FY 2020 PDUFA
FINANCIAL REPORT

REQUIRED BY THE

PRESCRIPTION DRUG USER FEE ACT

FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Executive Summary

The Prescription Drug User Fee Act of 1992 (PDUFA), as amended, requires the Food and Drug Administration (FDA or the Agency) to report annually on the financial aspects of PDUFA implementation. This is the third report under the sixth authorization of PDUFA (PDUFA VI) and covers fiscal year (FY) 2020.

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 2020, 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 balances, as well as comparative data from prior years.

In FY 2020, FDA had net collections of $1.020 billion in prescription drug user fees, spent $1.075 billion in user fees for the human drug review process, and carried a cumulative balance of $194 million forward for future fiscal years.

PDUFA user fees and non-user fee appropriations in FY 2020 supported 4,350 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 2020 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 the Agency) during the period of October 1, 2019, through September 30, 2020. 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) 2020 fee collections, carryover balances, obligations of user fees, and total costs of the process for the review of human drug applications from both Prescription Drug User Fee Act of 1992 (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**.

Management Discussion

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. FDA similarly 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

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 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 steady and 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.

[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 2020 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 2020, FDA's appropriation for salaries and expenses was $3,159,678,000 excluding user fees and rent payments to GSA. FDA's FY 1997 Salaries and Expenses Appropriation, excluding user fees and rent, was $1,309,907,772 after applying the FY 2020 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 Further Consolidated Appropriations Act, 2020 (Public Law 116-94) on December 20, 2019. It specified that $1,074,714,000 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 2020 is $236,366,343. In FY 2020, FDA obligated $395,658,018 from appropriations (exclusive of user fees) for the review of human drug applications. Because FDA spent more than the specified minimum amount in FY 2020, 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 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 is continuing 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

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

    - 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 will meet these commitments can be found in the Five-Year Forward View section of the PDUFA Five-Year Financial Plan.[3]

G. Performance Summary

Performance Goals

FDA noted a sustained increase in the number of original priority new molecular entities (NMEs), biologics license applications (BLAs), and priority non-NME new drug applications (NDAs) submissions in FY 2020 compared to past years. Compared to the most-recent 5-year averages, these were 56 percent and 47 percent higher respectively. Other submission types, such as priority NDA and BLA efficacy supplements, also showed sustained increases in FY 2020, including a 61 percent increase in the 5-year average. In addition, the marked trend increases of meeting management workload that started during PDUFA V continued with FDA receiving 4,678 formal meeting requests from sponsors in FY 2020—an increase of 907 or 24 percent above FY 2019 levels.

As of September 30, 2020, FDA had completed 2,006 actions for the FY 2020 cohort. FDA is currently meeting or exceeding 12 of the 12 review performance goals for FY 2020.

FDA is currently meeting or exceeding 7 of the 20 procedural and processing goals (i.e., meeting management, procedural responses, and procedural notifications) for the FY 2020 cohort. With 1,322 submissions currently under review and still within the PDUFA goal date, FDA has the potential to meet or exceed 7 of the 20 procedural and processing goals for FY 2020. FDA missed the following procedural goals related to formal meeting management: meeting request responses for Type A, Type B End-of-Phase (EOP), and Type C; meeting scheduling for Type A, B, B (EOP), and C; final written responses for Type A, Type B, Type B (EOP), and Type C; and meeting preliminary responses for Type B (EOP). Factors that contributed to missing the meeting management goals were the large volume of formal PDUFA

[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.

meeting requests (4,678 requests), the workload relating to the COVID-19 pandemic, and logistical challenges with finding time to schedule these meetings for signatories who must attend.

Program Commitments

Overall, by the end of FY 2020, PDUFA met 33 commitments and missed 9 commitments during the year. The missed commitments include the PDUFA hiring goal; the lack of timely posting of first quarter hiring data for PDUFA; the late publication of the interim assessment on hiring and retention and the late occurrence of the associated public meeting; the late publication of draft guidances on fit-for-purpose clinical outcome assessments, benefit-risk assessment, and evidentiary standards; and canceled meetings related to IT and e-submissions.

In FY 2019, CDER embarked on an initiative to modernize the New Drugs Regulatory Program. This effort allows CDER to better serve patients and better support staff in their work to carry out the Center's mission—to protect and promote public health by making sure that human drugs are safe and effective for their intended use, that they meet established quality standards, and that they are available to patients. CDER is working to build on its past successes and strengths by implementing problem-focused, interdisciplinary, team-based approaches to meet the challenges of evolving science, new drug platforms, and new drug targets, while incorporating the patient voice in development.

The modernization of the New Drugs Regulatory Program will be a long-term process of continuous improvement involving multiple initiatives. CDER began implementing some initiatives in FY 2019 and will continue implementing others over the course of several years.

