FIVE-YEAR FINANCIAL PLAN

Fiscal Years
2018-2019-2020-2021-2022
2022 Update

FOR THE

PRESCRIPTION DRUG USER FEE ACT PROGRAM

FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Five-Year Plan Overview

A. Scope

The purpose of the five-year financial plan is to communicate the anticipated financial position of the Prescription Drug User Fee Amendments of 2017 (PDUFA VI) program over the current five-year authorization period and to communicate how FDA plans to utilize user fee resources to execute the PDUFA VI commitments and build the PDUFA review program. This document addresses the plan for implementation and use of prescription drug user fees by the Food and Drug Administration (FDA or the Agency) during the period of October 1, 2017, through September 30, 2022.

B. Five-Year Plan Commitments

In accordance with *PDUFA Reauthorization Performance Goals and Procedures Fiscal Years FY 2018 Through 2022*, Title 2, Section B, FDA will publish a PDUFA five-year financial plan no later than the second quarter of fiscal year (FY) 2018. FDA will publish updates to the five-year financial plan no later than the second quarter of each subsequent fiscal year. The purpose of this document is to meet these commitments.

C. Updates to the Five-Year Plan

All estimates in the plan are subject to review and reassessment each fiscal year as the actual amounts for appropriations, obligations, and collections for the previous year become available. The five-year financial plan provides the baseline from which future changes will be made. Updates to the five-year financial plan will occur on an annual basis and cover the 5 years in the current reauthorization period.

Management Discussion

D. 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 the public's health. FDA helps to speed innovations that make medical products more effective, safer, and more affordable, and helps the public get accurate, science-based information needed to use medical products and consume foods to maintain and improve their health. FDA similarly plays a significant role in the nation's counterterrorism capability.

Program Organization

There are five major 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	Protects and advances the public health by helping to ensure that biological products are safe and effective, and are available to patients.
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 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 Agency 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 who 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 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 reacts to industry trends, plans and manages its research agenda in support of the user fee programs, and forecasts its user fee workload. The UFFMC will advise the Executive Committee and other Center- and Office-level bodies on a variety of financial and performance related topics.

E. User Fee Background and Structure

Under PDUFA, FDA collects fees from drug manufacturers to fund the human drug application review process. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by PDUFA, authorizes FDA to collect fees from industry to supplement 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 reauthorization of PDUFA, also known as PDUFA VI, which extends from October 1, 2017, through September 30, 2022. This five-year reauthorization ensures continued funding for FDA from FY 2018 through FY 2022 to support program operations, evaluation, and improvement. PDUFA VI continues to deliver 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 updates the fee structure to application fees and program fees with a greater proportion of the target revenue allocation shifted to program fees since it is a more predictable fee-paying type. The objective of this simpler and more efficient fee structure is to increase the predictability of funding, reduce administrative inefficiency, and improve management of funding.

Exhibit 2 outlines the PDUFA VI fee structure.

Exhibit 2: PDUFA VI Fee Structure

Fee Type		Definition
Application	*With Clinical Data*	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	Human drug application for which clinical data with respect to safety or effectiveness are not required for approval is assessed **one-half of a full fee** when the application is submitted.
Program		Prescription drug product program fees are assessed annually for eligible products. The program fees are assessed for each prescription drug product that is identified in such a human 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 to be published in the Federal Register each year; this typically occurs at the beginning of August (PDUFA User Fee Rates Archive).

PDUFA user fees collected are not a fee-for-service. The user fees that are collected are pooled and used for a wide range of allowable activities as set forth in the FD&C Act. Refer to **Appendix A** for a detailed list of allowable and excluded activities.

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

F. Forward View

The current authorization for the PDUFA program will expire at the conclusion of FY 2022 (September 30, 2022). The future of the program is dependent on timely reauthorization. The Agency has developed a package of recommendations developed through a process required in statute and the Secretary has transmitted these recommendations to the authorizing Committees. Information on this reauthorization process is available at https://www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-vii-fiscal-years-2023-2027.

As the current program is set to expire and is pending reauthorization at the time of publication of this plan, FDA cannot currently project the financial position of the program after FY 2022.

FDA does expect that many of the recent external factors impacting the program are likely to continue to impact the program in the coming years. This includes continued high levels of workload resulting from industry submissions, potential impact due to COVID-19 pandemic, and continued competition for the necessary scientific and technical talent needed to deliver PDUFA performance commitments and related public health priorities.

Discussion of Workload and Other Activities in PDUFA

Under PDUFA VI, FDA has implemented numerous commitments made under the user fee agreement as well as new programs mandated by Congress in FDARA. These have included enhancing patient input

and integrating it into regulatory decision making, enhancing regulatory science and use of real-world evidence, expediting drug development, enhancing benefit-risk assessment in regulatory decision making, enhancing regulatory decision tools to support drug development, reviewing, enhancing, and modernizing the FDA drug safety system, and improving the efficiency of human drug review through required electronic submissions and standardization of electronic drug application data.

