Financial Report to Congress

Prescription Drug User Fee Act of 1992

FY 2022

Table of Contents

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 fifth report under the sixth authorization of PDUFA (PDUFA VI) and covers fiscal year (FY) 2022.

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 2022, 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 2022, FDA had net collections of $1.159 billion in prescription drug user fees, spent $1.13 billion in user fees for the human drug review process, and carried $288 million forward.

PDUFA user fees and non-user fee appropriations in FY 2022 supported 4,583 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 2022 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, 2021, through September 30, 2022. 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 fiscal year (FY) 2022 fee collections, carryover, obligations of user fees, and total costs of the process for the review of human drug applications from both Prescription Drug User Fee Act (PDUFA) fees and non-user fee appropriations.

B. Report Requirements

In accordance with section 736(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 (September 30). Additional details on what is required to be included in this report are included in **Appendix A**.

C. Organization Background

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

User Fee Governance

The Agency's expanding level of user fees, the reporting of the Agency's performance commitments associated with these fees, and the need for FDA to convey how these fees are executed calls for strong financial governance. This governance 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 Reauthorization Act of 2017 (FDARA) includes the fifth reauthorization of PDUFA, also known as PDUFA VI, and authorizes continued funding for FDA from FY 2018 through FY 2022 to support program operations, evaluation, and improvements. So far, PDUFA VI 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.

PDUFA VI changed the fee structure to include application fees and program fees with a greater proportion of the target revenue allocation assigned to program fees, which provides a more predictable source of funding. The objectives of this simpler and more efficient fee structure are to increase the predictability of funding, reduce the administrative burden, and improve the management of funding.

Exhibit 2 outlines the PDUFA VI fee structure.

Exhibit 2: PDUFA VI 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, 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 2022.

[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 2022 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 2022, FDA's appropriation for salaries and expenses was $3,304,145,000 excluding user fees and rent payments to GSA. FDA's FY 1997 Salaries and Expenses Appropriation, excluding user fees and rent, was $1,348,771,938 after applying the FY 2022 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, 2022 (Public Law 117-103) on March 15, 2022. It specified that $1,200,129,000 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 2022 is $243,379,188. In FY 2022, FDA obligated $350,874,209 from appropriations (exclusive of user fees) for the review of human drug applications. Because FDA spent more than the specified minimum amount in FY 2022, 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 D**.

F. Strategic Plan

FDA is focused on utilizing PDUFA user fee and budget authority resources to achieve the performance goals and program enhancements outlined in the PDUFA VI Commitment Letter,[2] along with all applicable FDARA provisions. In addition to dedicating resources to ensure that the program is sufficiently staffed to manage

[2] The PDUFA VI Commitment Letter is available at https://www.fda.gov/media/99140/download.

workload within agreed-upon performance timelines, FDA committed, in the PDUFA VI Commitment Letter, to achieve several key performance enhancements. Below outlines the key performance enhancements the program continued to implement over the course of PDUFA VI:

- 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 development of drugs for rare diseases
    - Advancing development of combination products by CBER and CDER
    - Enhancing use of 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 capacity to support analysis data standards for product development and review
    - Enhancing the drug development tools qualification pathways for biomarkers

- Enhancing and modernizing FDA's drug safety system
    - Advancing postmarketing drug safety evaluation through expansion of the Sentinel system and integration into FDA's pharmacovigilance activities
    - Providing timely and effective evaluations and communications of postmarketing safety findings related to human drugs

- Enhancing the management of user fee resources through resource capacity planning and modernized time reporting

- Improving FDA's hiring and retention of qualified scientific and medical review staff

- Improving FDA's information technology (IT) related to electronic submissions and data standards

Additional details regarding how FDA met these commitments can be found in the Five-Year Forward View section of the PDUFA Five-Year Financial Plan.[3]

[3] The PDUFA Five-Year Financial Plan is available at https://www.fda.gov/about-fda/user-fee-reports/user-fee-five-year-financial-plans.

G. Performance Summary

Performance Goals

FDA noted a sustained increase in the number of original standard new molecular entities (NMEs) and biologics license applications (BLAs) in FY 2022, which was seven percent higher than the FY 2017 to FY 2021 5-year review workload average. Other submission types, such as Class 2 Resubmitted NDAs and BLAs and NDA and BLA manufacturing supplements requiring prior approval, also showed sustained increases in FY 2022, showing a 20- and 15-percent increase, respectively, when compared to the 5-year average.

As of September 30, 2022, FDA had completed 1,755 actions for the FY 2022 cohort. FDA has the potential to meet or exceed the 90 percent performance level for 12 of the 12 review performance goals for FY 2022.