In FY 2019, CBER initiated modernization of its business, data, and IT. This multi-year program has begun harmonizing and streamlining CBER's regulatory business processes for efficiency and effectiveness, applying master data management to improve data accessibility and management, and developing advanced, robust IT capabilities. These integrated improvements will allow for an improved review and internal management of novel and scientifically complex PDUFA biologics, leading to an enhanced review efficiency, effectiveness, and quality. These will also facilitate external interactions with developers, manufacturers, and other stakeholders, resulting in faster information exchange, data analysis, and dissemination of safety information, as well as better consistency of advice and decisions to guide and foster product development and review.

Details on the program performance can be found in the FY 2020 PDUFA Performance Report.[4]

Financial Information

This section provides an overview of the program financials for PDUFA for FYs 2019 and 2020. 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 2019 and FY 2020. The financial notes referenced in this table can be found in **Appendix E**.

[4] The FY 2020 PDUFA Performance Report is available at www.fda.gov/about-fda/user-fee-performance-reports/pdufa-performance-reports.

Table 1: Prescription Drug Collections, Obligations, and Carryover for FYs 2019 and 2020

Budgetary Resources	Notes	FY 2019	FY 2020
Target Revenue	Note 1	**$1,010,322,000**	**$1,074,714,000**
Total Carryover, Beginning of Year		$209,223,938	$220,088,812
Net Collections		$1,015,152,012	$1,020,229,037
Recoveries	Note 2	$12,857,171	$28,773,047
Total Budgetary Resources		**$1,237,233,121**	**1,269,090,895**

Obligations	Notes	FY 2019	FY 2020
Total Payroll and Operating	Note 3	$830,514,303	$884,915,129
Total Rent	Note 4	$52,437,964	$53,231,596
Total Shared Services	Note 5	$134,192,042	$137,340,185
Total Obligations		**$1,017,144,309**	**$1,075,486,910**

Carryover	Notes	FY 2019	FY 2020
Total Carryover, End of Year		**$220,088,812**	**$193,603,985**

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

Budgetary Resources: The "Budgetary Resources" component of **Table 1** illustrates the sum of available user fee funding (i.e., the existing available carryover balance and additional user fee collections) that was used to fund obligations. 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.

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 are available until expended. This means that the fees that are collected, appropriated, and not obligated at the end of a fiscal year remain available to FDA for use in future fiscal years. The unobligated PDUFA funds at the end of each fiscal year are referred to for purposes of this report as the "carryover balance." 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 amounts for FY 2020. The financial notes referenced in this table can be found in **Appendix E**.

Table 2: Prescription Drug Revenue and Collections Statement for FY 2020

Target Revenue	Notes	FY 2020
Base Amount		$1,001,479,592
Inflation Adjustment	Note 6	$23,999,457
Capacity Planning Adjustment	Note 7	$23,275,298
Additional Dollar Amounts	Note 8	$16,953,329
Operating Reserve Adjustment	Note 9	$0
Additional Direct Costs Adjustment	Note 10	$9,006,383
Target Revenue Total	**Note 1**	**$1,074,714,000**

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 direct cost adjustment. The amount after the additional dollar amounts becomes the base revenue for the 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 the report publication.

Cohort Year

The year in which user fee collections are originally due and reported. For example, a fee originally due in FY 2020 but received in FY 2021 is attributed to FY 2020 collections.

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 balance carried over from year to year is described in **Section K – User Fee Carryover**. An operating reserve adjustment exists to regulate the carryover user fee balance 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.

In FY 2020, the PDUFA program collected 19 percent fewer application fees than expected, an amount equal to over $40 million. This is believed to primarily be an impact of the global COVID-19 pandemic, resulting in delayed application submissions. Although the impact of this under collection can be absorbed with the existing carryover balance, FDA will need to monitor fee collection levels and obligation amounts to ensure it can maintain sufficient carryover reserves moving forward.

Table 3 outlines PDUFA collections by fee source and cohort year. Refer to **Section D** for more background and information regarding these changes.

Table 3: Prescription Drug User Fee Collections by Fee Source for Cohort Years 2019 and 2020

Fees Collected	Cohort Year FY 2019			Cohort Year FY 2020		
	Estimated†	Actual	% Diff	Estimated†	Actual	% Diff
Application Fees	$202,064,400	$212,770,978	5%	$214,942,800	$174,370,693	-19%
Program Fees	$808,257,600	$816,402,067	1%	$859,771,200	$859,812,593	0%
Total Collections	**$1,010,322,000**	**$1,029,173,045**	**2%**	**$1,074,714,000**	**$1,034,183,286**	**-4%**

Fees Receivable	Actual FY 2019	Actual FY 2020
Application Fees	$0	$0
Program Fees	$1,153,703	$2,886,431
Total Receivables	**$1,153,703**	**$2,886,431**

Numbers have been rounded to the nearest dollar.

†Estimated values were taken from the Prescription Drug User Fee Rates for FYs 2019 and 2020.

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 2 fiscal years. The financial notes can be found in **Appendix E**.

