees and non-user fee appropriations in FY 2024 supported 5,001 full-time equivalents, including salaries and operational expenses, to support the process for the review of human drug applications. Detailed program accomplishments can be found in the PDUFA Performance Report.[1]

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

Report Overview

A. Scope

This financial report addresses the implementation and use of prescription 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 prescription 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 the process for the review of human drug applications from both Prescription Drug User Fee Amendments (PDUFA) fees and non-user fee appropriations, and full-time equivalents (FTEs).

B. Report Requirements

In accordance with section 736B(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 human drug user fees during such 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 PDUFA, FDA assesses and collects fees from drug application holders to fund the human drug review process. The FD&C Act, as amended by PDUFA, authorizes FDA to assess and collect fees from industry to supplement the non-user fee appropriations that the Agency spends on the process for the review of human drug applications.

The Prescription Drug User Fee Act was enacted in 1992 and reauthorized in 1997 (PDUFA II), 2002 (PDUFA III), 2007 (PDUFA IV), 2012 (PDUFA V), 2017 (PDUFA VI), and most recently in 2022 (PDUFA VII). The FDA User Fee Reauthorization Act of 2022 includes the seventh authorization of PDUFA, also known as PDUFA VII, and authorizes continued funding for FDA from FY 2023 through FY 2027 to continue to build upon the successes of the existing review program and its performance goals while implementing enhancements as committed to under the PDUFA VII Commitment Letter.[2] PDUFA has delivered tremendous public health benefits by enhancing FDA's capacity to review novel drug products so that safe and effective products can come to the market more quickly.

FDA spends PDUFA user fee collections and non-user fee appropriations to hire, support, and maintain personnel for the review of human drug applications to ensure

[2] The PDUFA VII Commitment Letter is available at https://www.fda.gov/media/151712/download?attachment.

that safe, effective, and high-quality prescription drugs are available to the American public.

The fee structure remains unchanged from PDUFA VI with two types of fees: application fees and program fees.

Exhibit 1 outlines the PDUFA VII fee structure.

Exhibit 1: PDUFA VII Fee Structure

Fee Type	Definition
Application: With Clinical Data	A human drug application for which clinical data (other than bioavailability or bioequivalence studies) with respect to safety or effectiveness are required for approval is assessed a full application fee when the application is submitted.
Application: Without Clinical Data	A human drug application for which clinical data (other than bioavailability or bioequivalence studies) with respect to safety or effectiveness are not required for approval is assessed one-half of a full fee when the application is submitted.
Program	Prescription drug product program fees are assessed annually for eligible prescription drug products. The program fees are assessed annually for each drug product that is identified in an approved New Drug Application (NDA) or Biologics License Application (BLA) as of October 1st of such fiscal year, or in some cases, when a drug is returned to marketing during the fiscal year.

The statute specifies how the fees must be calculated each fiscal year, including adjustments for inflation, strategic hiring and retention, capacity planning, additional dollar amounts, operating reserve, and additional direct costs. The fee amounts are published in the *Federal Register* 60 days before the start of each fiscal year.[3]

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

Legal Conditions

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

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

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

Exhibit 2: PDUFA Legal Conditions

Legal Condition #	Details	
1	Description	The first condition requires that FDA's FY 2024 Salaries and Expenses Appropriation (excluding user fees and rent payments to the General Services Administration (GSA)[4]) be greater than or equal to FDA's Salaries and Expenses Appropriation (excluding user fees) for FY 1997, multiplied by the adjustment factor for inflation.
	Met By	FDA's FY 2024 total appropriation for salaries and expenses were $3,522,150,000 (excluding user fees and rent payments to GSA). FDA's FY 1997 Salaries and Expenses Appropriation (excluding user fees) was $1,543,658,545 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 $1,422,104,000 shall be derived from prescription drug user fees and that prescription 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, for the review of human drug applications plus certain specified costs. The minimum spending from such appropriations is the amount that FDA spent on the PDUFA program in FY 1997, multiplied by the adjustment factor.
	Met By	The specified minimum level for FY 2024 is $278,545,507. In FY 2024, FDA obligated $395,025,578 from appropriations (exclusive of user fees) for the review of human drug applications 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**.