FDA is currently meeting or exceeding the 90 percent performance level for 6 of the 20 procedural and processing goals (i.e., meeting management, procedural responses, and procedural notifications) for the FY 2022 cohort. With 1,275 submissions currently under review and still within the PDUFA goal date, FDA has the potential to meet or exceed the 90 percent performance level for 7 of the 20 procedural and processing goals for FY 2022. FDA missed the following procedural goals related to formal meeting management: meeting request responses for Type B End-of-Phase (EOP); meeting scheduling for Type A, B, B(EOP), and C; final written responses for Type A, B, B(EOP), and C; and meeting preliminary responses for Type B(EOP). Factors that contributed to missing the meeting management goals included an increased workload over pre-COVID levels (i.e., in FY 2022, there were 4,384 requests, which was 16 percent higher than in FY 2019), the focus on the COVID-19 pandemic, and limited resources.

Program Commitments

Overall, by the end of FY 2022, PDUFA had met 32 program enhancement commitments and missed six commitments during the fiscal year. The missed commitments included the PDUFA hiring goal, the timely quarterly posting of the hiring data (late twice), the publication of a final guidance on bridging studies, the publication of summary topics from a Model-Informed Drug Development public workshop on disease progression model development, and the publication of a focused guidance on specific biomarker uses and contexts to supplement the draft guidance on evidentiary standards. Details on the program performance can be found in the FY 2022 PDUFA Performance Report.[4]

[4] The FY 2022 PDUFA Performance Report is available at www.fda.gov/about-fda/user-fee-performance-reports/pdufa-performance-reports.

Financial Information

This section provides an overview of the program financials for PDUFA for FYs 2021 and 2022. 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 2021 and FY 2022. The financial notes referenced in this table can be found in **Appendix E**.

Table 1: Prescription Drug Collections, Obligations, and Carryover for FYs 2021 and 2022

Budgetary Resources	Notes	FY 2021	FY 2022
Target Revenue	Note 1	**$1,107,199,000**	**$1,200,129,000**
Total Carryover, Beginning of Year		$193,603,985	$244,902,650
Net Collections		$1,152,538,861	$1,159,139,951
Recoveries	Note 2	$7,945,861	$13,354,888
Total Budgetary Resources		**$1,354,088,707**	**$1,417,397,490**

Obligations	Notes	FY 2021	FY 2022
Total Payroll and Operating	Note 3	$922,626,574	$938,386,578
Total Rent	Note 4	$59,341,292	$59,443,256
Total Shared Services	Note 5	$127,218,191	$131,897,830
Total Obligations		**$1,109,186,057**	**$1,129,727,665**

Carryover	Notes	FY 2021	FY 2022
Total Carryover, End of Year		**$244,902,650**	**$287,669,825**

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" component is the annual revenue amount established when fees for the fiscal year are set. "Net Collections" component are the amounts collected during the fiscal year, net of refunds that have taken place (see section I).

PDUFA VI specifies how the fees must be calculated for each fiscal year, including annual adjustments that must be made for inflation and changes in the capacity needs of the program. FDA has applied those factors in the Target Revenue for annual fee setting. See **Table 2**.

Obligations: The "Obligations" component of **Table 1** shows the annual expenditure of PDUFA fee funds broken out into 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. For more information on the allowable and excluded costs. See **Appendix B**.

Carryover: PDUFA fees collected, appropriated, and not obligated at the end of a fiscal year remain available to FDA for use in future fiscal years. In this report, such fee funds, plus certain user fee funds that FDA has collected that are considered unappropriated[5] 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 program operations under such financial constraints.

I. User Fee Revenue

Table 2 outlines the annual target revenue amount for FY 2022. The financial notes referenced in this table can be found in **Appendix E**.

FDA assumes, for planning purposes, that net collections will equal the target revenue amount. Net collections may differ from the annual target revenue amount if the actual number of fee-paying units differ from the number of fee-paying units estimated when fees are set each year.

Table 2: Prescription Drug User Fee Revenue for FY 2022

Target Revenue	Notes	FY 2022
Base Amount		$1,098,077,960
Inflation Adjustment	Note 6	$24,171,990
Capacity Planning Adjustment	Note 7	$26,503,399
Additional Dollar Amounts	Note 8	$2,769,609
Operating Reserve Adjustment	Note 9	$39,402,923
Additional Direct Costs Adjustment	Note 10	$9,203,149
Target Revenue Total	**Note 1**	**$1,200,129,000**

Base Amount/Target Revenue numbers have 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 2018 is specified in the statute and is adjusted for the following factors, as applicable: inflation adjustment, capacity planning adjustment, additional dollar amounts (for negotiated FTE increases), operating reserve adjustment, and additional

[5] See Section K. and Note 11 for additional detail on funds considered unappropriated.

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.

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 collections.

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. 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. Net collections differ between the fiscal year and the cohort year. Cohort year collections reflect collections for a single year (e.g., FY 2022) across multiple fiscal years. Transactions such as late collections or refunds processed in a different fiscal year will be displayed in **Tables 3a, 3b,** and **3c** (e.g., a refund processed during FY 2023 for an FY 2022 payment) while other data tables use FY data that solely show the activity within that single fiscal year. To ensure the quality of the information provided in this financial report, FDA annually updates prior years' numbers.

FDA 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.

