Financial Report to Congress

Prescription Drug User Fee Act of 1992

FY 2023

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Executive Summary

The Prescription Drug User Fee Act of 1992 (PDUFA), as amended, requires the Food and Drug Administration (FDA) to report annually on the financial aspects of PDUFA implementation. This is the first report under the seventh authorization of PDUFA (PDUFA VII) and covers fiscal year (FY) 2023.

PDUFA 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 and rent payments to the General Services Administration) 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 provided in appropriation acts.

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

FDA met the three legal conditions in FY 2023, 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 2023, FDA had net collections of $1.223 billion in prescription drug user fees, spent $1.251 billion in user fees for the human drug review process, and carried $276 million forward for future fiscal years.

PDUFA user fees and non-user fee appropriations in FY 2023 supported 4,807 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 FY 2023 PDUFA Performance Report.

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, 2022, through September 30, 2023. It presents the legal conditions that FDA must satisfy to collect and spend prescription drug user fees each year and documents how FDA determined that it had met those requirements. In addition, this report presents summary statements of FY 2023 fee collections, carryover, obligations of user fees, and total costs of the process for the review of human drug applications from both PDUFA fees and non-user fee appropriations.

B. Report Requirements

In accordance with section 736B(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), FDA will publish an annual financial report on the implementation of the authority for 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. Additional details on what is required to be included in this report are included in **Appendix A**.

C. Agency Background

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

Program Organization

There are five major FDA components that support the PDUFA program: the Center for Drug Evaluation and Research (CDER), the Center for Biologics Evaluation and Research (CBER), the Center for Devices and Radiological Health (CDRH), the Office of Regulatory Affairs (ORA), and Headquarters (HQ).

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

Exhibit 1: User Fee Program Components

Component	Mission
CDER	Protects and promotes public health by helping to ensure that human drugs are safe and effective, meet established quality standards, and are available to patients.
CBER	Ensures the safety, purity, potency, and effectiveness of biological products including vaccines, allergenics, blood and blood products, and cells, tissues, and gene therapies for the prevention, diagnosis, and treatment of human diseases, conditions, or injury.
CDRH	Protects public health by assuring that patients and providers have timely and continued access to safe, effective, and high-quality medical devices and safe radiation-emitting products.
ORA	Protects consumers and enhances public health by maximizing compliance of FDA-regulated products and minimizing risk associated with those products.
HQ	Provides FDA-wide program direction and administrative services to ensure that FDA's consumer and patient safety programs are effectively and efficiently managed.

User Fee Governance

Strong financial governance is needed because of the Agency's expanding level of user fees, the required reporting of FDA's performance commitments associated with these fees, and the need for FDA to convey how these fees are executed. These includes an

understanding of the design of these programs, clear financial plans, data-driven decisions on resource allocation, consistency and transparency about assumptions, reliable financial forecasting, and accountability for resources spent.

FDA's user fee governance process leverages the User Fee Financial Management Committee (UFFMC), which consists of senior financial, business operations, and program experts across the Agency that evaluate user fee resource needs, develop financial allocation plans, and forecast resource requirements—both programmatic and administrative—to support user fee financial decisions. The UFFMC is responsible for providing oversight and support of appropriate standards and policies to ensure FDA's compliance with sound financial management practices, as well as compliance with statutory provisions that authorize FDA to collect and spend user fees. The UFFMC receives policy guidance and strategic direction directly from FDA's Executive Committee relative to how the Agency will forecast and react to industry trends, plan and manage its research agenda in support of the user fee programs, and forecast its user fee workload. The UFFMC advises the Executive Committee and other Center- and Office-level bodies on a variety of financial and performance-related topics.

D. User Fee Background and Structure

Under PDUFA, FDA collects fees from drug application holders to fund the human drug review process. The FD&C Act, as amended by PDUFA, authorizes FDA to 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 FDA User Fee Reauthorization Act of 2022 (FUFRA) includes the seventh authorization of PDUFA, also known as PDUFA VII, and authorizes continued funding for FDA from FY 2023 through FY 2027 to support program operations, evaluation, and improvements. 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 help ensure that safe, effective, and high-quality prescription drugs are available to the American public.

Exhibit 2 outlines the PDUFA VII fee structure.

Exhibit 2: PDUFA VII Fee Structure

Fee Type		Definition
Application	*With Clinical Data*	A human drug application for which clinical data (other than bioavailability or bioequivalence studies) with respect to safety or effectiveness are required for approval is assessed **a full application fee** when the application is submitted.
	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 covered prescription drug products. The program fees are assessed for each such drug product that is identified in a drug application approved as of October 1st of such fiscal year.

The statute specifies how the fees must be calculated each fiscal year, including annual adjustments that must be made for inflation, strategic hiring and retention, capacity planning, additional dollar amounts, additional direct costs, and operating reserve. The fee amounts are published in the *Federal Register* each year, typically at the beginning of August.[1]

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 B** for a detailed list of allowable and excluded activities.

Appendix C provides more information on the history of the user fee program.

E. 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 3** describes those legal conditions and provides a brief explanation as to how those legal conditions were met for FY 2023.

[1] 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 3: PDUFA Legal Conditions

Legal Condition #	Details	
1	Description	The first condition requires that FDA's FY 2023 Salaries and Expenses Appropriation (excluding user fees and rent payments to the General Services Administration (GSA)) be greater than or equal to FDA's Salaries and Expenses Appropriation (excluding user fees and rent payments to GSA) for FY 1997, multiplied by the adjustment factor for inflation.
	Met By	In FY 2023, FDA's appropriation for salaries and expenses was $3,530,150,000 excluding user fees and rent payments to GSA. FDA's FY 1997 Salaries and Expenses Appropriation, excluding user fees and rent, was $1,432,691,050 after applying the FY 2023 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 President signed the Consolidated Appropriations Act, 2023 (Public Law 117-328) on December 29, 2022. It specified that $1,310,319,000 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, on the PDUFA program. The minimum spending from 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 2023 is $258,521,975. In FY 2023, FDA obligated $435,291,088 from appropriations (exclusive of user fees) for the review of human drug applications. Because FDA spent more than the specified minimum amount in FY 2023, the third legal condition was satisfied.