[4] FDA has not included payments to GSA Rent in the current-year salaries and expenses amount for purposes of this trigger because in FY 1997, rent payments were not included in the Salaries and Expenses Appropriation.

Financial Information

This section provides an overview of the program financials for PDUFA 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 PDUFA financial position for FY 2023 and FY 2024.

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

Budgetary Resources	FY 2023	FY 2024
Total Carryover, Beginning of Year	$287,669,825	$275,515,520
Net Collections	$1,222,888,088	$1,381,243,203
Recoveries	$16,400,359	$17,785,244
Total Budgetary Resources	**$1,526,958,272**	**$1,674,543,967**
Obligations	**FY 2023**	**FY 2024**
Total Payroll	$813,591,182	$918,155,812
Total Operating	$238,169,945	$253,766,997
Total Rent	$48,137,237	$28,672,907
Total Shared Services	$151,544,388	$176,577,203
Total Obligations	**$1,251,442,752**	**$1,377,172,919**
Carryover	**FY 2023**	**FY 2024**
Total Carryover, End of Year	**$275,515,520**	**$297,371,048**

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 PDUFA fee funds broken out by major expense categories. PDUFA fees may be expended only for costs to support the "process for the review of human drug applications," as defined in PDUFA VII. For more information on the allowable and excluded costs and activities, see **Appendix A**.

Carryover: PDUFA fees collected, appropriated, and not obligated at the end of the fiscal year remain available to support the process for the review of human drug applications in future fiscal years. In this report, such fee funds, plus certain user fee

funds that FDA has collected that are considered unappropriated, are referred to as the "total carryover" or "PDUFA carryover." See **Section 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: Prescription Drug User Fee Revenue for FYs 2023 and 2024

Target Revenue	FY 2023	FY 2024
Annual Base Revenue Amount	$1,151,522,958	$1,256,844,387
Inflation Adjustment	$18,889,583	$48,886,219
Strategic Hiring and Retention Adjustment	$9,000,000	$4,000,000
Capacity Planning Adjustment	$11,658,153	$23,936,069
Additional Dollar Amounts	$65,773,693	$25,097,671
Operating Reserve Adjustment	$9,088,943	$0
Additional Direct Costs Adjustment	$44,386,150	$63,339,404
Target Revenue Total	**$1,310,319,000**	**$1,422,104,000**

Target Revenue Total is rounded to the nearest thousand dollars.

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

Inflation Adjustment: The inflation adjustment maintains the purchasing power of fee funds in consideration of inflation. This 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 3.8896 percent.

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

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

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. With its portion of the capacity planning adjustment funds, CDER hired 34 of the 38 established reviewer positions in support of the human drug program by the end of FY 2024. CBER established 34 reviewer positions, 25 of which were filled by the end of FY 2024.

Additional Dollar Amount: PDUFA VII provides for the hiring of 352 new positions to support the workload associated with initiatives established or expanded by PDUFA VII. These 352 new positions are scheduled to be hired over the 5 fiscal years of PDUFA VII. The dollar amounts for the new positions committed to being hired each year are specified in the statute.

Operating Reserve Adjustment: The operating reserve adjustment is intended to enhance the flexibility of the PDUFA program to manage financial risks while ensuring the program avoids accruing unnecessarily high carryover balances. For FY 2024, PDUFA VII provides minimum and maximum operating reserve balances of an amount equivalent to 9 to 14 weeks of operations. If operating reserves are expected to exceed 14 weeks of operations, this adjustment would lower the annual revenue amount by a commensurate amount. If operating reserves are expected to be lower than 9 weeks of operations, this adjustment would increase the annual revenue amount by a commensurate amount. The approximately $78 million in user fee collections that are considered unappropriated are not included in the calculation for the purposes of the operating reserve adjustment. The minimum amount increases to an equivalent of 10 weeks of operations starting in FY 2025. See **Appendix C.2** for additional details.