The COVID-19 global pandemic impacted the human drug review program beginning in FY 2020. The program shifted to work in a near 100% virtual environment, program staff worked to prioritize COVID-19-related activities, and the program workload increased as the industry adapted development programs in response to the pandemic. The human drug review program adapted to these changes and will continue to adapt as needed to deliver on its public health and user fee commitments.

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 2021 compared to past years. Compared to the most-recent 5-year averages, these were 38 percent and 56 percent higher respectively. Other submission types, such as NDA and BLA manufacturing supplements requiring prior approval, also showed sustained increases in FY 2021, including a 33 percent increase when compared to the 5-year average. Many of these increases in application submissions have cascading workload effects, such as increased pre-approval inspections and post-approval activities.

FDA has continued striving to improve the Agency's ability to attract, hire, and retain the top scientific talent required for drug development oversight. This includes delivering on a PDUFA VI commitment to establish a dedicated function to enhance hiring and retention of scientific staff as well as FDA's implementation of a new pay authority provided by the Cures Act. FDA has utilized user fee resources to establish a new scientific staffing function and to implement a new pay authority to enable the Agency to better compete with private sector to recruit and retain current and new highly qualified staff under the Cures Act.

During the PDUFA VI timeframe, FDA embarked on an initiative to modernize the New Drugs Regulatory Program and will continue this modernization over the remainder of PDUFA VI. These changes are intended to free up resources so that our scientists have more time to focus on drug development, particularly for unmet medical needs, and on the multiple collaborations needed to make sure candidate drugs are developed and assessed properly, with appropriate input from external scientists, expert physicians and patient communities. The initiative includes regulatory and review process changes, as well as organizational restructuring. FDA also intends to strengthen the institutional support structures, including personnel and information technology (IT), that underpin the regulatory process. The initiative highlights the following strategic objectives:

- Recruiting the best and brightest individuals to promote scientific leadership
- Enhancing FDA's focus on interdisciplinary teams
- Prioritizing operational excellence and improving knowledge management
- Emphasizing the importance of safety across a drug's lifecycle
- Incorporating the patients' voice in regulatory decision making

Changes to Fee Structure and Fee-Setting Mechanisms in PDUFA VI

As mentioned in **Section E**, the changes to the PDUFA VI fee structure are improving the predictability of FDA funding, maximizing efficiency by simplifying the administration of user fees, and enhancing the flexibility of financial mechanisms to improve management of PDUFA program funding. Some of the key changes to the fee structure and fee-setting mechanisms in PDUFA VI include:

- An increase in the proportion of the target revenue derived from the program fee (80 percent) compared to the application fee (20 percent), providing a more predictable user fee revenue source.
- The application of an interim and final capacity planning adjustment to adjust the target revenue to keep pace with increases in program workload.
- The application of an operating reserve adjustment[1] when setting fees each fiscal year so that FDA may adjust the annual target revenue to maintain a carryover balance of not more than 14 weeks of operating expenses, which mitigates certain financial risks, such as under collections and lapses in appropriations, while avoiding the accrual of higher carryover balances.

FDA acknowledges there are inherent challenges in estimating the target revenues, cash collections, obligations, and carryover balances for each fiscal year in this plan. FDA's focus over the course of PDUFA VI has been to ensure there is sufficient resource capacity to manage the program workload, meet performance and procedural goals, and deliver on commitments funded in PDUFA VI.

Efforts to Enhance Financial Management

Under PDUFA VI, FDA made commitments to establish a resource capacity planning function and to modernize its time reporting approach. CDER and CBER have now implemented modernized time reporting and have also established the foundational resource capacity planning capability. This capability will continue to mature over the coming years as more data are collected and workload forecasts are continually refined. This will enable better forecasting of workload and the ability to translate forecasts into more targeted human resource and financial needs helping to ensure FDA has the resources it needs to deliver on all its performance commitments in PDUFA.

With the foundational resource capacity planning capability now in place, FDA has implemented the new capacity planning adjustment methodology.[2] This methodology adjusts the annual target revenue amount to account for the resources required to respond to projected sustained changes in program workload. FDA implemented the capacity planning adjustment methodology through the process defined in statute which included a third-party evaluation[3] and a review of public comments on the evaluation.

FDA also made commitments in PDUFA VI to enhance efficiency and transparency in the administration of PDUFA's financial resources. This included a third-party evaluation of PDUFA program resource management in FY 2018.[4] It also included the publishing of a five-year plan (this plan), to be updated annually. FDA also holds an annual public meeting to discuss this five-year financial plan, along with the Agency's progress in implementing resource capacity planning, modernized time reporting, and the impact of the user fee structure changes under PDUFA VI.[5]

Working Capital Fund/Cost Allocation

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[1] The operating reserve adjustment provides that the Secretary may increase the fee revenue and fees if such an adjustment is necessary to provide for not more than 14 weeks of operating reserves of carryover user fees for the process for the review of human drug applications. If there is a carryover balance in excess of 14 weeks of such operating reserves, the Secretary shall decrease such fee revenue and fees to provide for not more than 14 weeks of such operating reserves.