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

F. Strategic Plan

FDA is focused on utilizing PDUFA user fee and budget authority resources not only to achieve the performance goals and program enhancements outlined in the PDUFA VII Commitment Letter but also to comply with all applicable statutory provisions. In addition to dedicating resources to ensure that the program is sufficiently staffed to manage workload within agreed-upon performance timelines, FDA committed, in the

PDUFA VII Commitment Letter, to achieve several key performance enhancements. Below outlines key performance enhancements the program is continuing to implement over the course of PDUFA VII:

- Enhancing regulatory science and expediting drug development
    - Promoting innovation through enhanced communication between FDA and sponsors during drug development
    - Ensuring sustained success of the Breakthrough Therapy Program
    - Providing early consultation on the use of surrogate endpoints
    - Advancing the development of drugs for rare diseases
    - Advancing the development of combination products by CBER and CDER
    - Advancing real-world evidence for use in regulatory decision-making
- Enhancing regulatory decision tools to support drug development and review
    - Enhancing the incorporation of the patient's voice in drug development and decision-making
    - Enhancing the benefit-risk assessment in regulatory decision-making
    - Advancing model-informed drug development
    - Enhancing the capacity to review complex innovative designs
    - Enhancing the Drug Development Tools Qualification Pathway for biomarkers
- Enhancing and modernizing FDA's drug safety system
    - Modernizing and improving REMS assessments
    - Optimizing the Sentinel Initiative
- Making enhancements for reviewing product quality and approaching chemistry, manufacturing, and controls, as well as advancing the utilization of innovative manufacturing technologies
    - Enhancing communication between FDA and sponsors during application review
    - Enhancing inspection communication for applications, not including supplements
    - Creating alternative tools to assess the manufacturing facilities named in pending applications
    - facilitating the chemistry, manufacturing, and controls readiness for products with accelerated clinical development
    - Advancing the utilization and implementation of innovative manufacturing
- Enhancing CBER's capacity to support the development, review, and approval of cell and gene therapy products

    - Providing patient-focused drug development
    - Providing novel approaches to the development of cell and gene therapies
    - Providing expedited programs for the development of regenerative medicine therapies
    - Leveraging knowledge

- Supporting the review of new allergenic extract products

Additional details regarding how FDA will meet these commitments can be found in the Five-Year Forward View section of the PDUFA Five-Year Financial Plan.

G. Performance Summary

Performance Goals

FDA noted an increase in the number of original priority non-new molecular entity (non-NME) new drug applications (NDAs) in FY 2023, which was 100 percent higher, compared to the FY 2018 to FY 2022 5-year review workload average.[2] Other submission types, such as Class 1 Resubmitted NDAs and BLAs, Class 2 Resubmitted NDAs and BLAs, NDA and BLA manufacturing supplements requiring prior approval and NDA and BLA manufacturing supplements not requiring prior approval, also showed sustained increases in FY 2023, showing a 29, 23, 22, and 3 percent increase, respectively, when compared to the 5-year average.

As of September 30, 2023, FDA had completed 1,940 review actions for the FY 2023 cohort. FDA has the potential to meet or exceed the 90 percent performance level for 9 out of the 10 review performance goals for FY 2023.

FDA is currently meeting or exceeding 15 of the 29 procedural and processing goals (i.e., meeting management, procedural responses, and procedural notifications) for the FY 2023 cohort. There are 30 procedural and processing goals, but only 29 had applicable submissions. With 1,239 submissions under review and still within the PDUFA goal date, FDA has the potential to meet or exceed 18 of the 28 applicable procedural and processing goal commitments for FY 2023.[3] FDA missed the following procedural goals related to formal meeting management: meeting request responses for Type A, B End-of-Phase (EOP), and D; meeting scheduling for Type A, B, B(EOP), and C; final written responses for Type B and C; and meeting preliminary responses for Type B(EOP), D, and Initial Targeted Engagement for Regulatory Advice on CBER/CDER Products. A sustained high workload (which included marketing

[2] The original non-NME NDA workload count includes 15 non-NME NDAs within the 60-day filing date. These applications have not yet had a priority or standard review designation assignment, so this percentage may decrease once review designations are made for these applications.

[3] The highest potential performance is not calculated for the two PMR goals as is it not possible to accurately predict the number of pending submissions that will be approved with PMRs.

applications, Emergency Use Authorizations, and meeting requests) continues to constrain FDA's resources and contributed to missing the meeting management goals.

Program Commitments

Overall, by the end of FY 2023, PDUFA had met 55 program enhancement commitments and missed three commitments during the fiscal year. The missed commitments include the PDUFA hiring goal, timely quarterly posting of the first quarter's hiring data, and publication of a *Federal Register* notice on the continuation of the Model-Informed Drug Development program. With the exception of the hiring goal, the late commitments were completed within two weeks of their due date. Details on the program performance can be found in the FY 2023 PDUFA Performance Report.

Financial Information

This section provides an overview of the program financials for PDUFA for FYs 2022 and 2023. These financials include user fee revenue, obligations, carryover, non-user fee appropriations, and full-time equivalents (FTEs).

H. User Fee Program Financials

Table 1 represents a summary of the PDUFA financial position for FY 2022 and FY 2023. The financial notes referenced in this table can be found in **Appendix E**.

Table 1: Prescription Drug Collections, Obligations, and Carryover for FYs 2022 and 2023

Budgetary Resources	Notes	FY 2022	FY 2023
Target Revenue	Note 1	**$1,200,129,000**	**$1,310,319,000**
Total Carryover, Beginning of Year		$244,902,650	$287,669,825
Net Collections		$1,159,139,951	$1,222,888,088
Recoveries	Note 2	$13,354,888	$16,400,359
Total Budgetary Resources		**$1,417,397,490**	**$1,526,958,272**
Obligations	**Notes**	**FY 2022**	**FY 2023**
Total Payroll and Operating	Note 3	$938,386,578	$1,051,761,127
Total Rent	Note 4	$59,443,256	$48,137,237
Total Shared Services	Note 5	$131,897,830	$151,544,388
Total Obligations		**$1,129,727,665**	**$1,251,442,752**
Carryover	**Notes**	**FY 2022**	**FY 2023**
Total Carryover, End of Year		**$287,669,825**	**$275,515,520**[4]

Target Revenue has been rounded to the nearest thousand dollars.
All other numbers have been rounded to the nearest dollar.

- **Budgetary Resources:** The "Total Budgetary Resources" component of **Table 1** illustrates the sum of total user fee funding (i.e., the existing total carryover and additional user fee collections). The "Target Revenue" is the annual revenue amount established when fees for the fiscal year are set. "Net Collections" are the amounts collected during the fiscal year net of refunds that have taken place (see section I).

- **Obligations:** The "Obligations" component of **Table 1** shows the annual expenditure of PDUFA fee funds broken out by major expense categories.

[4] Total Carryover, End of Year in Table 1 includes Unappropriated Amounts and Future year refunds allowance, set aside. Refer to **Table 6** for more background and information regarding these amounts.

PDUFA fees may be expended only for costs to support the "process for the review of human drug applications," as defined in PDUFA. For more information on the allowable and excluded costs, see **Appendix B**.

- **Carryover:** 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 risk of a lapse in appropriations, so that FDA can continue performing human drug application reviews under such financial constraints.