Additional Direct Cost Adjustment: The additional direct costs provide for non-payroll expenses associated with PDUFA VII initiatives. The amounts for each year are specified in the statute and are adjusted for inflation based on the DC-area CPI.

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. Eighty percent of this amount is allocated to be collected from program fees; 20 percent of this amount is allocated to be collected from application fees.

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

Collections

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.

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

In FY 2024, cohort year collections from application fees fell short of the target. Collections from application fees are impacted both by the overall number of NDA and BLA submissions and the number of waivers and exemptions. The resulting number of full application equivalents (FAEs) that pay a fee are historically volatile and therefore difficult to predict. See **Waivers, Exceptions, and Exemptions** below.

Tables 3a and **3b** outline PDUFA 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 PDUFA VII fee structure.

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

Fees Collected	Estimated†	Actual	% Diff
Application Fees	$262,063,800	$160,480,287	(39%)
Program Fees	$1,048,255,200	$1,098,693,610	5%
Total Collections	**$1,310,319,000**	**$1,259,173,897**	**(4%)**

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

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

Fees Collected	Estimated†	Actual	% Diff
Application Fees	$284,420,800	$219,641,663	(23%)
Program Fees	$1,137,683,200	$1,163,152,807	2%
Total Collections	**$1,422,104,000**	**$1,382,794,470**	**(3%)**

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

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

Fees Receivable	Cohort Year 2023 Actual	Cohort Year 2024 Actual
Application Fees	$0	$506,142
Program Fees	$9,045,986	$11,620,339
Total Receivables	**$9,045,986**	**$12,126,481**

Waivers, Exceptions, and Exemptions

FDA may waive, except, exempt, or reduce fees in certain circumstances:

- When a waiver is necessary to protect the public health.

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

[7] https://www.federalregister.gov/documents/2023/07/28/2023-15911/prescription-drug-user-fee-rates-for-fiscal-year-2024.

- When the assessment of a fee would present a significant barrier to innovation because of limited resources available to the person or other circumstances.
- When the applicant is a small business submitting its first human drug application to FDA for review.
- For certain fees for orphan designated, large volume parenteral and skin-test diagnostic products.
- For approved prescription drug products pharmaceutically equivalent to other marketed products.

Table 4 provides a summary of the total FAEs waived or excepted from FY 2018 to FY 2024, with a comparison to fee-paying FAEs.

Table 4: Total Application Fee Waivers and Exceptions as of September 30, 2024

Fiscal Year*	Orphan Exceptions	Small Business Waivers	Miscellaneous Waivers**	Total Non-Paying FAEs	Total Fee-Paying FAEs
FY 2018	44.75	11.875	6.5	63.125	68.875
FY 2019	40.75	20.75	4.5	66	80
FY 2020	59.75	14.5	5	79.25	56.75
FY 2021	45.75	21	2	68.75	78.875
FY 2022	51.75	20.75	2	74.5	45.125
FY 2023	45.625	22.5	1.5	69.625	49.5
FY 2024	45.625	15	0.5	61.125	54.25

* Data is updated annually for both the financial report and the fee-setting *Federal Register* notice to reflect new refunds.
** Waivers for Public Health and Barrier-to-Innovation.

Table 5 summarizes the total number of program fees waived, exempted, or excepted from FY 2018 to FY 2024, with a comparison to fee-paying programs.

Table 5: Total Program Fee Waivers, Exemptions, and Exceptions as of September 30, 2024

Fiscal Year*	Orphan Exemptions	Public Health Waivers	Barrier-to-Innovation Waivers	Exceptions**	Total Non-Paying Programs	Total Fee-Paying Programs
FY 2018	35	8	9	2,638	2,690	2,381
FY 2019	43	8	6	2,638	2,695	2,628
FY 2020	39	8	12	2,618	2,677	2,634
FY 2021	45	14	12	2,630	2,701	2,714
FY 2022	51	9	20	2,655	2,735	2,727
FY 2023	44	6	18	2,647	2,715	2,789
FY 2024	42	9	17	2,658	2,726	2,793

*Data is updated annually for both the financial report and the fee-setting *Federal Register* notice to reflect new refunds.
**Exceptions for products that are Large Volume Parenteral, Pharmaceutically Equivalent, and Skin-Test Diagnostic.