[2] https://www.federalregister.gov/documents/2020/08/03/2020-16833/prescription-drug-user-fee-rates-for-fiscal-year-2021

[3] https://www.fda.gov/media/136606/download

[4] https://www.fda.gov/drugs/development-resources/fiscal-year-2018-financial-management-evaluation-human-drug-user-fees-assessment-report

[5] https://www.fda.gov/drugs/news-events-human-drugs/financial-transparency-and-efficiency-prescription-drug-user-fee-act-biosimilar-user-fee-act-and

FDA has a Cost Allocation and Recovery framework to improve financial management of user fee resources for PDUFA, the Biosimilar User Fee Act (BsUFA) and the Generic Drug User Fee Amendments (GDUFA). Congress authorized FDA to establish a Working Capital Fund (WCF) to finance centralized services (see P.L. 115-141). The WCF benefits the financial management of Agency funds by:

- Increasing transparency through defining administrative activities performed for Centers and Offices and allocating costs based on Agency usage.
- Strengthening accountability by improving Agency tracking and management of administrative costs, including costs charged to user fees for administrative services.
- Promoting efficiency by optimizing customer usage and improving the management of user fee administrative costs over time.
- Leveraging the WCF governance structure to ensure FDA leadership is engaged in decision making relative to administrative costs, efficiency opportunities, recapitalization, and burden on all funding sources – including user fees.

Financial Information

This section provides an overview of the financial outlook for PDUFA through the FY 2018 – FY 2022 authorization period including user fee revenue, obligations, carryover, non-user fee appropriations requirements, and planned hiring. Refer to prior year PDUFA Five-Year Financial Plans for additional information on prior year estimates.[6]

G. User Fee Program Financials

Table 1 represents a summary of the forecasted PDUFA financial position, as it relates to user fee resources (collections and carryover). This table also provides an overview of planned obligations for which the user fee resources would be used. The financial notes can be found in **Appendix C**.

Table 1: Prescription Drug Collections, Obligations, and Carryover for Fiscal Year 2018 through Fiscal Year 2022[7]

[6] https://www.fda.gov/about-fda/user-fee-reports/user-fee-five-year-financial-plans

[7] The values in this table provide a year-to-year evaluation. Values are updated on a yearly basis. In the first year of the authorization period, estimates for all five years are included. In subsequent years of the authorization, the actual values replace the estimated values; the previous year's estimates are kept to compare with the actual values. The actual values are based on year-end reporting; thus, mid-year reporting in the current year does not occur in this report.

Budgetary Resources	Notes	FY18 Actual	FY19 Actual	FY20 Actual	FY21 Estimate	FY21 Actual	FY22 Estimate
Target Revenue	**Note 1**	**$911,346,000**	**$1,010,322,000**	**$1,074,714,000**	**$1,107,199,000**	**$1,107,199,000**	**$1,200,129,000**
Cash Collections		$908,077,723	$1,015,152,012	$1,020,229,037	$1,107,199,000	$1,152,538,861	$1,200,129,000
Recoveries	Note 2	$13,149,599	$12,857,171	$28,773,047	$12,000,000	$7,945,861	$12,000,000
Total Carryover, Beginning of Year		$350,108,200	$209,223,938	$220,088,812	$193,603,985	$193,603,985	$244,902,650
Total Budgetary Resources		**$1,271,335,522**	**$1,237,233,121**	**$1,269,090,895**	**$1,312,802,985**	**$1,354,088,707**	**$1,457,031,650**

Obligations	Notes	FY18 Actual	FY19 Actual	FY20 Actual	FY21 Estimate	FY21 Actual	FY22 Estimate
Total Payroll & Operating	Note 3	$881,209,920	$830,514,303	$884,915,129	$921,028,616	$922,626,574	$985,812,506
Total Rent	Note 4	$49,964,883	$52,437,964	$53,231,596	$66,590,414	$59,341,292	$63,162,874
Total Shared Services	Note 5	$130,936,781	$134,192,042	$137,340,185	$135,434,813	$127,218,191	$124,845,109
Total Obligations		**$1,062,111,583**	**$1,017,144,309**	**$1,075,486,910**	**$1,123,053,843**	**$1,109,186,057**	**$1,173,820,489**

Carryover	Notes	FY18 Actual	FY19 Actual	FY20 Actual	FY21 Estimate	FY21 Actual	FY22 Estimate
Total Carryover, End of Year		$209,223,938	$220,088,812	$193,603,985	$189,749,142	$244,902,650	$283,211,161
Unappropriated Amounts		($78,850,995)	($78,850,995)	($78,850,995)	($78,850,995)	($78,850,995)	($78,850,995)
Future Year Refunds Allowance, Set Aside		($5,000,000)	($5,000,000)	($20,000,000)	($20,000,000)	($20,000,000)	($20,000,000)
Carryover Net of Unavailable and Set Aside, End of Year		**$125,372,943**	**$136,237,817**	**$94,752,990**	**$90,898,147**	**$146,051,655**	**$184,360,166**

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) for FY 2018 through FY 2021 actuals and the estimate for FY 2022. The "Target Revenue" is the annual revenue amount established when fees for the fiscal year are set. Cash collections are the actual amount collected during the fiscal year and are estimated to be equal to the target revenue. PDUFA VI specifies how the fees must be calculated each fiscal year, including annual adjustments that must be made for inflation and changes in the capacity needs of the program.