I. User Fee Revenue

Table 2 outlines the annual target revenue amount for FY 2023. The financial notes referenced in this table can be found in **Appendix E**.

Table 2: Prescription Drug User Fee Revenue for FY 2023

Target Revenue	Notes	FY 2023
Base Amount		$1,151,522,958
Inflation Adjustment	Note 6	$18,889,583
Strategic Hiring and Retention Adjustment	Note 7	$9,000,000
Capacity Planning Adjustment	Note 8	$11,658,153
Additional Dollar Amounts	Note 9	$65,773,693
Operating Reserve Adjustment	Note 10	$9,088,943
Additional Direct Costs Adjustment	Note 11	$44,386,150
Target Revenue Total		**$1,310,319,000**

Target Revenue Total has been rounded to the nearest thousand dollars.
All other numbers have been rounded to the nearest dollar.

The process for setting the annual target revenue is defined in the statute. The base amount for FY 2023 is specified in the statute and is adjusted for the following factors, as applicable: inflation adjustment, strategic hiring and retention adjustment, capacity planning adjustment, additional dollar amounts (for negotiated FTE increases), operating reserve adjustment, and additional direct cost adjustment. The amount after the additional dollar amounts becomes the base revenue for each subsequent fiscal year. Please refer to the respective notes for more details and definitions of each adjustment.

PDUFA provides for the assessment of the following: (1) application fees are assessed on certain types of applications for the review of human drug and biological products and (2) prescription drug program fees are assessed on certain approved products. Generally, user fee collections are recognized and reported in the year that the fee was originally due (referred to as the "cohort year"). Totals reported for each fiscal year are net of any refunds for the cohort year. To ensure the quality of the information provided in this financial report, FDA annually updates prior years' numbers to account for any refunds processed after publication of the report.

Cohort Year
The year in which user fee collections are originally due and reported. For example, a fee originally due in FY 2022, but received in FY 2023, is attributed to FY 2022 cohort year collections.

FDA generally issues invoices for program fees twice a year: in August for fees due on October 1 and in December after the close of the fiscal year for any new program fees not previously assessed. The initial round of invoices for fiscal year 2023 was sent in October, instead of August, due to the late enactment of FUFRA on September 30, 2022.

Under PDUFA, fees collected and appropriated but not spent by the end of the fiscal year continue to remain available for FDA to spend in future years as they are classified as "no-year funding." The funds carried over from year to year are described in **Section K – User Fee Carryover**. An operating reserve adjustment exists to regulate the carryover over time. For PDUFA VII, the operating reserve adjustment was refined to support management of the carryover within minimum and maximum amounts. The maximum amount during PDUFA VII is 14 weeks. The minimum amount for FY 2023 was 8 weeks; this amount increases to 9 weeks in FY 2024 and 10 weeks in FY 2025.

In FY 2023, fee collections, most notably from applications, fell short of the target. The result was a net decrease in the carryover. See **Section K** below.

Tables 3a, **3b**, and **3c** outline PDUFA collections by fee source and cohort year. Refer to **Section D** for more background and information regarding these changes.

Table 3a: Prescription Drug User Fee Collections by Fee Source for Cohort Year 2022

Fees Collected	Estimated †	Actual	% Diff
Application Fees	$240,025,800	$140,664,462	(41%)
Program Fees	$960,103,200	$1,007,019,838	5%
Total Collections	**$1,200,129,000**	**$1,147,684,300**	**(4%)**

Numbers have been rounded to the nearest dollar.
† Estimated values were taken from the Prescription Drug User Fee Rates for FYs 2022 and 2023.

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

Fees Collected	Estimated †	Actual	% Diff
Application Fees	$262,063,800	$183,579,697	(30%)
Program Fees	$1,048,255,200	$1,077,266,228	3%
Total Collections	**$1,310,319,000**	**$1,260,845,925**	**(4%)**

Numbers have been rounded to the nearest dollar.
† Estimated values were taken from the Prescription Drug User Fee Rates for FYs 2022 and 2023.

Table 3c: Prescription Drug User Fees Receivable by Fee Source for Cohort Years 2022 and 2023

Fees Receivable	Cohort Year 2022 Actual	Cohort Year 2023 Actual
Application Fees	$0	$25
Program Fees	$6,280,021	$9,200,986
Total Receivables	**$6,280,021**	**$9,201,011**

Numbers have been rounded to the nearest dollar.

J. User Fee Obligations

PDUFA fees may be expended only for costs to support the "process for the review of human drug applications," as defined in PDUFA. For more information on the allowable and excluded costs. See **Appendix B**.

Table 4 provides a comparison of user fee obligations by expense category during the past two fiscal years. The financial notes can be found in **Appendix E**.

Table 4: Prescription Drug User Fee Obligations by Expense Category for FYs 2023 and 2022

User Fee Obligations	Notes	FY 2022	FY 2023
Payroll & Operating	Note 3		
CBER		$160,804,109	$195,551,429
CDER		$712,050,050	$782,635,425
CDRH		$3,176,215	$2,647,796
ORA		$7,671,485	$8,090,718
HQ		$54,684,720	$62,835,758
Total Rent	Note 4	$59,443,256	$48,137,237
Total Shared Services	Note 5	$131,897,830	$151,544,388
Total Obligations		**$1,129,727,665**	**$1,251,442,752**

Numbers have been rounded to the nearest dollar.

Total Obligations include payroll and operating, rent, and shared services costs. The details of each component of Total Obligations are as follows:

- **Payroll and Operating:** These obligations provide for all payroll and operating costs that support the allowable activities for which PDUFA fees may be expended, as set forth in the statute. Such payroll and operating activities include, for example, core regulatory review functions, pre-approval inspections, guidance and policy development activities, scientific activities, and management and administrative functions that support the PDUFA program.

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

- **Shared Services:** FDA has several shared services organizations that provide support across the user fee programs, such as human resources and IT.

Obligations in the PDUFA program increased in FY 2023 from FY 2022. This increase in PDUFA user fee obligations can be attributed to a growth in payroll and operating costs and shared services. FDA has continued to make investments in the PDUFA program to ensure that it is continuing to operate on a strong foundation, to deliver on its PDUFA VII commitments, and to modernize to meet evolving workload demands and scientific innovation.

The PDUFA VII agreement stipulated that the Agency, beginning with this annual financial report, report on how certain PDUFA funds dedicated to the Sentinel program were spent across five categories. See **Appendix F**.

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 and maintain performance on its review timelines.

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 established and filled 21 of 27 reviewer positions in support of the new drug program, with an additional five reviewers with future on-board dates. CBER established 10 reviewer positions, eight of which have been filled.

For historical context, **Table 5** provides the total amount spent by FDA and by each FDA organization on the PDUFA program for the past 5 fiscal years.