F. User Fee Obligations

PDUFA fees may be expended only for costs necessary to support the "process for the review of human drug applications," as defined in section 735(6) of the FD&C Act. For more information on the allowable and excluded costs, see **Appendix A**.

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

The PDUFA VII agreement stipulated that the Agency report each year on how certain PDUFA funds dedicated to the Sentinel program were spent across five categories. These are reported in **Appendix D**.

Table 6 provides a comparison of user fee obligations by expense category during the past 2 fiscal years.

Table 6: Prescription Drug User Fee Obligations by Expense Category for FYs 2023 and 2024

User Fee Obligations	FY 2023	FY 2024
Payroll	**$813,591,182**	**$918,149,134**
CBER	$135,448,033	$159,563,624
CDER	$626,848,682	$711,497,874
CDRH	$2,646,738	$3,058,788
ORA	$6,898,327	$7,653,639
HQ	$41,749,402	$36,381,887
Operating	**$238,169,945**	**$253,773,675**
CBER	$60,103,396	$73,196,127
CDER	$155,786,743	$160,904,091
CDRH	$1,058	$0
ORA	$1,192,391	$1,419,359
HQ	$21,086,357	$18,247,420
Total Rent	**$48,137,237**	**$28,672,907**
Total Shared Services	**$151,544,388**	**$176,577,203**
Total Obligations	**$1,251,442,752**	**$1,377,172,919**

Payroll and Operating Costs: These obligations provide for certain payroll and operating costs for which PDUFA fees may be expended to support the process for the review of human drug applications, as defined in the statute. These allowable activities include, for example, core regulatory review functions, pre-approval inspections, guidance and policy development activities, scientific activities, and management and

[8] See section 736(f)(3) of the FD&C Act.

administrative functions that support the PDUFA program. See **Appendix A** for a listing of those activities. The payroll and operating costs associated with the PDUFA program are based on obligations attributed to CBER, CDER, CDRH, 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 drug activities. If an operating activity solely supports the process for the review of human drug applications, it can be fully funded by PDUFA fees (and/or non-user fee appropriations). If the operating activity is supported by multiple user fee programs, PDUFA fees may fund the activity up to the appropriate proportion of the benefit from such activity that accrues to human drug activities.

Rent Costs: 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. Since rent is an allowable support cost for the process for the review of human drug applications, a portion of those charges is paid from non-user fee appropriations, and a portion is paid from PDUFA fees.

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 7 provides the total amount obligated by each FDA organization on the PDUFA program for the past 5 fiscal years, including both user fee and non-user fee appropriations. As illustrated by the table, total program costs increased noticeably starting in FY 2023. This increase is a reflection of the additional resources negotiated for PDUFA VII enhancements.

Table 7: PDUFA Program Historical Trend of Total Costs by Organization as of September 30 for FYs 2020 and 2024

Total Cost by Organization	FY 2020	FY 2021	FY 2022	FY 2023	FY2024
CBER Spent($)	$306,794,435	$330,234,507	$328,872,841	$401,367,598	$401,573,364
CBER Percentage(%)	21%	22%	22%	24%	23%
CDER Spent($)	$1,018,915,025	$1,020,287,927	$999,122,621	$1,117,250,103	$1,203,487,797
CDER Percentage(%)	69%	68%	67%	66%	68%
CDRH Spent($)	$4,829,906	$5,525,062	$4,901,258	$4,634,817	$4,232,165
CDRH Percentage(%)	0%	0%	0%	0%	0%
ORA Spent($)	$39,118,104	$38,480,292	$42,305,499	$48,270,693	$50,040,691
ORA Percentage(%)	3%	3%	3%	3%	3%
HQ Spent($)	$101,487,458	$104,536,268	$105,399,656	$115,210,630	$112,864,480
HQ Percentage(%)	7%	7%	7%	7%	6%
Total Spent	**$1,471,144,928**	**$1,499,064,056**	**$1,480,601,875**	**$1,686,733,841**	**$1,772,198,497**

G. User Fee Carryover

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

The net change in PDUFA carryover each year is equal to net collections minus net obligations. This is demonstrated best in **Table 8** below.