Table 4: Prescription Drug User Fee Obligations by Expense Category for FYs 2019 and 2020

User Fee Obligations	Notes	FY 2019	FY 2020
Payroll & Operating	Note 3		
CBER		$132,847,629	$136,614,045
CDER		$632,811,258	$685,618,671
CDRH		$1,501,379	$3,360,240
ORA		$7,443,695	$7,553,941
HQ		$55,910,342	$51,768,233
Total Rent	Note 4	$52,437,964	$53,231,596
Total Shared Services	Note 5	$134,192,042	$137,340,185
Total Obligations		**$1,017,144,309**	**$1,075,486,910**

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. Payroll and operating includes, 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 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 service organizations that provide support across the user fee programs, such as human resources and IT.

Obligations in the PDUFA program increased in FY 2020 from FY 2019. The increase in PDUFA user fee obligations was attributed to a growth in the payroll and operating costs. The payroll cost increase is attributable to payroll cost inflation and salary increases due to Centers and Offices converting employees under CURES Authority pay bands. PDUFA process FTEs decreased due to the Centers and Offices prioritizing COVID-19 pandemic-related work. The COVID-19-related work is not considered process for the review of human drug applications. In FY 2020, FDA 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. These investments were made in areas including pre-market review, post-market safety (including investments in the Sentinel Initiative and the FDA Adverse Event Reporting System), and IT. FDA also invested in activities to modernize CDER's New Drugs Regulatory Program.

Capacity Planning Adjustment (Interim Methodology)

FDA recognizes that revenue generated 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. In the PDUFA VI Commitment Letter, FDA committed to documenting in each annual financial report how the revenue from this adjustment is being utilized.[5]

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 helps to 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 toFY 2020. The interim methodology accounts for five types of regulatory review submissions: NDAs and BLAs, commercial investigational new drugs (INDs) with activity, efficacy supplements, manufacturing supplements, and formal PDUFA industry meetings.[6,7] These submission types are then weighted based on the percentage of total PDUFA time that CDER and CBER spent on the review of each submission type. A new capacity planning adjustment methodology was established in the *Federal Register* for FY 2021.[8]

In FY 2020, the capacity planning adjustment added $23,275,298 to the fee revenue amount for FY 2020. This increase was driven by the fact that the counts of elements for 2019 (year ending June 30) were at or near the highest levels since the first incorporation of the workload adjuster in FY 2003. The NDA/BLA count in FY 2019 was the second highest annual number recorded since the advent of the workload adjuster methodology in FY 2003. Active commercial INDs, efficacy supplements, and meetings/written responses only (WROs) were higher in 2019 than in any previous year recorded in the workload adjuster.[9] In FY 2020, the manufacturing supplement count was approximately 6 percent below the highest number recorded in the history of the workload adjuster. Comparing FY 2019 to FY

[5] See page 37, section II.A.4, of the PDUFA VI Commitment Letter at https://www.fda.gov/media/99140/download.
[6] See the fee-setting *Federal Register* notice (83 FR 37504) published on August 1, 2018, at https://www.federalregister.gov/documents/2018/08/01/2018-16387/prescription-drug-user-fee-rates-for-fiscal-year-2019.
[7] The number of PDUFA industry meetings scheduled was added to the adjustment for the first time in PDUFA VI. This was in recognition of the significant and growing demand for meetings with industry, which typically involve a substantial scientific review and necessitate the input of senior management.
[8] See the fee-setting *Federal Register* notice (85 FR 46651) published on August 3, 2020, at https://www.federalregister.gov/documents/2020/08/03/2020-16833/prescription-drug-user-fee-rates-for-fiscal-year-2021.
[9] Meetings/WROs have been recorded only since FY 2014, while the other elements have been recorded since FY 2003.

2016, the first year included in the average in column 1 in the adjustment, NDA/BLAs are 14 percent higher, active commercial INDs were 11 percent higher, efficacy supplements were 39 percent higher, manufacturing supplements were 2 percent higher, and meetings scheduled and WROs were16 percent higher. This significant and across the board increase in submission activity was the driver of the $23,275,298 upward adjustment to the fee revenue amount in FY 2020.[10]

FDA allocated the capacity planning adjustment funds to CDER and CBER based on the submission drivers in the capacity planning adjustment and FDA's expectations for growth areas in the future. This resulted in an allocation of approximately $20 million to CDER and $3 million to CBER to support direct review functions.

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 years.