For the purposes of this plan, future year recoveries are estimated to be $12 million annually. Additional details on recoveries are included in **Note 2**.

Obligations: The obligations component of **Table 1** shows the FY 2018 through FY 2021 actual expenditure and planned expenditure for FY 2022 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 VI.

Carryover: PDUFA fees that are collected, appropriated, and not obligated at the end of the fiscal year remain available to FDA for use in future fiscal years. 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. Additionally, FDA has collected some fees that are considered unappropriated, and are therefore considered currently unavailable for obligation. The unobligated PDUFA funds at the end of each fiscal year are referred to for purposes of this report as the "carryover" in **Table 1**.

H. User Fee Revenue

Table 2 outlines the estimated annual target revenue amounts for each fiscal year. The financial notes referenced in this table can be found in **Appendix C**.

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

Annual updates to this plan will inform the actual target revenue amounts for the current fiscal year and the actual collections amount from the preceding fiscal year.

Table 2: Prescription Drug Revenue and Collections Statement for Fiscal Year 2018 through Fiscal Year 2022

Budgetary Resources	Notes	FY18	FY19	FY20	FY21	FY22
		Actual	Actual	Actual	Actual	Actual
Statutory Base		$878,590,000	$935,903,507	$1,001,479,592	$1,065,707,676	$1,098,077,960
Inflation Adjustment		$14,820,056	$16,572,979	$23,999,457	$14,379,594	$24,171,990
Capacity Planning Adjustment		$22,415,658	$27,685,634	$23,275,298	$12,563,794	$26,503,399
Additional Dollar Amounts	Note 6	$20,077,793	$21,317,472	$16,953,329	$5,426,896	$2,769,609
Operating Reserve Adjustment	Note 7	($33,287,582)	$0	$0	$0	$39,402,923
Additional Direct Costs Adjustments	Note 8	$8,730,000	$8,842,303	$9,006,383	$9,121,165	$9,203,149
Target Revenue Total	Note 1	**$ 911,346,000**	**$ 1,010,322,000**	**$ 1,074,714,000**	**$ 1,107,199,000**	**$ 1,200,129,000**

Budgetary Resources	Notes	FY18	FY19	FY20	FY21	FY21	FY22
		Actual	Actual	Actual	Estimate	Actual	Estimate
Cash Collections		$908,077,723	$1,015,152,012	$1,020,229,037	$1,107,199,000	$1,152,538,861	$1,200,129,000
Recoveries	Note 2	$13,149,599	$12,857,171	$28,773,047	$12,000,000	$7,945,861	$12,000,000
Total Carryover, Beginning of Year		$350,108,200	$209,223,938	$220,088,812	$193,603,985	$193,603,985	$244,902,650
Total Budgetary Resources		**$ 1,271,335,522**	**$ 1,237,233,121**	**$ 1,269,090,895**	**$ 1,312,802,985**	**$ 1,354,088,707**	**$ 1,457,031,650**

Numbers have been rounded to the nearest dollar

The base revenue for FY 2018 is specified in statute ($878,590,000). The annual base revenue for each subsequent year is equal to the prior year's base plus inflation, capacity planning, and additional dollar amount adjustments. See **Note 1** for a diagram of this process.

The process for setting of the annual target revenue is defined in statute. Each year's base revenue is adjusted for the following factors:

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

  The actual inflation adjustment utilized was 1.6868 percent in FY 2018, 1.7708 percent in FY 2019, 2.3964 percent in FY 2020, 1.3493 in FY 2021, and 2.2013 in FY 2022.

- **Capacity Planning Adjustment:** The capacity planning adjustment adjusts the inflation-adjusted base amount according to changes in the resource capacity needs of the PDUFA program; the revenue amounts generated by this adjustment support direct review functions of the program.

  Section F above, as well as the references provided in that section, describe the implementation and mechanisms of the capacity planning adjustment.

  The capacity planning adjustment utilized under the interim methodology was 2.509 percent in FY 2018, 2.9067 percent in FY 2019, and 2.2697 percent in FY 2020. The updated methodology, first utilized for FY 2021, discontinued the use of a percentage and instead produced a dollar amount to fund the needed 42 additional full-time equivalents. This amount was $12.6 million for FY 2021. In FY 2022 the dollar amount to fund the needed 85 additional full-time equivalents was $26.5 million.

- **Additional Dollar Amounts:** PDUFA VI provided for the hiring of 230 new positions to support workload associated with initiatives established or expanded by PDUFA VI. These 230 new positions were 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 statute. For details, please see **Section L** – Planned Hiring.

- **Operating Reserve Adjustment:** The operating reserve adjustment was established in 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 is required to reduce the target revenue amount for the next fiscal year by a commensurate amount.

  Should the amount fall 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 purposes of the operating reserve adjustment, the total carryover amount is utilized, inclusive of both appropriated and unappropriated carryover. For PDUFA VI, approximately $78,850,995 in unappropriated collections (see **Note 9**) count towards the 14-week carryover cap.