Table 8: Prescription Drug User Fee Carryover for the Current Reauthorization Period

Current Carryover	FY 2023	FY 2024
Total Carryover, Beginning of Year	**$287,669,825**	**$275,515,520**
Net Collections	$1,222,888,088	$1,381,243,203
Recoveries	$16,400,359	$17,785,244
Obligations	($1,251,442,752)	($1,377,172,919)
Total Carryover, End of Year	**$275,515,520**	**$297,371,048**

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 the process for the review of human drug applications 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.

As noted in **Section E** above, PDUFA VII requires a downward adjustment if the carryover amount exceeds 14 weeks of operations. PDUFA VII also requires an upward adjustment to certain levels. These levels are 8 weeks of operating reserves in FY 2023, 9 weeks of operations in FY 2024, and 10 weeks of operations in FY 2025, FY 2026, and FY 2027. For PDUFA VII purposes, FDA interprets these thresholds to be based on the total available carryover. This includes all available fee funds, including set asides for future fiscal years, and excludes $78,850,995 in collections that are considered unappropriated and therefore currently unavailable for obligation. **Appendix C.2** provides more details on how the need for any operating reserve adjustment is assessed; **Appendix C.3** provides details on the amounts considered unappropriated.

Table 9 details the PDUFA carryover at the end of FY 2023 and FY 2024.

Table 9: Prescription Drug User Fee Carryover for FYs 2023 and 2024

Carryover	FY 2023	FY 2024
Total Carryover, End of Year	**$275,515,520**	**$297,371,048**
Unappropriated Amounts	($78,850,995)	($78,850,995)
Total Available Carryover, End of Year	**$196,664,525**	**$218,520,053**
Future Year Refunds Allowance, Set Aside	($20,000,000)	($25,229,000)
Carryover Net of Unavailable and Set Aside, End of Year	**$176,664,525**	**$193,291,053**

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

Unappropriated Amounts: FDA's PDUFA carryover includes $78,850,995 in fee collections that are considered unappropriated and therefore are currently unavailable for obligation. This amount is the cumulative total of fee collections that exceeded the annual level of PDUFA fees appropriated for a given year, prior to a technical fix that was added to the appropriations language to ensure that all fee collections would be considered appropriated. See **Appendix C.3** for additional details.

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

Future Year Refunds Allowance, Set Aside: FDA maintains a small amount to provide for any refunds, as a matter of prudent operations. In FY 2024, FDA estimated future year refund set asides using a 3-year average of actual refunds from the most recently completed prior fiscal years. The estimated amount of $25,229,000 in fee funds available for obligation is being set aside. See **Appendix C.4** for additional details.

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

The operations in FY 2024 resulted in a net increase of the carryover of $21,855,528, from $275,515,520 at the end of FY 2023 to $297,371,048 at the end of FY 2024. Although fee collections were lower than estimated by three percent overall (see **Table 3b**), obligations for the year (see **Table 6**) were also lower than the target revenue by approximately three percent (see **Table 2**). The Total Available Carryover at the end of FY 2024 provides for approximately 8 weeks of operating reserves in FY 2025 to mitigate the financial risks to the program.[9]

Table 10 reflects the historical amounts of fees collected, obligated, and carried over during the previous authorization periods.