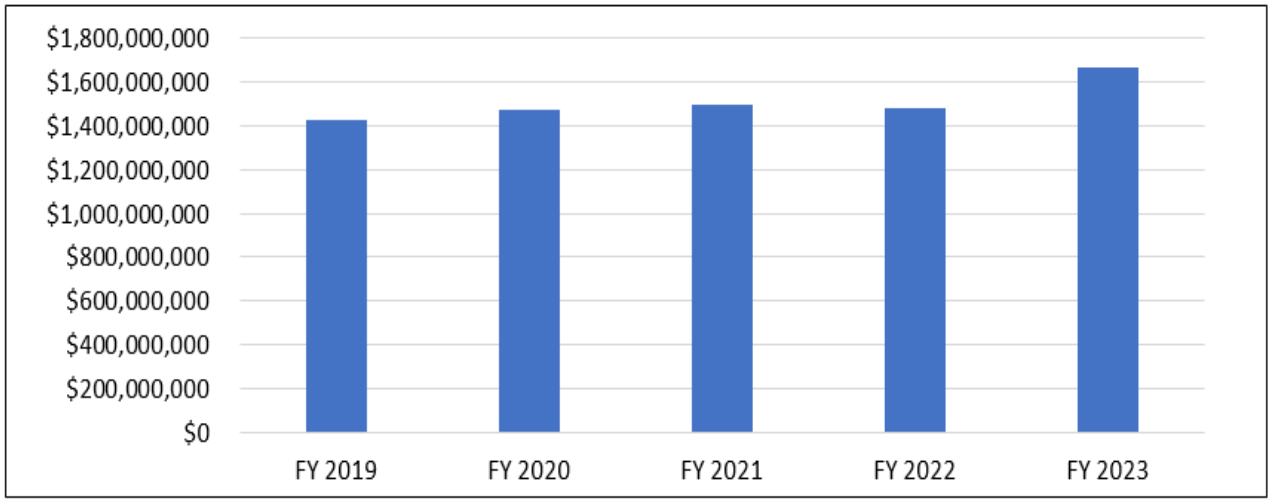
Table 5: PDUFA Program Historical Trend of Total Costs by Organization as of September 30 of Each Fiscal Year

	FY 2019	FY 2020	FY 2021	FY 2022	FY 2023
CBER Spent($)	$291,232,610	$306,794,435	$330,234,507	$328,872,841	$401,367,598
CBER Percentage(%)	20%	21%	22%	22%	24%
CDER Spent($)	$987,464,724	$1,018,915,025	$1,020,287,927	$999,122,621	$1,117,250,103
CDER Percentage(%)	69%	69%	68%	67%	66%
CDRH Spent($)	$3,918,206	$4,829,906	$5,525,062	$4,901,258	$4,634,817
CDRH Percentage(%)	0%	0%	0%	0%	0%
ORA Spent($)	$40,345,646	$39,118,104	$38,480,292	$42,305,499	$48,270,693
ORA Percentage(%)	3%	3%	3%	3%	3%
HQ Spent($)	$107,377,702	$101,487,458	$104,536,268	$105,399,656	$115,210,630
HQ Percentage(%)	8%	7%	7%	7%	7%
Total Spent	**$1,430,338,888**	**$1,471,144,928**	**$1,499,064,056**	**$1,480,601,875**	**$1,686,733,841**

Numbers have been rounded to the nearest dollar.

Exhibit 4 below provides an illustration of historical PDUFA costs.

Exhibit 4: Historical Total Costs by Fiscal Year



The total cost of the PDUFA program increased 12.5 percent in FY23.

K. 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."

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 risk of a lapse in appropriations, so that FDA can continue performing activities related to the process for the review of human drug applications under such financial constraints. FDA manages the appropriated and available fee funds in the total carryover within the range required by statute to mitigate these risks. FDA may also set aside available user fee funds in the carryover for certain purposes, including, for example, for processing of future year refunds.

The statute establishes a cap of 14 weeks of operating reserves of carryover user fees that can be maintained at the end of each fiscal year and a minimum amount of 8 weeks for FY 2023. For PDUFA VII purposes, FDA interprets this statutory cap to set a limit on the total available carryover to be retained. 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 (see **Table 6** and **Note 12**).

The net change in PDUFA carryover each year is equal to net collections minus net obligations. This is demonstrated best in **Table 1** above.

Table 6 provides PDUFA carryover at the end of FY 2022 and FY 2023. The financial notes can be found in **Appendix E**.

Table 6: PDUFA Carryover for FYs 2022 and 2023

Carryover	Notes	FY 2022	FY 2023
Total Carryover, End of Year		**$287,669,825**	**$275,515,520**
Unappropriated Amounts	Note 12	($78,850,995)	($78,850,995)
Total Available Carryover, End of Year		**$208,818,830**	**$196,664,525**
Future Year Refunds Allowance, Set Aside	Note 13	($20,000,000)	($20,000,000)
Carryover Net of Unavailable and Set Aside, End of Year		**$188,818,830**	**$176,664,525**

Numbers have been rounded to the nearest dollar.

These terms are defined below:

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

- **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 **Note 12** 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. For that purpose, a total of $20,000,000 in fee funds that are available for obligation is being set aside annually. See **Note 13** 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 2023 resulted in a net decrease of the carryover of $12,154,305, from $287,669,825 at the end of FY 2022 to $275,515,520 at the end of FY 2023. Although fee collections were lower than estimated by four percent overall (see **Table 3**), obligations for the year (see **Table 4**) were also lower than the estimated target revenue by approximately four percent (see **Table 1**). The net impact was a decrease in the carryover balance. The Total Available Carryover at the end of FY 2023 provides for approximately 7 weeks of operating reserves in FY 2024 to mitigate the financial risks to the program.[5]

Tables 7a and **7b** reflect the historical amount of fees collected and the amount obligated during the previous and current reauthorization periods.

Table 7a: Historical Prescription Drug User Fee Collections, Obligations, and Carryover by Reauthorization Period

	NOTES	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 Year		**$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	Note 2	$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 Year		**$36,462,154**	**$22,683,224**	**$130,816,093**	**$178,468,707**	**$350,108,200**	**$287,669,825**

Numbers have been rounded to the nearest dollar.

[5] To calculate the available operating reserves by week, the FY 2024 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.