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 is described in **Section K – User Fee Carryover**. An operating reserve adjustment exists to regulate the carryover over time. The operating reserve adjustment was established in the statute to provide a mechanism to support the carryover of up to 14 weeks of operating reserve from year to year.

Tables 3a, 3b, and **3c** outlines PDUFA collections by fee source and cohort year. Refer to **Section D** for more background and information on the PDUFA VI fee structure.

Table 3a: Prescription Drug User Fee Collections by Fee Source for Cohort Year 2021

Fees Collected	Estimated†	Actual	% Diff
Application Fees	$221,439,800	$236,820,443	7%
Program Fees	$885,759,200	$913,452,880	3%
Total Collections	**$1,107,199,000**	**$1,150,273,323**	**4%**

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

Fees Collected	Estimated†	Actual	% Diff
Application Fees	$240,025,800	$168,137,850	-30%
Program Fees	$960,103,200	$1,007,389,251	5%
Total Collections	**$1,200,129,000**	**$1,175,527,101**	**-2%**

Table 3c: Prescription Drug User Fees Receivable by Fee Source for Cohort Years 2021 and 2022

Fees Receivable	Cohort Year 2021 Actual	Cohort Year 2022 Actual
Application Fees	$0	$0
Program Fees	$3,324,320	$7,018,847
Total Receivables	**$3,324,320**	**$7,018,847**

Numbers have been rounded to the nearest dollar.
† Estimated values were taken from the Prescription Drug User Fee Rates for FYs 2021 and 2022.

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 2021 and 2022

User Fee Obligations	Notes	FY 2021	FY 2022
Payroll & Operating	Note 3		
CBER		$150,521,826	$160,804,109
CDER		$704,118,513	$712,050,050
CDRH		$2,344,727	$3,176,215
ORA		$7,143,725	$7,671,485
HQ		$58,497,784	$54,684,720
Total Rent	Note 4	$59,341,292	$59,443,256
Total Shared Services	Note 5	$127,218,191	$131,897,830
Total Obligations		**$1,109,186,057**	**$1,129,727,665**

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 2022 from FY 2021. 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 VI commitments, and to modernize to meet evolving workload demands and scientific innovation.

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.

The interim capacity planning adjustment was in place for FY 2018 to FY 2020. Per the process provided by section 736(c)(2) of the FD&C Act, FDA established the new capacity planning adjustment methodology and utilized this new methodology for the first time in FY 2021. As a first step toward implementing the new methodology, FDA established a modernized time reporting and a resource capacity planning capability, as committed to in the PDUFA VI Commitment Letter. In the statute, FDA was directed to commission an independent report evaluating options and recommendations for a new methodology to accurately assess changes in the resource and capacity needs of the process for the review of human drug applications; this assessment was to be informed by personnel time reporting data as an input. FDA was also directed to publish the report for public comment.

The independent evaluation was conducted by Booz Allen Hamilton and published on FDA's website in April 2020.[6] A *Federal Register* docket was then opened to receive

[6] The independent evaluation is available at https://www.fda.gov/media/136606/download.

public comment.[7] After FDA reviewed the evaluation and the public comment, it established and implemented the new methodology for the setting of FY 2021 fee amounts. This methodology, which was established and implemented in FY 2021, is described in the *Federal Register* notice establishing fee amounts for FY 2021.[8]

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 64 of 78 reviewer positions in support of the new drug program. CBER established seven reviewer positions, six 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 7: PDUFA Program – Historical Trend of Total Costs by Organization as of September 30 of Each Fiscal Year

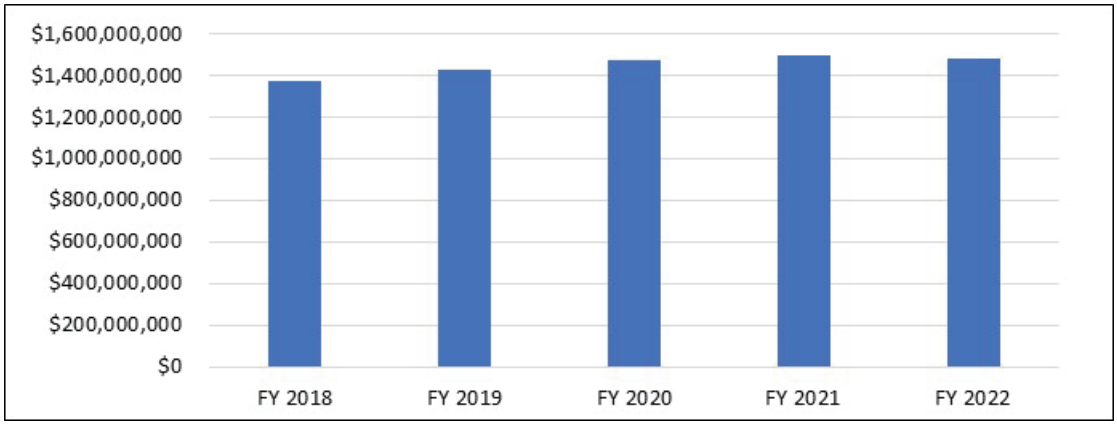
	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
CBER Spent ($)	$268,624,105	$291,232,610	$306,794,435	$330,234,507	$328,872,841
CBER Percent (%)	20%	20%	21%	22%	22%
CDER Spent ($)	$954,062,652	$987,464,724	$1,018,915,025	$1,020,287,927	$999,122,621
CDER Percent (%)	69%	69%	69%	68%	67%
CDRH Spent ($)	$4,260,126	$3,918,206	$4,829,906	$5,525,062	$4,901,258
CDRH Percent (%)	0%	0%	0%	0%	0%
ORA Spent ($)	$40,956,402	$40,345,646	$39,118,104	$38,480,292	$42,305,499
ORA Percent (%)	3%	3%	3%	3%	3%
HQ Spent ($)	$106,605,242	$107,377,702	$101,487,458	$104,536,268	$105,399,656
HQ Percent (%)	8%	8%	7%	7%	7%
Total Spent	**$1,374,508,527**	**$1,430,338,888**	**$1,471,144,928**	**$1,499,064,056**	**$1,480,601,875**