Table 10: Historical Prescription Drug User Fee Carryover by Reauthorization Period

Historical Carryover	PDUFA I (FY 1993 1997)	PDUFA II (FY 1998 2002)	PDUFA III (FY 2003 2007)	PDUFA IV (FY 2008 2012)	PDUFA V (FY 2013 2017)	PDUFA VI (FY 2018 2022)
Total Carryover, Beginning of Authorization Period	**$0**	**$36,462,154**	**$22,683,224**	**$130,816,093**	**$178,468,707**	**$350,108,200**
Net Collections	$328,768,265	$680,152,170	$1,435,876,426	$2,848,504,459	$4,101,728,493	$5,255,137,583
Recoveries	$0	$0	$0	$0	$8,749,852	$76,080,566
Total Obligations	($292,306,111)	($693,931,100)	($1,327,743,557)	($2,800,851,845)	($3,938,838,851)	($5,393,656,524)
Total Carryover, End of Authorization Period	**$36,462,154**	**$22,683,224**	**$130,816,093**	**$178,468,707**	**$350,108,201**	**$287,669,825**

[9] To calculate the available operating reserves by week, the FY 2025 target revenue amount before the operating reserve adjustment and the additional direct cost adjustment 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.

H. Non-User Fee Appropriations

For FDA to obligate user fees collected under PDUFA, a certain amount of non-user fee appropriations must be spent on the process for the review of human drug applications plus certain other costs during that fiscal year. This is often referred to as a "non-user fee spending trigger." The spending trigger was $278,545,507 for FY 2024, less than the $395,025,578 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 the base amount of non-user fee appropriations spent on the human drug review process in FY 1997 (i.e., $147,959,689) times the adjustment factor for the applicable fiscal year. See **Appendix B.1** for more details on the adjustment factor.

Table 11 provides the total amounts spent on the PDUFA program for the past 5 fiscal years, as well as the dollar amounts and percentages derived from user fee and non-user fee appropriations.

Table 11: Historical Prescription 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 ($)	$395,658,018	$389,877,999	$350,874,209	$435,291,088	$395,025,578
Non-User Fee Appropriations Obligated: Percent (%)	27%	26%	24%	25%	23%
User Fee Funds Obligated: Total ($)	$1,075,486,910	$1,109,186,057	$1,129,727,666	$1,251,442,753	$1,377,172,919
User Fee Funds Obligated: Percent (%)	73%	74%	76%	75%	77%
Total Obligated	**$1,471,144,928**	**$1,499,064,056**	**$1,480,601,875**	**$1,686,733,841**	**$1,772,198,497**

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 PDUFA, FTEs are referred to as "Process FTEs," which are how FDA measures a paid staff year devoted to the PDUFA program. In the table below, an FTE does not represent an accounting of individual people but rather an estimate of labor hours expended on PDUFA activities. Funding is distributed to FDA's Centers based on the workload to support payroll to accomplish the program goals.

Table 12 presents total Process FTE levels, paid from user fee and non-user fee appropriations, that support the PDUFA program. The data covers the past 5 fiscal years and is arranged by FDA's organizational components (CBER, CDER, CDRH,

ORA, and HQ). Staff in the consolidated shared services organizations (e.g., procurement, IT services, etc.) are included in the FTE levels for various components.

Table 12: 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	835	893	918	977	999
CDER	3,055	3,119	3,196	3,341	3,528
CDRH	23	25	21	18	17
ORA	147	152	158	165	169
HQ	290	272	289	306	288
TOTAL	**4,350**	**4,461**	**4,582**	**4,807**	**5,001**

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 mandates 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 PDUFA