  Should FDA make an operating reserve adjustment, either up or down, FDA must explain its rationale in the annual fee-setting Federal Register notices.

  In FY 2018, FDA applied a downward operating reserve adjustment of $33,287,583. Because the estimated FY 2019, FY 2020, and FY 2021 PDUFA operating reserve did not exceed 14 weeks, FDA did not reduce the FY 2019, FY 2020, or FY 2021 PDUFA target fee revenue. In FY 2022, FDA applied an upward operating reserve adjustment of $39,402,902.

- **Additional Direct Costs Adjustment:** Additional direct costs provide for non-payroll costs associated with PDUFA VI initiatives (see **Table 2**). The amount for FY 2018 is specified in statute and adjusted by inflation each year. The additional direct costs amounts, being only operating and not payroll funds, use an inflation adjustment that is based only on changes in the CPI.

Fee rates are established each year and revenues from application fees provide 20 percent of the total revenue and prescription drug program fees provide 80 percent of the total revenue. User fee collections are recognized and reported in the year 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. **Table 3** presents the forecasted and actual total annual collections by fee type and cohort year.

Table 3: PDUFA VI Collections by Cohort Year

Fee Type	Cohort Year	2018	2019	2020	2021	2021	2022
	Cost Type	Actual	Actual	Actual	Estimate	Actual	Estimate
Application Fees		$154,673,005	$212,770,978	$167,013,280	$221,439,800	$253,356,534	$240,025,800
Program Fees		$726,034,694	$816,402,067	$858,270,332	$885,759,200	$912,740,016	$960,103,200
Total Cash Collections		**$880,707,699**	**$1,029,173,045**	**$1,025,283,612**	**$1,107,199,000**	**$1,166,096,550**	**$1,200,129,000**

Estimated Total Cash Collections have been rounded to the nearest thousand dollars
All other numbers have been rounded to the nearest dollar

I. User Fee Obligations

Table 4 provides a breakout of planned user fee obligations by expense category for the 5 years represented in this plan. This plan provides actual amounts for the preceding fiscal years, as well as updated planned amounts for the remaining fiscal year. The financial notes can be found in **Appendix C**.

Table 4: Prescription Drug User Fee Obligations by Expense Category for Fiscal Year 2018 through Fiscal Year 2022

User Fee Obligations	Notes	FY18	FY19	FY20	FY21	FY21	FY22
		Actual	Actual	Actual	Estimate	Actual	Estimate
Payroll & Operating	Note 3						
CBER		$129,543,398	$132,847,629	$136,614,045	$149,475,247	$150,521,826	$163,802,977
CDER		$688,935,477	$632,811,258	$685,618,671	$698,930,717	$704,118,513	$753,055,633
CDRH		$786,091	$1,501,379	$3,360,240	$4,122,893	$2,344,727	$4,239,557
ORA		$7,733,467	$7,443,695	$7,553,941	$8,753,009	$7,143,725	$9,312,383
HQ		$54,211,488	$55,910,342	$51,768,233	$59,746,750	$58,497,784	$55,401,955
Total Rent	Note 4	$49,964,883	$52,437,964	$53,231,596	$66,590,414	$59,341,292	$63,162,874
Total Shared Services	Note 5	$130,936,781	$134,192,042	$137,340,185	$135,434,813	$127,218,191	$124,845,109
Total Obligations		**$ 1,062,111,585**	**$ 1,017,144,309**	**$ 1,075,486,910**	**$ 1,123,053,843**	**$ 1,109,186,057**	**$ 1,173,820,489**

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 statute. This

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. **Appendix A** provides additional information regarding allowable and excluded costs for the PDUFA program.

- **Rent:** This is paid to the General Services Administration (GSA) for the Federal buildings that FDA occupies, as well as to non-Federal sources for direct leases and services (see **Note 4**). Rent is charged at different rates depending 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. Shared services at FDA are funded through the WCF. Yearly costs are determined by the Cost Allocation and Recovery framework discussed previously. In FY 2021, the WCF absorbed the funding of several offices that were previously funded through HQ. This change is responsible for the variance in HQ and Shared Services from the original plan, published in FY 2018, for FY 2021 and beyond. **Note 5** provides a full list of what is funded through the WCF.

Variances occurred between the original FY 2021 plan and the actuals in some areas:

- **CDRH Obligations:** CDRH obligations of the fee in FY 2021 were lower than estimated due to an increase in budget authority dollars spent towards the process. CDRH's total PDUFA workload and process costs increased from FY20 to FY21.