Numbers have been rounded to the nearest dollar.

[7] The public comments are available at https://www.regulations.gov/comment/FDA-2020-N-0989-0002.
[8] FY 2021 PDUFA fee rates are available at https://www.federalregister.gov/documents/2020/08/03/2020-16833/prescription-drug-user-fee-rates-for-fiscal-year-2021.

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 has remained fairly steady over the past few fiscal years.

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 considers maintaining between 8 to 10 weeks of appropriated and available fee funds in the total carryover as a reasonable range to mitigate these risks. FDA does, however, weigh those risks against strategic programmatic needs that may take precedence, causing the carryover of such funds to, at times, dip below this range. 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. For PDUFA VI purposes, FDA interprets this statutory cap to set a limit on the total carryover to be retained, i.e., all amounts identified in **Table 6**. This includes all available fee funds, including set asides for future fiscal years, and $78,850,995 in collections that are considered unappropriated and therefore currently unavailable for obligation (see **Table 6** and **Note 11**). In effect, the statutory cap of 14 weeks of operating reserves of total carryover equates to a cap of approximately 10 weeks of carryover funds that are considered appropriated and available for obligation. FDA may increase the annual target revenue to provide funds to increase the total carryover up to the 14-week level.

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 2021 and FY 2022. The financial notes can be found in **Appendix E**.

Table 6: PDUFA Carryover for FYs 2021 and 2022

Carryover	Notes	FY 2021	FY 2022
Total Carryover, End of Year		**$244,902,650**	**$287,669,825**
Unappropriated Amounts	Note 11	($78,850,995)	($78,850,995)
Future Year Refunds Allowance, Set Aside	Note 12	($20,000,000)	($20,000,000)
Carryover Net of Unavailable and Set Aside, End of Year		**$146,051,655**	**$188,818,830**

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 11** for additional details.

- **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 12** 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 2022 resulted in a net increase of the carryover of $42,767,175, from $244,902,650 at the end of FY 2021 to $287,669,825 at the end of FY 2022. Although fee collections were lower than estimated by two percent overall (see **Table 3**), obligations for the year (see **Table 4**) were lower than the estimated target revenue by approximately six percent (see **Table 1**). The result was an increase in the carryover balance. The increase in this balance will provide FDA with approximately 12 weeks of operations at the beginning of FY 2023 from the total carryover. However, accounting

for the unappropriated funds, approximately 9 weeks of funds will actually be available in FY 2023 to mitigate the financial risks to the program.[9]

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

Table 9*a*: Historical Prescription Drug User Fee Carryover by Reauthorization Period

	Notes	PDUFA I (FY 93 97)	PDUFA II (FY 98 02)	PDUFA III (FY 03 07)	PDUFA IV (FY 08 12)	PDUFA V (FY 13 17)
Total Carryover, Beginning of Year		**$0**	**$36,462,154**	**$22,683,224**	**$130,816,093**	**$178,468,707**
Net Collections		$328,768,265	$680,152,170	$1,435,876,426	$2,848,504,459	$4,101,728,493
Recoveries	Note 2	$0	$0	$0	$0	$8,749,852
Total Obligations		($292,306,111)	($693,931,100)	($1,327,743,557)	($2,800,851,845)	($3,938,838,852)
Total Carryover, End of Year		**$36,462,154**	**$22,683,224**	**$130,816,093**	**$178,468,707**	**$350,108,200**

Table 10*b*: Historical Prescription Drug User Fee Carryover for the Current Reauthorization Period