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

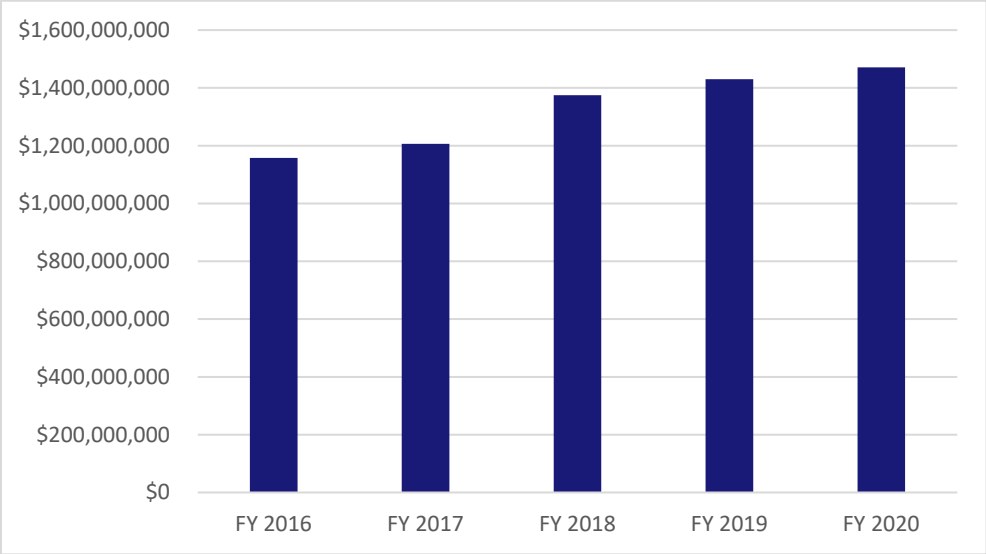
Costs		FY 2016	FY 2017	FY 2018	FY 2019	FY 2020
Total Spent		$1,157,817,695	$1,206,657,268	$1,374,508,527	$1,430,338,888	$1,471,144,928
CBER	Spent	$228,314,238	$231,880,788	$268,624,105	$291,232,610	$306,794,435
	Percent	20%	19%	20%	20%	21%
CDER	Spent	$801,353,416	$833,856,973	$954,062,652	$987,464,724	$1,018,915,025
	Percent	69%	69%	69%	69%	69%
CDRH	Spent	$0	$0	$4,260,126	$3,918,206	$4,829,906
	Percent	0%	0%	0%	0%	0%
ORA	Spent	$40,513,807	$44,814,804	$40,956,402	$40,345,646	$39,118,104
	Percent	3%	4%	3%	3%	3%
HQ	Spent	$87,636,234	$96,104,703	$106,605,242	$107,377,702	$101,487,458
	Percent	8%	8%	8%	8%	7%

Numbers have been rounded to the nearest dollar.

[10] 84 FR 37882 (August 2, 2019), available at https://www.federalregister.gov/documents/2019/08/02/2019-16435/prescription-drug-user-fee-rates-for-fiscal-year-2020.

Exhibit 4 below provides an illustration of historical PDUFA costs.

Exhibit 4: Historic Total Costs by Fiscal Year



As demonstrated by **Exhibit 4**, there has been a steady increase in program needs in the past 5 years, with obligations growing at an average rate of six percent. This graph includes the additional dollar amounts provided each year to provide for hiring of new positions that are capitalized into the subsequent year's base. Additionally, the inflation adjustment helps maintain the program's purchasing power and has run at a consistent rate of close to two percent since the start of PDUFA V. The capacity planning adjustment has demonstrated consistent increases in the submissions and activities it measures.

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. This balance is referred to as the "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. FDA considers maintaining a carryover balance of between 8 to 10 weeks of available funds as a reasonable range to mitigate these risks. FDA does, however, weigh those risks against strategic programmatic needs that may take precedence, causing the balance to, at times, dip below this range.

As noted above, the statute establishes a cap of 14 weeks of total carryover that can be maintained at the end of each fiscal year. This statutory cap on the total carryover includes amounts that are unavailable for use, including nearly $79 million in unappropriated collections (see **Table 6** and **Note 11**). As such, the statutory cap of 14 weeks of total carryover equates to approximately 10 weeks of operations that can actually be supported with available funds.

FDA may increase the annual target revenue to provide funds to increase the total carryover up to the 14-week level.

The carryover balance includes two categories:

- **Carryover Unavailable for Use** – This value represents carryover funds subject to claims or restrictions that preclude FDA from obligating the carryover funds.
- **Carryover Available for Use** – This value represents carryover funds that are not subject to any claims or restrictions and are therefore available for obligation.

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

Table 6 provides PDUFA carryover balances at the end of FY 2019 and FY 2020. The financial notes can be found in **Appendix E**.

Table 6: PDUFA Carryover for FYs 2019 and 2020

Carryover	Notes	FY 2019	FY 2020
Total Carryover, End of Year		**$220,088,812**	**$193,603,985**
Unappropriated Amounts	Note 11	($78,850,995)	($78,850,995)
Refunds	Note 12	($5,000,000)	($5,000,000)
Operating Reserve Adjustment	Note 9	$0	$0
Carryover Unavailable for Use, End of Year		**($83,850,995)**	**($83,850,995)**
Carryover Available for Use, End of Year		**$136,237,817**	**$109,752,990**

Numbers have been rounded to the nearest dollar.