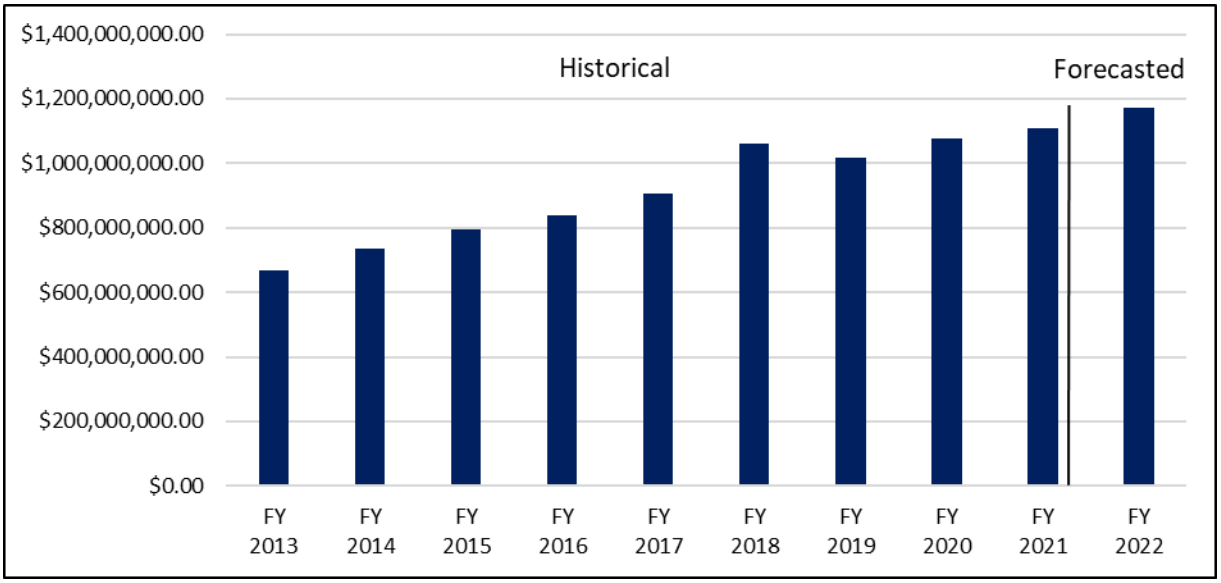
- **ORA Obligations:** Actual ORA obligations in PDUFA were lower than anticipated due to the Agency reducing foreign travel out of safety concerns for employees related to the pandemic. This led to lower than planned spending on foreign inspectional travel.

- **Rent:** The variances in rent actuals for FY 2021 were due to a lower rent bill than anticipated. While small fluctuations are common, FDA does not anticipate large variances in the Rent account in future fiscal years.

- **Shared Services:** Shared Services obligations were adjusted to reflect a redistribution of costs by funding source, which caused an overall decrease of PDUFA user fee obligations in Shared Services in FY 2021.

For historical context, **Exhibit 3** below provides an illustration of historical PDUFA V obligations and projected PDUFA VI needs.

Exhibit 3: Historical and Forecasted User Fee Obligations by Fiscal Year



Obligations in the PDUFA program increased in FY 2021 from FY 2020. This increase in PDUFA user fee obligations can be attributed to a growth in payroll and operating costs. 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.

J. 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 total carryover that can be maintained at the end of each fiscal year. FDA also may increase the annual target revenue up to that cap.

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 5**. 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 5** and **Note 9**). 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 carryover balance each year is equal to cash collections minus net obligations. This is shown in **Table 1** above.

Table 5 provides projections of PDUFA carryover balances at the end of each fiscal year. The financial notes can be found in **Appendix C**.

Table 5: PDUFA Carryover by Fiscal Year

Carryover	Notes	FY18 Actual	FY19 Actual	FY20 Actual	FY21 Estimate	FY21 Actual	FY22 Estimate
Total Carryover, End of Year		**$209,223,938**	**$220,088,812**	**$193,603,985**	**$189,749,142**	**$244,902,650**	**$283,211,161**
Unappropriated Amounts	Note 9	($78,850,995)	($78,850,995)	($78,850,995)	($78,850,995)	($78,850,995)	($78,850,995)
Future Year Refunds Allowance, Set Aside	Note 10	($5,000,000)	($5,000,000)	($20,000,000)	($20,000,000)	($20,000,000)	($20,000,000)
Carryover Net of Unavailable and Set Aside, End of Year		**$125,372,943**	**$136,237,817**	**$94,752,990**	**$90,898,147**	**$146,051,655**	**$184,360,166**