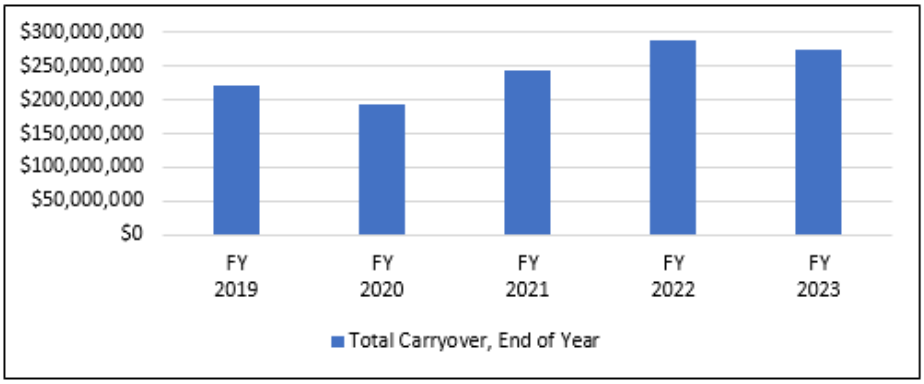
Table 7b: Historical Prescription User Fee Carryover for Current Reauthorization Period

Category	Notes	FY 2023
Total Carryover, Beginning of Year		**$287,669,825**
Net Collections		$1,222,888,088
Recoveries	Note 2	$16,400,359
Obligations		($1,251,442,752)
Total Carryover, End of Year		**$275,515,520**

Numbers have been rounded to the nearest dollar.

Exhibit 5 provides a historical perspective on the carryover for the last 5 fiscal years.

Exhibit 5: Historical Total Carryover by Fiscal Year



L. Non-User Fee Appropriations

For FDA to obligate user fees collected under PDUFA, a certain amount of non-user fee appropriations must be spent on the process for the review of human drug applications during that fiscal year. This is often referred to as a "non-user fee spending trigger." The spending trigger was $243,379,188 for FY 2022 and $258,521,975 for FY 2023.

The non-user fee spending trigger amount is determined by multiplying the base amount 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 **Note 14** for more details on the adjustment factor.

Table 8 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 8: Historical Prescription Drug User Fee Obligations by Funding Source as of September 30 of Each Fiscal Year

Funding Source	FY 2019	FY 2020	FY 2021	FY 2022	FY 2023
Non-User Fee Appropriations Obligated: Total ($)	$413,194,579	$395,658,018	$389,877,999	$350,824,209	$435,291,088
Non-User Fee Appropriations Obligated: Percent (%)	29%	27%	26%	24%	25%
User Fee Funds Obligated: Total ($)	$1,017,144,309	$1,075,486,910	$1,109,186,057	$1,129,727,665	$1,251,442,753
User Fee Funds Obligated: Percent (%)	71%	73%	74%	76%	75%
Total Obligated	**$1,430,338,888**	**$1,471,144,928**	**$1,499,064,056**	**$1,480,601,875**	**$1,686,733,841**

Numbers have been rounded to the nearest dollar.

M. 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 (OMB 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.

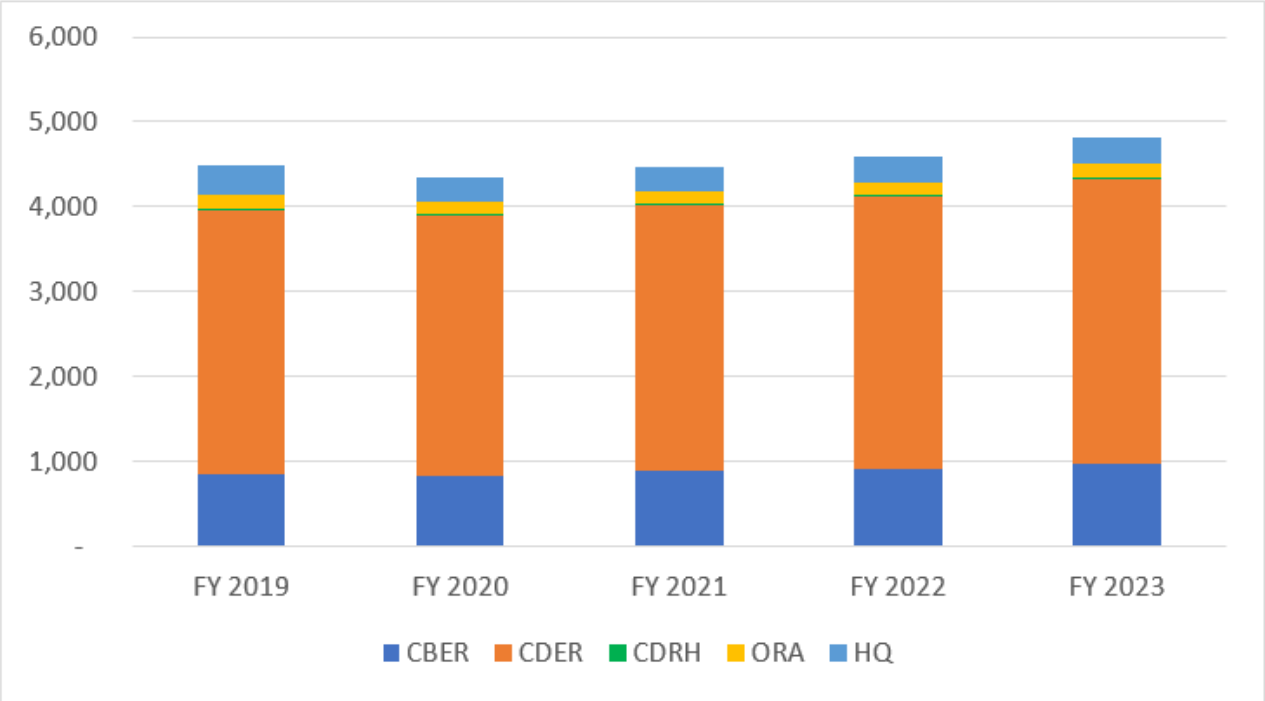
Table 9 presents total Process FTE levels, paid from user fee and non-user fee appropriations, that support the PDUFA program. The data cover the past 5 fiscal years and are arranged by FDA's organizational components (CDER, CBER, CDRH, ORA, and HQ). Staff in the consolidated shared services organizations (e.g., facilities, procurement, IT services, etc.) are included in the FTE levels for various components.

Table 9: Historical Trend of Total Process FTEs Utilized by Organization as of September 30 of Each Fiscal Year

Fiscal Year	FY 2019	FY 2020	FY 2021	FY 2022	FY 2023
CBER	857	835	893	918	977
CDER	3,103	3,055	3,119	3,196	3,341
CDRH	20	23	25	21	18
ORA	163	147	152	158	165
HQ	352	290	272	289	306
TOTAL	**4,495**	**4,350**	**4,461**	**4,583**	**4,807**

Exhibit 6 provides the historical trend of Process FTE distributions and levels across FDA's organizations for the past 5 fiscal years.

Exhibit 6: Historical Total Process FTE Levels by FDA's Organization



Planned Hiring

PDUFA VII provides for the hiring of 352 new positions over the course of the 5-year authorization to support the workload associated with initiatives established or expanded by PDUFA VII. **Table 10** presents the hiring targets for these new positions for FY 2023 for PDUFA VII.