To determine how much carryover is available for obligation at the end of a fiscal year, the following factors must be considered:

- **Total Carryover, End of Year** – This is the total amount of unobligated fee funds at the end of the fiscal year.
- **Carryover Unavailable for Use, End of Year** – As noted above, this value includes unobligated fee funds subject to any claims or restrictions on fees collected. This includes:
    - **Unappropriated Amounts** – FDA's PDUFA carryover balance includes approximately $78,850,955 in fee collections that are considered unappropriated. This amount is the cumulative total of fee collections that exceeded the annual level of PDUFA funds appropriated for a given year, in fiscal years prior to FY 2010. Beginning in FY 2010, a technical fix was added to the appropriations language to ensure that all fee collections would be considered appropriated. In the absence of an appropriation for the nearly $78,850,955, it is unclear whether or not FDA can obligate these funds. See **Note 11** for additional details.
    - **Refunds** – FDA maintains a small amount to provide for any refunds, as a matter of prudent operations. For that purpose, a total of $5,000,000 is being set aside. See **Note 12** for additional details.
    - **Operating Reserve Adjustment** – Should a negative operating reserve adjustment be necessary, FDA would reduce the target revenue amount by the operating reserve adjustment. FDA would then reserve a commensurate amount in the carryover balance to support operations for that fiscal year.
- **Carryover Available for Use, End of Year** – As noted above, this is the total carryover less any carryover unavailable for use. These funds become the carryover available for use at the beginning of the next fiscal year.

The operations in FY 2020 resulted in a net decrease of the carryover balance of $26,484,826, from $220,088,812 at the end of FY 2019 to $193,603,985 at the end of FY 2020. This decrease is a result of

lower application fee collections and higher refunds than planned for. The decrease in the balance will provide FDA with about 9 weeks of operations in FY 2021 from the total carryover balance. However, accounting for the unavailable funds, approximately 5 weeks of funds will actually be available in FY 2021 to mitigate the financial risks to the program.[11] FDA may consider the need for an upward operating reserve adjustment in the setting of FY 2022 fees to ensure its ability to mitigate financial risks to the continued operation of the program.

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

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

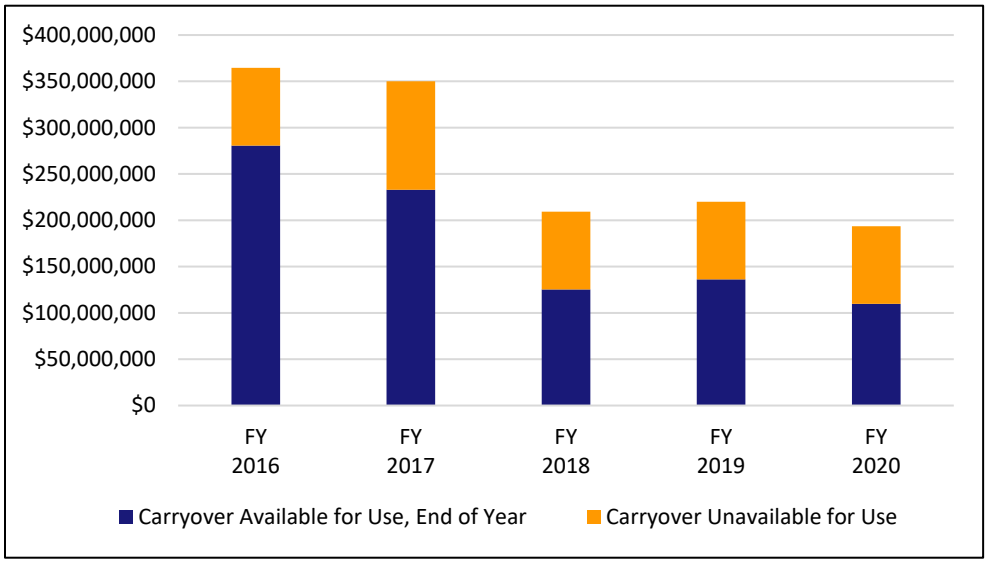
Carryover	Notes	PDUFA	PDUFA II	PDUFA III	PDUFA IV	PDUFA V	PDUFA VI		
		FY 93 – 97	FY 98 – 02	FY 03 – 07	FY 08 – 12	FY 13 – 17	FY 18	FY 19	FY 20
Total Carryover, Beginning of Year		**$0**	**$36,462,154**	**$22,683,224**	**$130,816,093**	**$178,468,707**	**$350,108,200**	**$209,223,938**	**$220,088,812**
Net Collections		$328,768,265	$680,152,170	$1,435,876,426	$2,848,504,459	$4,101,728,493	$908,077,723	$1,015,152,012	$1,020,229,037
Recoveries	Note 2	$0	$0	$0	$0	$8,749,852	$13,149,599	$12,857,171	$28,773,047
Total Obligations		($292,306,111)	($693,931,100)	($1,327,743,557)	($2,800,851,845)	($3,938,838,852)	($1,062,111,583)	($1,017,144,309)	($1,075,486,910)
Total Carryover, End of Year		**$36,462,154**	**$22,683,224**	**$130,816,093**	**$178,468,707**	**$350,108,200**	**$209,223,938**	**$220,088,812**	**$193,603,985**

Numbers have been rounded to the nearest dollar.