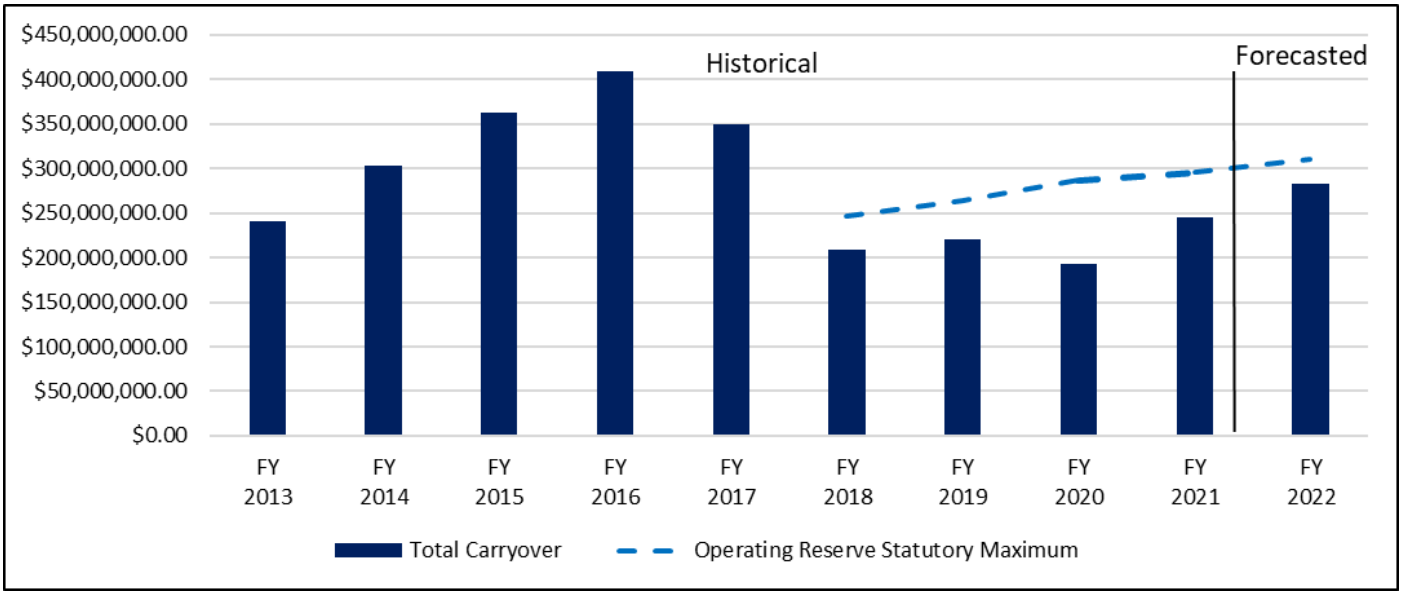
Numbers have been rounded to the nearest dollar

These terms are defined below:

- **Total Carryover, End of Year** – This is the total amount of unobligated 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 9** 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 10** 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.

Exhibit 4 below shows the historic trend of carryover in PDUFA V and the forecasted carryover in PDUFA VI.

Exhibit 4: Historical and Forecasted Carryover by Fiscal Year



The operations in FY 2021 resulted in a net increase of the carryover balance due to an increase in application fee and program fee collections. The carryover net of unavailable and set-aside is now approximately seven weeks of available operating reserve levels.

K. 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".[8] **Table 6** presents actual non-user fee spending triggers for FY 2018 through FY 2022.

Table 6: Minimum Allocation of PDUFA Non-User Fee Appropriations by Fiscal Year

FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Actual	Actual	Actual	Actual	Actual
$225,939,032	$230,550,787	$236,366,343	$240,535,847	$243,379,188

Numbers have been rounded to the nearest dollar

The non-user fee spending trigger amount is determined by multiplying the base amount spent on the human drug review process in FY 1997 ($147,959,689) times the adjustment factor for the fiscal year. See **Note 11** for more details on the adjustment factor.

FDA is committed to spend at least the required minimum from non-user fee appropriations in each fiscal year. In years when FDA programs do not receive appropriations to cover costs of inflation and mandatory pay increases, FDA activities other than human drug review may be reduced to assure that the allocation of non-user fee appropriations for drug review meets the requirements of this trigger.

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

L. Planned Hiring

PDUFA VI provides for the hiring of 230 new positions to support workload associated with initiatives established or expanded by PDUFA VI. **Table 7** presents the hiring targets for these new positions each fiscal year of PDUFA VI and the actual hiring for FY 2021. The cumulative progress made towards the hiring goals can be found on the FDA website.[9]

Table 7: Target New Hires by Organization for PDUFA VI

Organization	2018	2019	2020	2021		2022
	Actual	Actual	Actual	Target	Actual	Target
CDER	37	40	37	17	14	9
CBER	16	8	7	1	1	0
Other FDA	10	3	4	0	0	0
Total Hires	**63**	**51**	**48**	**18**	**15**	**9**

Management Assurance

M. 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 Director as

[9] https://www.fda.gov/industry/prescription-drug-user-fee-amendments/food-and-drug-administration-reauthorization-act-2017-fdara-hiring-data

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 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 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 2021, FDA's annual assessment of internal controls included tests of 80 business, charge card, and IT controls across 18 transaction sub-cycles to identify recommendations to strengthen internal controls and compliance. This assessment included 27 IT controls related to the User Fee System (UFS). Annually, FDA conducts an improper payments risk assessment and performs improper payment testing. In March 2021, FDA completed this testing, which involved 100 payments related to user fee funding, including payments for vendors (64), purchase cards (16), grants (14), and travel (6). Any deficiencies identified during FDA's internal control testing are tracked under a Continuous Monitoring Program to facilitate timely remediation. UFS is compliant with HHS guidelines and with OMB Circular A-123 Appendix D, Compliance with the Federal Financial Management Improvement Act of 1996. FDA's Integrated Budget and Acquisition Planning System (IBAPS) not only is used to support FDA's budget formulation, budget execution, acquisition planning, and payroll planning but also meets FDA's and HHS's system requirements.

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 is presented in HHS's consolidated financial statements. The FY 2021 HHS audit found that FDA's financial statements fairly present, in all material respects, the consolidated financial position of HHS as of September 30, 2021, and 2020, and related notes are in accordance with generally accepted accounting principles in the United States. Further, FDA's FY 2021 Assurance Statement found no material weaknesses or financial system nonconformances.