Table 10: PDUFA VII Target Versus Actual New Hires for FY 2023

Organization	Target New Hires	Actual New Hires
CDER	77	41
CBER	132	109
Other FDA	1	1
Total Hires	**210**[6]	**151**

[6] A "hire" is defined as someone who has been confirmed as on board by the date indicated in a full-time position at the noted Center. The total target new hires figure includes some PDUFA VII hiring completed prior to FY 2023.

N. Internal Controls

The Federal Managers' Financial Integrity Act of 1982 (FMFIA) is intended to strengthen internal controls and accounting systems. OMB Circular A-123, Management's Responsibility for Enterprise Risk Management and Internal Control, implements the FMFIA requirements. FMFIA requires that management establish and maintain effective internal control to achieve the following objectives:

1. Effective and efficient operations
2. Reliable reporting
3. Compliance with applicable laws and regulations

The Department of Health and Human Services (HHS) provides guidance to its operating divisions (OpDivs) to implement FMFIA through its FMFIA Guidelines. OpDivs, including FDA, are responsible for developing and maintaining internal control and compliance programs that include programmatic and operational controls, as well as reporting controls to support sound financial management. The Government Accountability Office's Standards for Internal Control in the Federal Government (Green Book) states: "Management is responsible for an effective internal control system. As part of this responsibility, management sets the entity's objectives, implements controls, and evaluates the internal control system." OMB Circular A-123 requires an annual internal control assessment, and FMFIA requires the head of each executive agency to report annually on the effectiveness of the internal controls and any identified material weaknesses in those controls.

In alignment with FMFIA, OMB A-123, OMB A-11, the Green Book, and HHS guidelines, FDA established an Enterprise Risk Management (ERM) Program, with an ERM Council (ERMC) as the governance body responsible for providing overall oversight and accountability. The ERMC's purview includes deciding on and managing the Agency's Enterprise Risk Profile and ensuring integration with FDA's FMFIA, budget formulation, and strategic planning activities. The ERMC has senior executive representatives from each FDA Center and Office and is chaired by FDA's Chief Operating Officer, with a Center Director as Co-Chair and FDA's Chief Financial Officer (CFO) as President Pro Tempore. FDA's ERM Program supports the ERMC in managing the Agency's Enterprise Risk Profile, facilitates risk response planning, collaborates with Center and Office senior leaders and staff in conducting a range of analyses to manage risks, and provides communications and training opportunities that promote a risk-informed culture.

Additionally, FDA has an established Senior Assessment Team (SAT) to act as the governance body responsible for providing oversight and accountability for FDA's internal control over reporting, including overseeing the FMFIA and OMB Circular A-123 assessments, and for fostering an environment that promotes strong internal controls and reduces the risk of fraud, waste, and abuse. The SAT is chaired by FDA's CFO and co-chaired by the Deputy CFO and Director of the Office of Financial

Management, as well as a Program Co-Chair who is a Center Deputy Executive Officer appointed by the CFO. The SAT members are representatives from each FDA Center and Office.

FDA's internal control program includes integrated management controls covering the OMB Circular A-123 appendices. Specifically:

1. Reporting controls to include business and IT controls are implemented in accordance with Appendix A, Management of Reporting and Data Integrity Risk

2. Charge card controls are implemented in accordance with Appendix B, A Risk Management Framework for Government Charge Card Programs

3. Controls over financial disbursements are implemented in accordance with Appendix C, Requirements for Payment Integrity Improvement

4. Financial system controls are implemented in accordance with Appendix D, Compliance with the Federal Financial Management Improvement Act of 1996

In FY 2023, FDA's annual assessment of internal controls included tests of 94 business and IT controls across nine major transaction cycles and 21 transaction sub-cycles to develop recommendations to strengthen internal controls and compliance. This assessment included 11 IT controls related to the User Fee System. Further, in FY 2023, FDA enhanced its integration with HHS to focus on IT controls, align with HHS's standardized IT controls guidance, and overall collaboration with HHS.

Annually, FDA conducts an improper payments risk assessment and performs improper payment testing to assess financial disbursements. In FY 2023, FDA completed the FDA FY 2023 Improper Payments risk assessment to identify FDA Programs that were susceptible to significant improper payments. Six FDA Programs—including FDA User fees (Non-General Fund), Animal Drugs and Feed, FDA Other Activities (FDA Headquarters), Payment to FDA Innovation Account, National Center for Toxicological Research, Coronavirus Emergency Funding Supplemental and FDA Buildings and Facilities Foods, Human Drugs, Biologics, CURES Activities, Reimbursable Program (Federal Sources), Opioids – IMF Programs—were deemed to not be susceptible to significant improper payments. The Biologics Program and the Devices and Radiological Health Program were selected for improper payments transactional testing. Neither the Biologics nor the Devices and Radiological Health Programs were found to be susceptible to significant improper payments.

The Unified Financial Management System FDA-set-of-books—which is the Integrated Budget and Acquisition Planning Systems (IBAPS) —and the User Fee System are compliant with HHS guidelines and with OMB Circular A-123 Appendix D, Compliance with the Federal Financial Management Improvement Act of 1996.

FDA has also implemented other internal control procedures, including the performance of Organizational Risk Reviews, which are reviews of targeted financial and non-

financial management processes to identify potential recommendations to enhance internal controls. Also, FDA maintains a Continuous Monitoring Program to oversee the timely implementation of corrective action plans for any deficiencies identified through any of its control assessments.

As a component of HHS, FDA's financial data are presented in HHS's consolidated financial statements. The FY 2023 HHS audit found that FDA's financial statements fairly present, in all material respects, the consolidated financial position of HHS as of September 30, 2023, and 2022, and related notes are in accordance with generally accepted accounting principles in the United States. Further, FDA's FY 2023 Assurance Statement found no material weaknesses or financial system nonconformances.

O. Risks and Challenges

Financial Risks and Mitigation

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

- **Under-Executing Planned Spend:** Historically, PDUFA budgetary resources have been under-spent because of the uncertainty around the timing of revenue (user fee and non-user fee) availability, non-user fee spending trigger requirements, and difficulties with hiring. To minimize this risk, FDA continued to enhance its planning and execution around the hiring of new staff and contract actions. By putting more emphasis on the initial planning of initiatives in the early years of the 5-year cycle, FDA predicts that there will be less variance in planned allocations versus actual expenditures than FDA has experienced in the past.

- **Uncertainty of Non-User Fee Appropriations Levels:** It is difficult to predict the amount of non-user fee appropriations that will be approved by Congress, which creates planning challenges since non-user fee fund levels are often uncertain for a good portion of the fiscal year. With Continuing Resolutions (CRs) becoming more prevalent, FDA has been required to spend at or slightly below levels from the prior authorized fiscal year during

the CR period, thus limiting its ability to spend the non-user fee appropriations from the onset.