[11] To calculate the available operating balance for FY 2021, first divide the FY 2021 target revenue by 52 weeks to get the estimated amount needed to operate the program each week ($1,107,199,000/52 weeks = ~$21,292,288), then divide the carryover available for use by this weekly operating cost ($109,752,990/$21,292,288 = ~5 weeks of available funds).

Exhibit 5 provides a historical perspective on the carryover for the last 5 fiscal years. Prior to PDUFA VI, the carryover had been trending upward. Starting in FY 2018, FDA made investments in the program that resulted in a reduction in the carryover. In FY 2020, an undercollection of application fees contributed to the carryover balance reduction.

Exhibit 5: Historical 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 sometimes referred to as a "non-user fee spending trigger."[12] The spending trigger was $230,550,787 for FY 2019 and $236,366,343 for FY 2020.

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 amount spent on the PDUFA program for the past 5 years, as well as the dollar amount 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

Obligations		FY 2016	FY 2017	FY 2018	FY 2019	FY 2020
Total Obligated		$1,157,817,695	$1,206,657,269	$1,374,508,527	$1,430,338,888	$1,471,144,928
Non-User Fee Appropriations	Total	$320,942,599	$301,385,040	$312,396,943	$413,194,579	$395,658,018
	Percent	28%	25%	23%	29%	27%
User Fee Revenue	Total	$836,875,096	$905,272,229	$1,062,111,583	$1,017,144,309	$1,075,486,910
	Percent	72%	75%	77%	71%	73%

Numbers have been rounded to the nearest dollar.

[12] The "non-user spending trigger" is a minimum spending amount from appropriations, excluding user fees, on the PDUFA program. The "minimum spending amount from appropriations" is the amount that FDA spent on the PDUFA program in FY 1997, multiplied by the adjustment factor.

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 (OMB 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 it specifically relates 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.

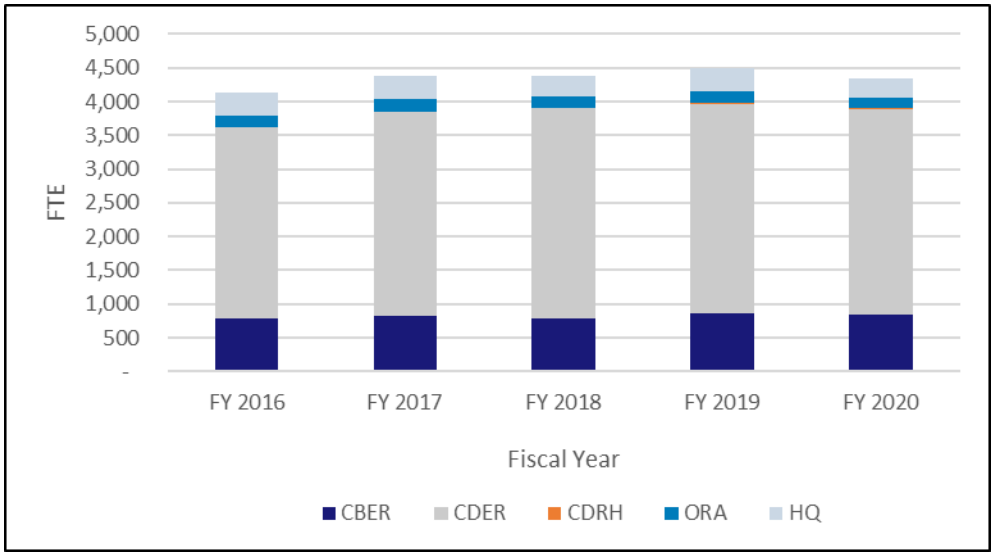
Table 9 presents total Process FTE levels, paid from user fee and non-user fee appropriations, that support the PDUFA program. The data cover the past 5 years and are arranged by FDA's organizational components (CDER, CBER, CDRH, ORA, and HQ). Staff in the consolidated shared services organizations (e.g., 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 2016	FY 2017	FY 2018	FY 2019	FY 2020
CBER	782	833	791	857	835
CDER	2,833	3,016	3,110	3,103	3,055
CDRH	N/A	N/A	25	20	23
ORA	180	192	168	163	147
HQ	330	343	318	352	290
Total	**4,125**	**4,384**	**4,412**	**4,495**	**4,350**

Exhibit 6 provides the historical trend of Process FTE distribution and levels across FDA's organizations for the past 5 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 2020 for PDUFA VI.