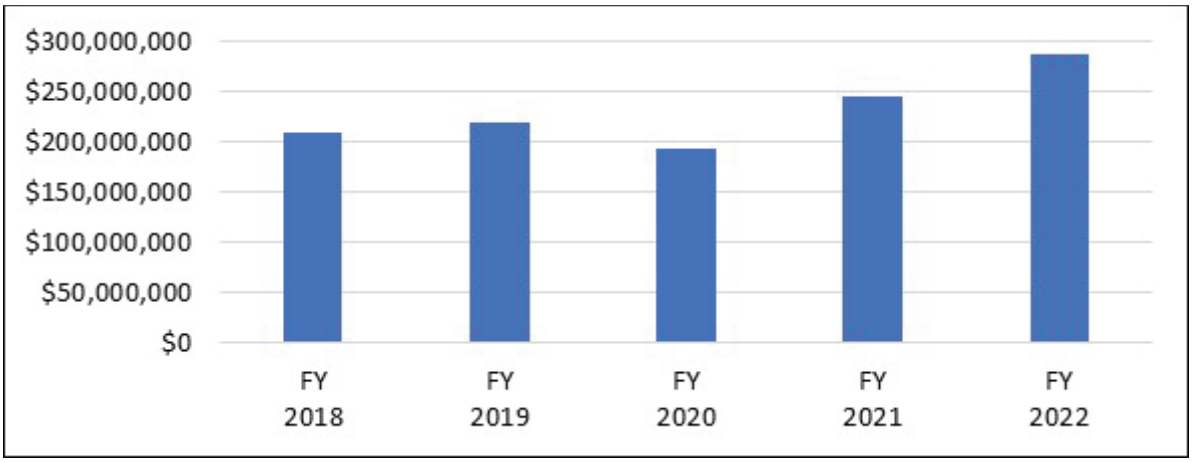
	Notes	FY 18	FY 19	FY 20	FY 21	FY 22
Total Carryover, Beginning of Year		**$350,108,200**	**$209,223,938**	**$220,088,812**	**$193,603,985**	**$244,902,650**
Net Collections		$908,077,723	$1,015,152,012	$1,020,229,037	$1,152,538,861	$1,159,139,951
Recoveries	Note 2	$13,149,599	$12,857,171	$28,773,047	$7,945,861	$13,354,888
Total Obligations		($1,062,111,583)	($1,017,144,309)	($1,075,486,910)	($1,109,186,057)	($1,129,727,665)
Total Carryover, End of Year		**$209,223,938**	**$220,088,812**	**$193,603,985**	**$244,902,650**	**$287,669,825**

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 Carryover by Fiscal Year

[9] To calculate this figure for FY 2023, first divide the FY 2023 base revenue adjusted for inflation, strategic hiring and retention, capacity planning, and additional dollar amounts by 52 weeks to get the estimated amount needed to operate the program each week $1,256,844,387/52 weeks = ~$24,170,084), then divide the carryover available for obligation by this weekly operating cost ($208,818,830/$24,170,084 = ~9 weeks of funds that are authorized and appropriated).



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 $240,535,847 for FY 2021 and $243,379,188 for FY 2022.

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 13** 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 amount 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 of Each Fiscal Year

Funding Source	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Non-User Fee Appropriations Obligated: Total ($)	$312,396,943	$413,194,579	$395,658,018	$389,877,999	$350,824,209
Non-User Fee Appropriations Obligated: Percent (%)	23%	29%	27%	26%	24%
User Fee Funds Obligated: Total ($)	$1,062,111,583	$1,017,144,309	$1,075,486,910	$1,109,186,057	$1,129,727,665
User Fee Funds Obligated: Percent (%)	77%	71%	73%	74%	76%

Total Obligated	**$1,374,508,527**	**$1,430,338,888**	**$1,471,144,928**	**$1,499,064,056**	**$1,480,601,875**

Numbers have been rounded to the nearest dollar.

M. Full-Time Equivalents

"FTE employment" (often referred to as "staff year"), as defined by the Office of Management and Budget (OMB) Circular A-11, section 85, 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 they relate to PDUFA, FTEs are referred to as "Process FTEs." This is 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.