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

Exhibit 3: Included Activities

Included Activities	
1. All investigational new drug review activities, including amendments 2. All review activities for new drug applications (NDAs) and biologics license applications (BLAs), including supplements and amendments 3. Regulation and policy development activities related to the review of human drug applications 4. Development of product standards for products subject to review and evaluation 5. Meetings between FDA and the sponsor of a covered application or supplement 6. Review of labeling prior to approval of a covered application or supplement and the review of the initial pre-launch advertising 7. Review of post-marketing studies and clinical trials that have been agreed to by sponsors as a condition for approval 8. Inspections of facilities undertaken as part of the review of pending applications or supplements 9. Lot release activities for covered biological products	10. Assay development and validation to ensure batch-to-batch consistency and reliability for covered biological products 11. Monitoring of clinical and other research conducted in connection with the review of human drug applications 12. User Fee Act implementation activities 13. Research related to the human drug review process 14. Post-market safety activities with respect to drugs approved under human drug applications or supplements, including the following activities: collecting, developing, and reviewing safety information on approved drugs, including adverse event reports; developing and using improved adverse event data-collection systems, including information technology systems; developing and using improved analytical tools to assess potential safety problems, including access to external databases; implementing and enforcing section 505(o) (relating to post-approval studies and clinical trials and labeling changes) and section 505(p) (relating to risk evaluation and mitigation strategies); and carrying out section 505(k)(5) (relating to adverse event reports and post-market safety activities)

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

Exhibit 4: Included Expenses

Included Expenses
1. Officers and employees of FDA, contractors of FDA, advisory committees, and costs related to such officers, employees, committees, and contracts
2. Management of information, and the acquisition, maintenance, and repair of computer resources
3. Leasing and necessary scientific equipment[10]
4. Collecting user fees under section 736 of the FD&C Act and accounting for resources allocated for the review of human drug applications and supplements

The PDUFA program also excludes costs related to the following products and activities:

Exhibit 5: Excluded Products and Activities

Excluded Products	Excluded Activities
1. Generic drugs	1. Enforcement policy development not related to sections 505(o) and (p) of the FD&C Act
2. Over-the-counter drugs not associated with an NDA or NDA supplement	2. Post-approval compliance activities not related to the enforcement of sections 505(o) and (p) of the FD&C Act
3. Large-volume parenteral drug products approved before September 1, 1992	3. Advertising review activities once marketing of the product has begun
4. Certain allergenic extract products	4. Inspections unrelated to the review of covered applications, unless undertaken for the enforcement of sections 505(o) and (p) of the FD&C Act
5. Whole blood or a blood component for transfusion	5. Research unrelated to the human drug review process
6. In vitro diagnostic biologic products	
7. Certain drugs derived from bovine blood	
8. Biological products for further manufacturing use only	
9. A drug that is not distributed commercially and is the subject of an application or supplement submitted by a State or Federal Government entity	

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

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 735(8) 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 (CPI) for all urban consumers (all items, United States city average) for October of the preceding fiscal year divided by such Index for October 1996.

The CPI for October 2022, the October of the fiscal year preceding FY 2024, was 298.012. The CPI for October 1996 was 158.3. Dividing the CPI of October 2022 by the CPI of October 1996 yields an adjustment factor of 1.882577 (rounded to the sixth decimal place) for FY 2024.

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	736(f)(1)	Fees under subsection (a) shall be refunded for a fiscal year beginning after fiscal year 1997 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 the fiscal year 1997 (excluding the amount of fees appropriated for such fiscal year) multiplied by the adjustment factor applicable to the fiscal year involved.
2	736(g)(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	736(g)(2)(A)(ii)	The fees authorized by this section-(ii) shall be available to defray increases in the costs of the resources allocated for the process for the review of human drug applications (including increases in such costs for an additional number of full-time equivalent positions in the Department of Health and Human Services to be engaged in such process) over such costs, excluding costs paid from fees collected under this section, for fiscal year 1997 multiplied by the adjustment factor.

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

PDUFA VII updates the operating reserve adjustment to provide for a defined minimum required amount of operating reserves. This requires FDA to increase the annual revenue amount used to set fees, if needed, to provide for the defined minimum required amount of operating reserves. To minimize the impact on fee amounts from large changes in any year, this defined minimum amount is phased in: 8 weeks of operating reserves for FY 2023, 9 weeks of operating reserves for FY 2024, and 10 weeks of operating reserves for FY 2025 and subsequent fiscal years.