- **Lapse in Non-User Fee Appropriations:** FDA cannot control this risk; however, PDUFA VII grants FDA the authority to maintain up to 14 weeks of an operating reserve, which can be utilized to continue program operations in the event of a lapse in appropriations. PDUFA VII requires that FDA maintain the following minimum operating reserves: 8 weeks in FY 2023, 9 weeks in FY 2024, and 10 weeks in FY 2025 and subsequent fiscal years.

- **Under Collecting and Over Collecting Fees:** If FDA does not receive the estimated number of industry submissions, there may be a deficit in its targeted revenue. When FDA under collects user fees, it leverages its available operating reserves to maintain continuity in operations. When FDA over collects, the carryover may increase without additional planned expenditures being identified to obligate those funds. The operating reserve adjustment provides a tool to adjust the annual revenue target amount to maintain the operating reserves within the statutory bounds. Resource capacity planning helps improve fee setting and allows FDA to adjust for sustained increases in workload. In addition, FDA monitors collections throughout the fiscal year, and the User Fee Financial Management Committee and other FDA senior leaders determine how to mitigate any instances when user fee revenue deviates from forecasted estimates.

In addition to these mitigation strategies, FDA implemented IBAPS to enable greater and more timely insight into budget activity across the Agency. IBAPS improves the accuracy and availability of budget and acquisition information that enables FDA to better plan, forecast, track, and analyze the data to make more informed decisions about the best use of its resources.

Appendices

A. Reporting Requirements

The following table provides details regarding the fiscal reporting requirements for PDUFA.

Requirement	Details
Secs. 1004-5, FUFRA, Title I.	Extends FDA's requirements for financial reports and consultations on the reauthorization of PDUFA fees through FY 2027.
FD&C Act Section 736B(b) of the FD&C Act (21 U.S.C. Code § 379h–2)	Requires that a fiscal report, will be submitted no later than 120 days after the end of each fiscal year for which fees are collected. This report should include information on the implementation and use of fees collected during that fiscal year.

FDA committed, as part of the PDUFA Reauthorization Goals and Procedures FY 2023-2027, to include in the annual report how the workload adjuster and resource capacity planning adjustment fee revenues are being utilized.

B. Allowable and Excluded Costs 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.

Included Activities	
1. All investigational new drug review activities, including amendments 2. All review activities for new drug applications (NDAs) and biologic license applications (BLAs), including supplements and amendments 3. Regulation and policy development activities related to the review of human drug applications 4. Development of product standards for products subject to review and evaluation 5. Meetings between FDA and the sponsor of a covered application or supplement 6. Review of labeling prior to approval of a covered application or supplement and the review of the initial pre-launch advertising 7. Review of post-marketing studies and clinical trials that have been agreed to by sponsors as a condition for approval 8. Inspections of facilities undertaken as part of the review of pending applications or supplements 9. Lot release activities for covered biological products	10. Assay development and validation to ensure batch-to-batch consistency and reliability for covered biological products 11. Monitoring of clinical and other research conducted in connection with the review of human drug applications 12. User Fee Act implementation activities 13. Research related to the human drug review process 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:

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, maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, scientific equipment, and other necessary materials and supplies 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 excludes costs related to the following:

Excluded Products	Excluded Activities
1. Generic drugs 2. Over-the-counter drugs not associated with an NDA or NDA supplement 3. Large-volume parenteral drug products approved before September 1, 1992 4. Allergenic extract products licensed before October 1, 2022, or certain standardized allergenic extract products licensed after October 1, 2022 5. Whole blood or a blood component for transfusion 6. In vitro diagnostic biologic products 7. Certain drugs derived from bovine blood	1. Enforcement policy development not related to sections 505(o) and (p) of the FD&C Act 2. Post-approval compliance activities not related to the enforcement of sections 505(o) and (p) of the FD&C Act 3. Advertising review activities once marketing of the product has begun 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. Research unrelated to the human drug review process

C. User Fee Program History

PDUFA was enacted in 1992 to enable FDA to collect fees from drug manufacturers to support funding for the new drug approval process to speed application review without compromising the Agency's high standards for new drug safety, efficacy, and quality. The FD&C Act, as amended by PDUFA, authorizes FDA to collect fees from industry to supplement non-user fee appropriations spent on FDA's human drug review process. FDA spends PDUFA fee revenues and non-user fee appropriations to hire, support, and maintain personnel for the review of human drug applications to help ensure that safe, effective, and high-quality prescription drugs are available to the American public.

PDUFA was reauthorized in 1997 (PDUFA II), 2002 (PDUFA III), 2007 (PDUFA IV), 2012 (PDUFA V), 2017 (PDUFA VI), and in 2022 (PDUFA VII) with the support of industry, other stakeholders, Congress, and the Administration. Over time, PDUFA has been a great success, creating a predictable, streamlined review process; significantly reducing the average time to new drug approval; and permitting earlier access to innovative treatments.

D. Conditions for Assessment and Use of Fees

Introduction

The FD&C Act, as amended by PDUFA, specifies three legal conditions that must be met each fiscal year for FDA to collect and spend prescription drug user fees. This appendix describes these conditions and the applicable adjustment factor, as listed in the FD&C Act.

Adjustment Factor

To determine whether the legal conditions are satisfied, FDA must calculate and incorporate adjustment factors (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 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 Consumer Price Index (CPI) for October 2021, the October of the fiscal year preceding FY 2023, was 276.589. The CPI for October 1996 was 158.3. Dividing the CPI of October 2021 by the CPI of October 1996 yields an adjustment factor of 1.747246 (rounded to the sixth decimal place) for FY 2023.

Legal Conditions

Exhibit 7 below provides the details regarding each legal condition, as quoted from the FD&C Act.

Exhibit 7: 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.

E. Financial Notes

Note 1. Annual Target Revenue Methodology

Exhibit 8 is a flowchart that outlines PDUFA VII's Annual Target Revenue Methodology.