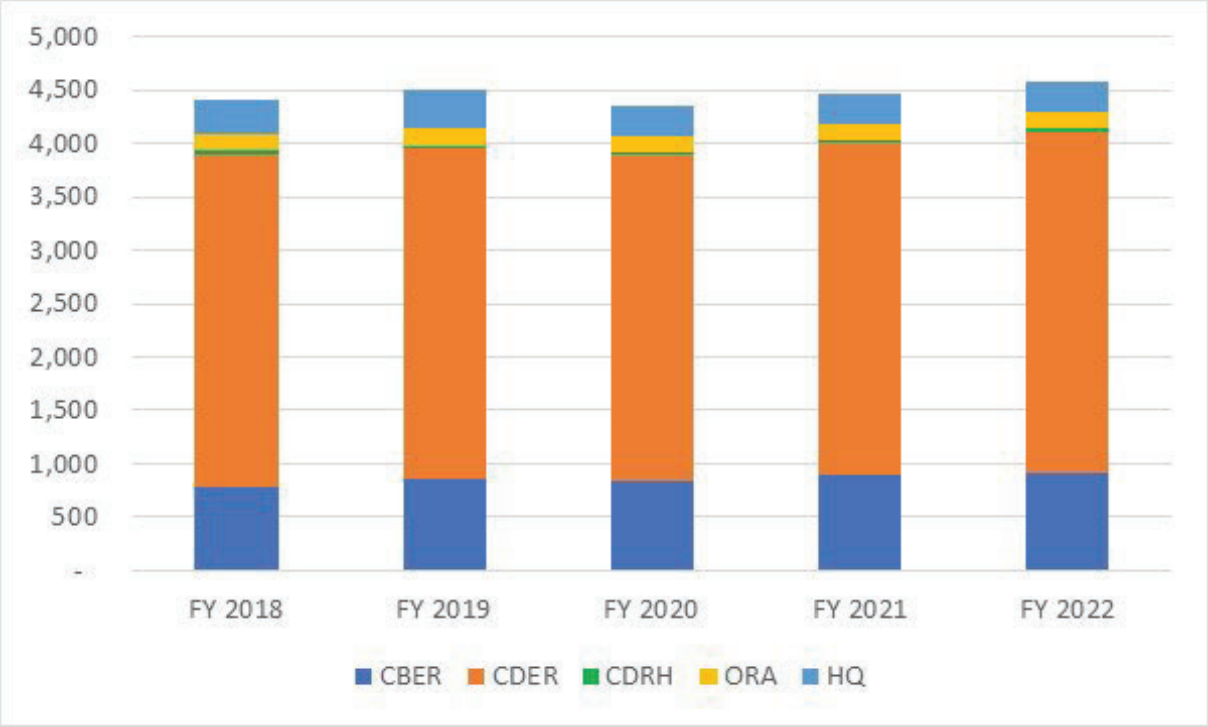
Table 9 presents total Process FTE levels, paid from user fee and non-user fee appropriations, that support the PDUFA program. The data cover the past 5 fiscal years and are arranged by FDA's organizational components (CDER, CBER, CDRH, ORA, and HQ). Staff in the consolidated shared services organizations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

Table 12: Historical Trend of Total Process FTEs Utilized by Organization as of September 30 of Each Fiscal Year

Fiscal Year	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
CBER	791	857	835	893	918
CDER	3,110	3,103	3,055	3,119	3,196
CDRH	25	20	23	25	21
ORA	168	163	147	152	158
HQ	318	352	290	272	289
Total	**4,412**	**4,495**	**4,350**	**4,461**	**4,583**

Exhibit 6 provides the historical trend of 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 VI provides for the hiring of 230 new positions to support the workload associated with initiatives established or expanded by PDUFA VI. **Table 10** presents the hiring targets for these new positions for FY 2022 for PDUFA VI.

Table 13: PDUFA VI Target Versus Actual New Hires for FY 2022

Organization	Target New Hires	Actual New Hires
CDER	9	5
CBER	0	0
Other FDA	0	0
Total Hires	**9**	**5**

Management Assurance

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, and
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 as the governance body responsible for providing overall oversight and accountability. The Council'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 ERM Council has senior executive representatives from each FDA Center and Office, and is chaired by the Chief Operating Officer, with a Center Director as Co-Chair and Chief Financial Officer (CFO) as President Pro Tempore. FDA's ERM Program supports the Council 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; and

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

In FY 2022, FDA's annual assessment of internal controls included tests of 95 business and IT controls across 14 major transaction cycles and 27 transaction sub-cycles to identify recommendations to strengthen internal controls and compliance. This assessment included 36 IT controls related to the User Fee System. Further, FDA has enhanced its integration with HHS to focus on IT controls, align with HHS standardized IT controls guidance, and overall collaborate with HHS (Appendices A and B).

Annually, FDA conducts an improper payments risk assessment and performs improper payment testing to assess financial disbursements. In FY 2022, FDA completed the FDA FY 2022 Improper Payments risk assessment to identify FDA Programs that were susceptible to significant improper payments. The FDA Programs - 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 were deemed to not be susceptible to significant improper payments. The Biologics and Devices & Radiological Health programs were selected for transactional testing (Appendix C).

The Unified Financial Management System FDA-set-of-books 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 (Appendix D).

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 2022 HHS audit found that FDA's financial statements fairly present, in all material respects, the consolidated financial position of HHS as of September 30, 2022, and 2021, and related notes are in accordance with generally accepted accounting principles in the United States. Further, FDA's FY 2022 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; these contingency plans help ensure FDA is able to 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.

- **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 VI grants 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. Currently, FDA has about 12 weeks of total carryover but, because of the unappropriated amounts, this equates to about 9 weeks of available operating reserves to help mitigate this risk. See **Note 11** for additional details.

- **Under Collecting and Over Collecting Fees:** If FDA does not receive the estimated number of industry submissions, there may be an excess or deficit in 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 changes in the fee structure, the minimization of clean-up billing, and the operating reserve are meant to mitigate these risks in PDUFA VI. 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.

- **Global Pandemic:** There is currently some degree of uncertainty regarding the potential long-term impact of COVID-19 on collections and application submissions. FDA is continually monitoring these potential impacts and will seek to address financial ramifications as warranted.