Table 10: PDUFA VI Target Versus Actual New Hires for FY 2020

Organization	Target New Hires	Actual New Hires
CDER	45	37
CBER	7	7
Other FDA	6	4
Total Hires	**58**	**48**

FDA missed the FY 2020 new hire target by 10 hires. FDA acknowledges there are systemic issues with the Agency's hiring process, as noted in the report *Initial Assessment of FDA Hiring and Retention – A Path Forward,*[13] which impacts PDUFA hiring. The Agency is making progress, as noted in the 2020 FDA Interim Hiring and Retention Assessment[14] and the Management's Response to the FDA Interim Hiring and Retention Assessment.[15] FDA expects to see improvements in hiring in FY 2021 and beyond.

[13] This report is available at https://www.fda.gov/media/108866/download.
[14] This assessment is available at https://www.fda.gov/media/138662/download. See also https://www.fda.gov/industry/prescription-drug-user-fee-amendments/fda-interim-hiring-and-retention-assessment-report.
[15] This response is available at https://www.fda.gov/media/138664/download. See also https://www.fda.gov/industry/prescription-drug-user-fee-amendments/fda-interim-hiring-and-retention-assessment-report.

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 Internal Control and Enterprise Risk Management (OMB A-123), 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 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 Deputy 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 A-123 assessments, and for fostering an environment that promotes strong internal control. 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 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 A-123 appendices. Specifically, reporting controls are implemented in accordance with Appendix A, Management of Reporting and Data Integrity Risk; charge card controls in accordance with Appendix B, A Risk Management Framework for Government Charge Card Programs; controls over financial disbursements in accordance with Appendix C, Requirements for Payment Integrity Improvement; and financial system controls in accordance with Appendix D, Compliance with the Federal Financial Management Improvement Act of 1996. FDA's reimbursable activity cycle memo is specifically focused

on the reporting controls related to the accounts receivable and payment processes associated with the user fee programs. This cycle memo describes the processes and controls performed by FDA to monitor the user fee cash receipts process and includes controls over reconciliation performance, aging, write-offs, and the interface between the User Fee System and the Unified Financial Management System.

In FY 2020, FDA's annual assessment of internal controls included tests of 90 business, charge card, and IT controls across 21 transaction subcycles to identify recommendations to strengthen internal controls and compliance. Also, FDA conducted an improper payment risk assessment and performs annual improper payment testing. FDA's User Fee System is compliant with HHS and Appendix D of OMB A-123. FDA's Integrated Budget and Acquisition Planning System (IBAPS) is used to support FDA's budget formulation, budget execution, acquisition planning, and payroll planning and meets FDA's and HHS's system requirements.

FDA has also implemented other internal control procedures, including the performance of Organizational Risk Reviews (ORRs), 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 is presented in HHS's consolidated financial statements. The FY 2020 HHS audit found that FDA's financial statements fairly present, in all material respects, the consolidated financial position of HHS as of September 30, 2020, and 2019, and related notes are in accordance with generally accepted accounting principles in the United States. Further, FDA's FY 2020 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 in the second year of the reauthorization. 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 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 9 weeks of total operating reserve but, because of the unavailable amounts, this equates to about 5 weeks of actual available operating reserve 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 carryover balance 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 Health 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 impacts and will seek to address financial ramifications as warranted.

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.

Strategic Challenges

While the PDUFA program has begun to experience increases in hiring and retention, this increase has been coupled with record submission volumes and significant impacts on workload resulting from the COVID-19 pandemic. FDA will work to ensure optimal staffing levels to deliver on its PDUFA program commitments and public health mission within its available tools and flexibilities.

Appendices

A. Reporting Requirements

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

Requirement	Details
FDARA, Title I, Section 103	Extends through FY 2022, FDA's requirements for financial reports and consultations on the reauthorization of PDUFA fees.
FDARA, Title IX, Section 903	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.
FD&C Act Section 736B(b)	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 2018, the October of the fiscal year preceding FY 2020, was 252.885. The CPI for October 1996 was 158.3. Dividing the CPI of October 2018 by the CPI of October 1996 yields an adjustment factor of 1.597505 (rounded to the sixth decimal place) for FY 2020.