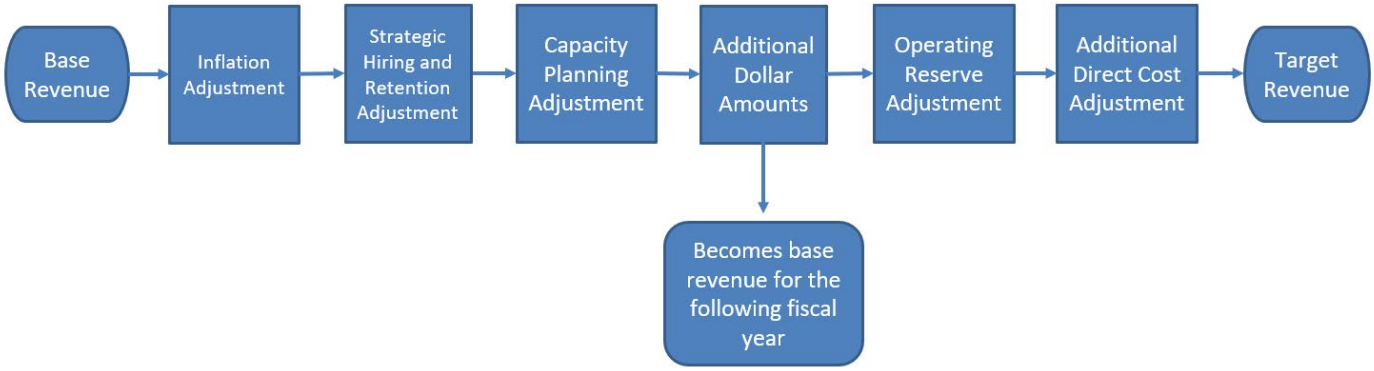


Exhibit 8: PDUFA VII's Annual Target Revenue Methodology

Note 2. Recoveries

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

Note 3. Payroll and Operating Costs

Payroll and operating costs associated with the PDUFA program are based on obligations attributed to CBER, CDER, CDRH, ORA, and HQ. These costs relate to how much of the PDUFA revenue is going toward payroll and operating expenses.

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

Note 4. 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. Because rent is an essential 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. Also included in this account are recurring costs that FDA pays to non-federal sources under the delegation of direct lease and service authority. These services include the rental of space and all recurring services for building operations such as overtime utilities, janitorial services,

guards, and ground maintenance. The amount of rent and rent-related costs each Center pays is directly related to the number of employees that must be housed.

Note 5. Shared Services Costs

FDA has several shared service organizations, located with the Working Capital Fund, that provide support across the user fee programs. The shared service organizations in FY 2023 include the following:

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

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

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

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

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

- **Office of Digital Transformation:** Provides the information, communication, and knowledge infrastructure and services that enhance, transform, and sustain the ability of FDA to protect and promote the public health. Provides support to all FDA employees requesting administrative, IT, facilities, human resources, and other employee services.

- **Division of Budget Execution and Control:** Initiates, monitors, and analyzes FDA's budget resources. The Agency's budget is comprised of several appropriation accounts including Salaries and Expenses, Revolving Fund for Color Certification and other Services, Cooperative Research and Development Agreement, Contingency Fund, Building and Facilities, and Royalties.

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

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

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

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

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

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

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

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

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

Note 6. Inflation Adjustment

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

The inflation adjustment utilized in FY 2023 was 1.6404 percent.

Note 7. Strategic Hiring and Retention Adjustment

The strategic hiring and retention adjustment increases the inflation-adjusted base amount to cover the costs of hiring and retaining highly qualified scientific and technical staff for the process for the review of human drug applications.

Note 8. 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 and maintain performance on its review timelines.

Note 9. Additional Dollar Amounts Adjustment

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. For FY 2023, the Additional Dollar Amounts Adjustment is $65,773,693.

Note 10. Operating Reserve Adjustment

The operating reserve adjustment was established in the statute to provide a mechanism to support the carryover of no more than 14 weeks of operating reserve from year to year. The statute directs FDA to make adjustments, as needed, to keep the adjustment above certain minimum amounts. The minimum amounts are as follows: 8 weeks for FY 2023, 9 weeks for FY 2024, and 10 weeks for FYs 2025 to 2027.

The statute defines a cap on the carryover at an amount equivalent to 14 weeks of operations. 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 (see **Note 12**) does not count toward the 14-week carryover cap.

To determine the 14-week cap on the operating reserve for FY 2023, the FY 2023 annual base revenue is adjusted for inflation and capacity planning, and additional dollar amount, $1,256,844,387, is divided by 52 and then multiplied by 14. The 14-week cap on the operating reserve amount for FY 2023 is $338,381,181.

To determine the end-of-year operating reserve amount, the Agency must assess its actual operating reserve at the end of the third quarter of the fiscal year and forecast collections and obligations in the fourth quarter of the fiscal year. The estimated end-of-year FY 2022 operating reserve at the time that FY 2023 fees were set was $184,271,732.

Because the estimated end-of-year FY 2023 PDUFA operating reserve did not exceed the 14-week operating reserve for FY 2023, FDA did not reduce the FY 2023 PDUFA target fee amount.

FDA decided to make an available operating reserve adjustment that was intended to increase the amount of available funds to approximately 8 weeks by the end of FY 2023. Before the operating adjustment, the estimated end of year FY 2023 available operating reserve was $184,271,732, which equated to about 7.6 weeks of available operating reserves. Adding the FY 2023 operating reserve adjustment of $9,088,943 to this amount was expected to provide approximately 8 weeks of available operating reserves, or $193,360,675 (including $20,000,000 in available fee funds maintained for

any future refunds), and a total carryover of operating reserves (including unavailable funds) of $292,211,670.

Note 11. Additional Direct Costs Adjustment

PDUFA VII specifies in the statute that $44,386,150 be added in addition to the operating reserve adjustment to account for additional direct costs in PDUFA VII for FY 2023. Additional direct costs provide for non-payroll costs associated with PDUFA VII initiatives.

Note 12. Unappropriated Amounts

The unappropriated amount is the amount that FDA collected in user fees in excess of the amount specified in appropriation acts prior to FY 2010. FDA's ability to access and obligate these collections remains uncertain. **Table 11** outlines the excess user fees by fiscal year.

Table 11: Prescription Drug User Fees Collected, Collection Amounts Specified in Appropriation Acts, and Excess Amounts as of September 30, 2023

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

Numbers have been rounded to the nearest dollar.

Note 13. 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 withdrawn. If an application is refused to file or withdrawn before it is filed, FDA refunds 75 percent of the fee. Additionally, if firms are granted waivers, exemptions, or refunds for program fees, FDA may refund fees that were already paid by the firm.

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

Note 14. Minimum Non-User Fee Appropriations Adjustment Factor

FDA must calculate and incorporate adjustment factors (defined in section 735(8) of the FD&C Act as amended). 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 1996."

F. 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 2023, 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 12shows how FDA expended $10 million in funds from PDUFA VII in FY 2023 for these core functional areas.

Table 12: Funding Allocation by Core Sentinel System Functional Area for FY 2023

Core Sentinel System Functional Areas	Funds Expended in FY 2023
Data Infrastructure	$1,497,124
Analytic Capabilities	$1,881,986
Safety Issue Analyses	$1,755,324
Dissemination of Relevant Product and Safety Information	$98,284
Sentinel System Development	$4,767,282
Total	$10,000,000

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