In addition to these mitigation strategies, FDA implemented Integrated Budget and Acquisition Planning System (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.

Strategic Challenges

The PDUFA program maintained a stable staffing footprint through hiring and retention efforts. This was coupled with a high level of submission volumes and significant impacts on workload resulting from FDA's sustained response to the COVID-19 pandemic. FDA will continue to leverage available tools and flexibilities to ensure optimal staffing levels to achieve its PDUFA program commitments and public health mission.

Appendices

A. Reporting Requirements

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

Requirement	Details
Section 103 of FDARA, Title I	Extends through FY 2022, FDA's requirements for financial reports and consultations on the reauthorization of PDUFA fees.
Section 903 of FDARA, Title IX	Revises the requirements for performance reports under user fee provisions for prescription drugs, medical devices, generic drugs, and biosimilars, including to require the quarterly publication of information regarding certain guidance documents and meetings. Annual performance reports must include the following: (1) an analysis of changes in the number of FTEs hired under user fee agreements and the number funded under FDA's budget, (2) an analysis of changes in user fee revenue amounts and review costs, and (3) the number of employees in specified FDA offices for whom time reporting is required and the number for whom it is not required.
Section 736B(b) of the FD&C Act	Requires that a fiscal report, beginning with FY 2018, 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 that fiscal year.
PDUFA Reauthorization Goals and Procedure FYs 2018 Through 2022, Title 2, Section A, Number 4	Requires FDA to document in its annual financial report how the workload adjuster and resource capacity adjustment fee revenues are being utilized.
PDUFA Reauthorization Goals and Procedure FYs 2018 Through 2022, Title VI, Section B	Requires FDA to include in its annual PDUFA Financial Report information on the Agency's progress in the hiring of new staff used to support the new initiatives as identified in Section III.

B. Allowable and Excluded Costs for the PDUFA Program

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 this 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; and 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; and 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; 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), and in 2017 (PDUFA VI) 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 2020, the October of the fiscal year preceding FY 2022, was 260.388. The CPI for October 1996 was 158.3. Dividing the CPI of October 2020 by the CPI of October 1996 yields an adjustment factor of 1.644902 (rounded to the sixth decimal place) for FY 2022.

Legal Conditions

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

Exhibit 7: Legal Conditions

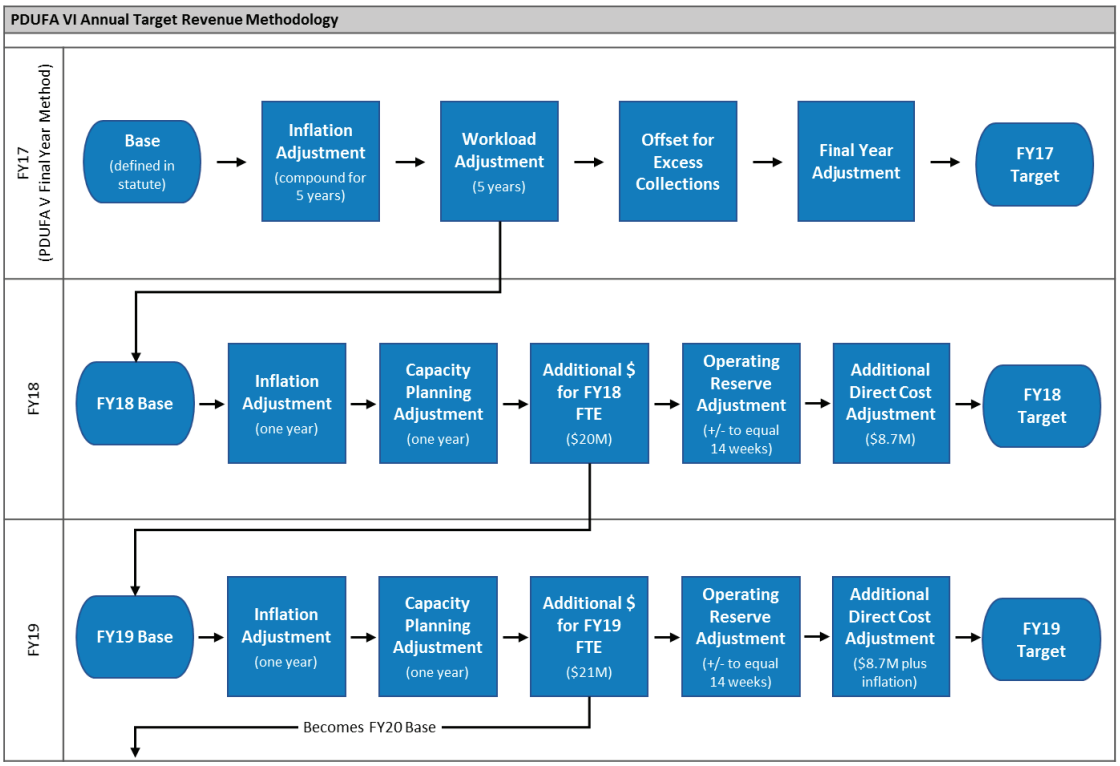
Legal Condition #	FD&C Act Section	Details
1	736(f)(1)	Fees under subsection (a) shall be refunded for a fiscal year beginning after fiscal year 1997 unless appropriations for salaries and expenses of the Food and Drug Administration for such fiscal year (excluding the amount of fees appropriated for 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 VI's Annual Target Revenue Methodology.