Legal Conditions

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

Exhibit 7: Legal Conditions

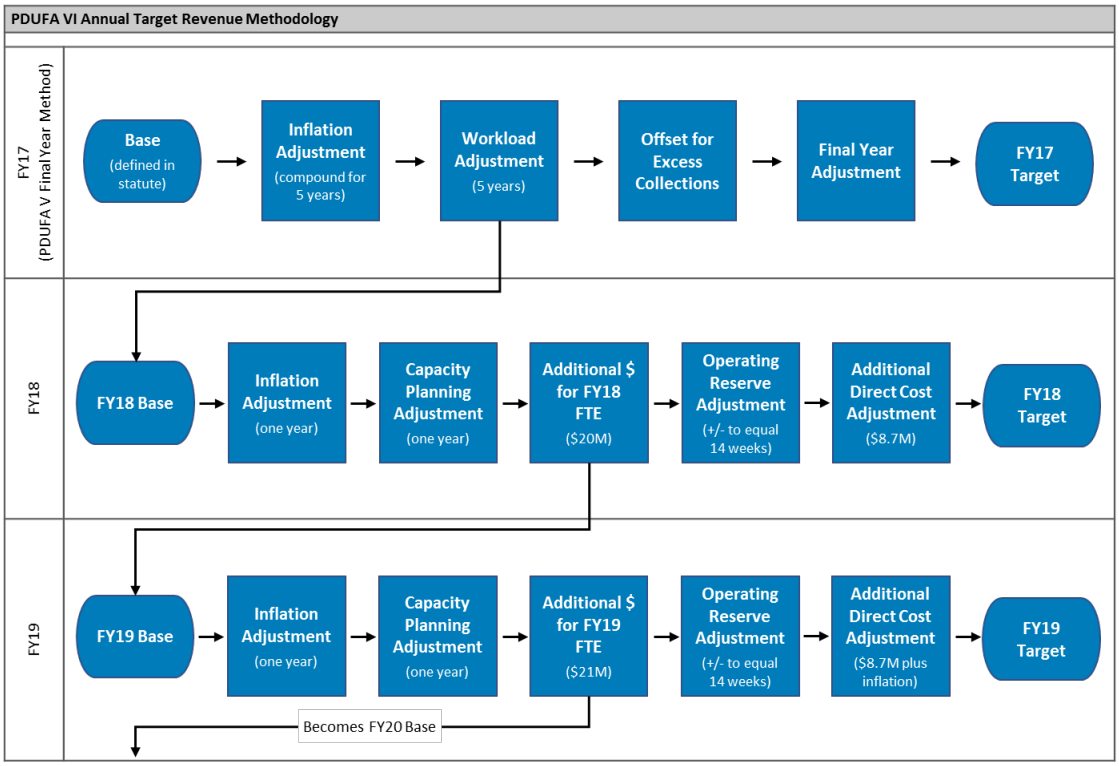
Legal Condition #	FD&C Act Section	Details
1	736(f)(1)	Fees under subsection (a) shall be refunded for a fiscal year beginning after fiscal year 1997 unless appropriations for salaries and expenses of the Food and Drug Administration for such fiscal year (excluding the amount of fees appropriated for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

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 Service Costs

FDA contains several shared service organizations that provide support across the user fee programs. The shared service organizations 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 an 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 composed 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 External Affairs – History:** Provides research, documentation, and preservation of significant FDA historical resources, as well as serving as historian for the Agency.
- **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.
- **Paperwork Reduction Act:** Acts as the liaison between FDA's Centers, HHS, and OMB on all information collection matters.
- **Office of Laboratory Safety:** Reinforces FDA's expectations for safety and laboratory security, enhances communications among FDA safety staff, and provides program support.
- **Office of 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 Manag`ement Services:** Informs operational objectives and guides strategic management planning to facilitate increased Agency effectiveness and efficiency.
- **Program Alignment Team:** Provides advice and guidance on reorganizations and delegations of authority.
- **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.

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 2020 was 2.3964 percent.

Note 7. Capacity Planning Adjustment *(interim method)*

The capacity planning adjustment is intended to adjust the inflation-adjusted base amount based on changes in the resource capacity needs of the PDUFA program; the revenue amounts generated by this adjustment are intended to support direct review functions of the program.

The inputs included in the adjustment, as prescribed in the statute, include the number of NDAs and BLAs, the number of commercial investigational drugs with activity, the number of efficacy supplements, the number of manufacturing supplements, and the number of formal meetings scheduled (Type A, B, B (EoP), C, and WRO).

The current capacity planning adjustment is referred to in the statute as the "interim" methodology; this is because the authorizing statute provides a procedure to develop a new methodology for this adjustment. The new capacity planning adjustment methodology was implemented for FY 2021 fee setting.

The capacity planning adjustment utilized in FY 2020 was 2.2697 percent.

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 years of PDUFA VI. The dollar amounts for the new positions committed to being hired each year are specified in the statute. For FY 2020, the Additional Dollar Amounts Adjustment is $16,953,329.

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 balance at an amount equivalent to 14 weeks of operations. Should FDA have a carryover balance above this cap, it would be required to reduce the target revenue amount for the next fiscal year by a commensurate amount.

If the 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 available and unavailable 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 2020, the FY 2020 annual base revenue is adjusted for inflation and capacity planning, and additional dollar amounts, $1,065,707,676, is divided

by 52 and then multiplied by 14. The 14-week cap on the operating reserve amount for FY 2020 is $286,921,297.

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 2019 operating reserve at the time that FY 2020 fees were set was $186,273,705.

Because the estimated end-of-year FY 2019 PDUFA operating reserve did not exceed the 14-week operating reserve for FY 2020, FDA did not reduce the FY 2020 PDUFA target fee amount.[16]

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. 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

This 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, 2020

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 12. Refunds

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.

[16] See https://www.federalregister.gov/documents/2018/08/01/2018-16387/prescription-drug-user-fee-rates-for-fiscal-year-2019.

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."