The statute also establishes a cap of 14 weeks of operating reserves of carryover user fees that can be maintained at the end of each fiscal year. Should FDA have carryover above this cap, it would be required to reduce the target revenue amount for the next fiscal year by a commensurate amount.

For the operating reserve adjustment, the available carryover amount, which excludes unappropriated amounts, is utilized. Approximately $78,850,995 in unappropriated collections does not count toward the 14-week carryover cap (see **Appendix C.3**). Should FDA make an operating reserve adjustment, either up or down, FDA must explain its rationale in the annual PDUFA fee-setting *Federal Register* notice.

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

To determine the FY 2023 end-of-year operating reserves of carryover user fees, the Agency assessed the operating reserve of carryover fees at the end of July 2023 and forecast collections and obligations in the fourth quarter of FY 2023 combined. During this exercise, the Agency underestimated the fourth quarter obligations by $94,899,220. This resulted in an estimated end-of-year FY 2023 operating reserve of carryover user fees, or $321,648,510, which equates to 12.3 weeks of operating reserves. Therefore, FDA did not increase the annual revenue amount used to set fees for FY 2024.

Had the correct fourth quarter obligations estimate been used, the estimated FY 2023 end-of-year reserve of carryover calculation would have been $206,749,290, which would have equated to 7.9 weeks of operating reserve, which would have been below the 9-week threshold and would have required an upward operating reserve adjustment.

C.3. Unappropriated Amounts

The unappropriated amount is the amount that FDA collected in user fees in excess of the amount specified in appropriation acts prior to FY 2010. FDA's ability to access and obligate these collections remains uncertain. **Table 13** outlines the excess user fees by fiscal year.

Table 13: Prescription Drug User Fees Collected, Collection Amounts Specified in Appropriation Acts, and Excess Amounts as of September 30, 2024

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

C.4. Future Year Refunds Allowance, Set Aside

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

Table 14 outlines the actual refunds by fiscal year that are used to calculate the estimated refund set aside.

Table 14: Prescription 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	($14,608,530)	($17,860,165)	($43,218,203)	($25,229,000)

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

The FY 2024 actual refunds for PDUFA were $28,265,814.

D. Sentinel Obligations

Under PDUFA VII, for FYs 2023 to 2027, FDA will annually report, in its PDUFA financial report, its obligations for updated PDUFA VI commitments for the PDUFA VII Sentinel Initiative. This reporting will provide details for spending categories (e.g., data infrastructure, analytical capabilities, safety issue analyses, dissemination of relevant product and safety information, and Sentinel system development). In FY 2024, Sentinel Initiative funds supported CDER's and CBER's performance of key safety surveillance activities of medical products, the expansion of new capabilities for post-

market surveillance, and the fulfillment of congressional mandates and PDUFA VII commitments.

The core Sentinel System functional areas in which the PDUFA VII funds are allocated include the following:

- **Data Infrastructure:** Provide data access and maintenance services
- **Analytic Capabilities:** Maintain or enhance the Sentinel System's analytic capabilities
- **Safety Issue Analyses:** Analyze (including answering regulatory questions) all safety surveillance issues and the general public health surveillance issues
- **Dissemination of Relevant Product and Safety Information:** Communicate ongoing studies, safety analyses programing packages, study results, sponsor notifications, and Sentinel System updates
- **Sentinel System Development:** Develop infrastructure operations, FDA staff training, and program management support

Table 15 shows how FDA expended $10 million in funds from PDUFA VII in FY 2024 for these core functional areas.

Table 15: Funding Allocation by Core Sentinel System Functional Area for FY 2024

Core Sentinel System Functional Areas	Funds Expended in FY 2024
Data Infrastructure	$1,234,297
Analytic Capabilities	$1,575,000
Safety Issue Analyses	$2,366,250
Dissemination of Relevant Product and Safety Information	$300,000
Sentinel System Development	$4,524,453
Total	**$10,000,000**

This report was prepared by FDA's Office of Financial Management.
For information on obtaining additional copies, please contact:

U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

This report is available on FDA's home page at https://www.fda.gov.