Exhibit 8: PDUFA VI'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

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 2022 include:

- **FDA Central**: Provides for Center-wide and Agency-wide services such as telecommunications, training, printing, mail and document management, IT systems, employee health units, and other support and miscellaneous services.
- **Employee Resource & Information Center**: Provides support to all FDA employees requesting administrative, IT, facilities, human resources, and other employee 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 Information Management and Technology**: Provides the information, communication, and knowledge infrastructure and services that enhance, transform, and sustain the ability of FDA to protect and promote public health.
- **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 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 2022 was 2.2013 percent.

Note 7. 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.

The interim capacity planning adjustment was in place for FY 2018 to FY 2020. Per the process provided by section 736(c)(2) of the FD&C Act, FDA established the new capacity planning adjustment methodology and utilized this new methodology for the first time in FY 2021. As a first step toward implementing the new methodology, FDA established a modernized time reporting and a resource capacity planning capability, as committed to in the PDUFA VI Commitment Letter. In the statute, FDA was directed to commission an independent report evaluating options and recommendations for a new methodology to accurately assess changes in the resource and capacity needs of the process for the review of human drug applications; this assessment was to be informed by personnel time reporting data as an input. FDA was also directed to publish the report for public comment.

The independent evaluation was conducted by Booz Allen Hamilton and published on FDA's website in April 2020.[10] A *Federal Register* docket was then opened to receive public comment.[11] After FDA reviewed the evaluation and the public comment, it established and implemented the new methodology for the setting of FY 2021 fee amounts. This methodology, which was established and implemented in FY 2021, is described in the *Federal Register* notice establishing fee amounts for FY 2021.[12]

Note 8. Additional Dollar Amounts Adjustment

PDUFA VI provides for the hiring of 230 new positions to support the workload associated with initiatives established or expanded by PDUFA VI. These 230 new positions are scheduled to be hired over the 5 fiscal years of PDUFA VI. The dollar amounts for the new positions committed to being hired each year are specified in the statute. For FY 2022, the Additional Dollar Amounts Adjustment is $2,769,609.

Note 9. Operating Reserve Adjustment

The operating reserve adjustment was established in the statute to provide a mechanism to support the carryover of up to 14 weeks of operating reserve from year to year.

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. If the carryover amount falls below this cap, FDA may increase the fee revenue and fees for a fiscal year to maintain up to 14 weeks of operating reserve of carryover fees.

For the operating reserve adjustment, the total carryover amount is utilized, inclusive of both appropriated and unappropriated carryover. Approximately $78,850,995 in unappropriated collections (see **Note 11**) count toward the 14-week carryover cap.

To determine the 14-week cap on the operating reserve for FY 2022, the FY 2022 annual base revenue is adjusted for inflation and capacity planning, and additional dollar amount, $1,151,522,958, is divided by 52 and then multiplied by 14. The 14-week cap on the operating reserve amount for FY 2022 is $310,025,412.

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 2021 operating reserve at the time that FY 2022 fees were set was $225,724,631.

---

[10] The independent evaluation is available at https://www.fda.gov/media/136606/download.
[11] The public comments are available at https://www.regulations.gov/comment/FDA-2020-N-0989-0002.
[12] FY 2021 PDUFA fee rates are available at https://www.federalregister.gov/documents/2020/08/03/2020-16833/prescription-drug-user-fee-rates-for-fiscal-year-2021.

Because the estimated end-of-year FY 2021 PDUFA operating reserve did not exceed the 14-week operating reserve for FY 2022, FDA did not reduce the FY 2022 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 2022. Before the operating adjustment, the estimated end of year FY 2022 available operating reserve was $145,677,240, which equated to about 6.5 weeks of available operating reserves. Adding the FY 2022 operating reserve adjustment of $39,402,923 to this amount was expected to provide approximately 8 weeks of available operating reserves, or $185,080,162 (including $20,000,000 in available fee funds maintained for any future refunds), and a total carryover of operating reserves (including unavailable funds) of $263,931,157. [13]

Note 10. Additional Direct Costs Adjustment

PDUFA VI specifies in the statute that $8,730,000 be added in addition to the operating reserve adjustment to account for additional direct costs in PDUFA VI for FY 2018. For FY 2022, the additional direct costs were $9,203,149. The amount is adjusted by inflation each year. Additional direct costs provide for non-payroll costs associated with PDUFA VI initiatives.

Note 11. 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, 2022

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.

[13] The FY 2022 PDUFA fee rates are available at https://www.federalregister.gov/documents/2022/03/28/2022-06427/prescription-drug-user-fee-rates-for-fiscal-year-2022-correction.

Note 12. 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 13. 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.”

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/.