N. 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 only assume 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 listing of foreseeable risks associated with the collections and obligations of funds for which FDA has identified contingency plans in order to move forward in the best interests of the program.

- **Under-Executing Planned Spend:** Historically, PDUFA budgetary resources have been under-spent due to the uncertainty around the timing of revenue availability (user fee and non-user fee), 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 (CR) 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 11 weeks of total operating reserve but, because of the unappropriated amounts, this equates to about 7 weeks of actual available operating reserve to help mitigate risk. See **Note 7** for additional details.

- **Under Collecting and Over Collecting Fees:** If FDA does not receive the estimated number of fees, there may be an excess or deficit in collected revenue. When FDA under collects user fees, it leverages its carryover balance to maintain continuity in operations. In FY 2021 FDA collected 104 percent of its target revenue, which resulted in an increased carryover balance in FY 2022. When FDA over collects, the carryover may increase without additional planned expenditures being identified to obligate those funds towards. The changes in the fee structure, 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 UFFMC 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 better informed decisions about the best use of its resources.

Strategic Challenges

The PDUFA program maintained a stable staffing footprint through hiring and retention efforts, and this was coupled with record submission volumes and significant impacts on workload resulting from the COVID-19 pandemic. FDA worked to ensure optimal staffing levels to deliver on its PDUFA program commitments and public health mission within its available tools and flexibilities.

Appendices

A. 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

B. User Fee Program History

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.

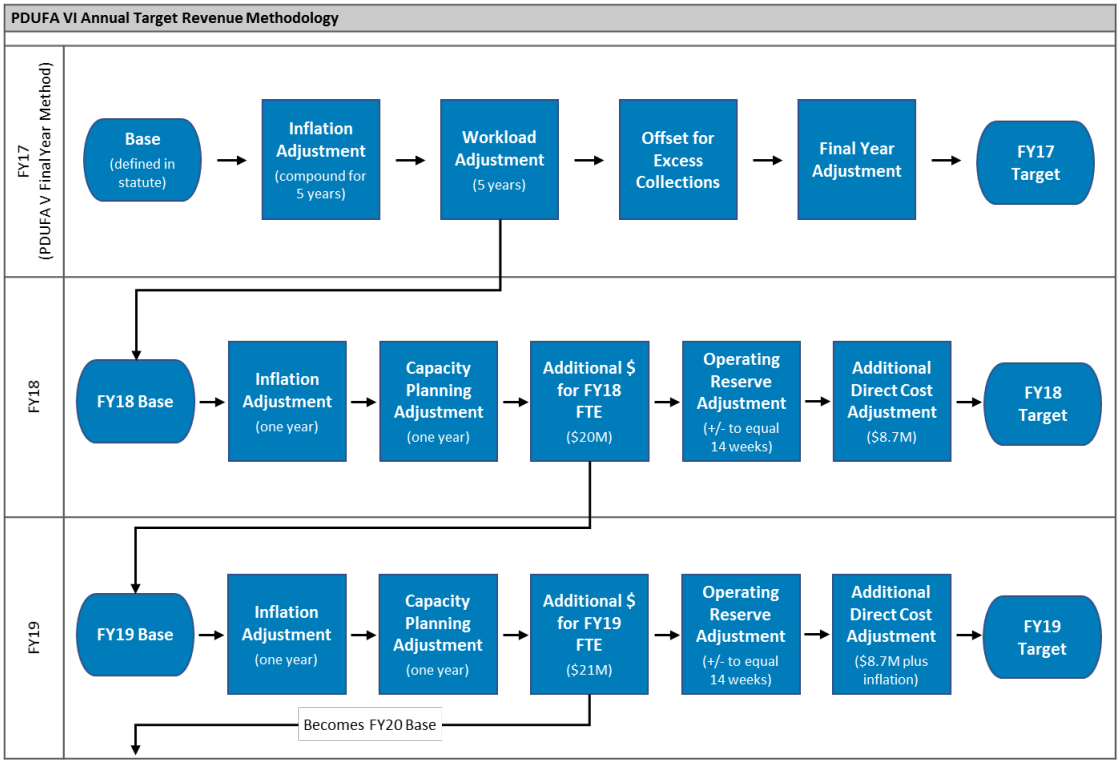
Originally authorized in 1992, PDUFA was reauthorized in 1997 (PDUFA II), 2002 (PDUFA III), 2007 (PDUFA IV), 2012 (PDUFA V), and in 2017 (PDUFA VI) with the support of industry, other stakeholders, Congress, and the Administration. Over time, PDUFA has been a success, creating a predictable, streamlined review process and dramatically reducing the average time to new drug approval.

C. Financial Notes

Note 1. Annual Target Revenue Methodology

Exhibit 5 is a flow chart delineating the PDUFA VI Annual Target Revenue Methodology.

Exhibit 5: PDUFA VI 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. Pay and Operating Costs

Pay and operating costs associated with the PDUFA program are based on obligations attributed to CBER, CDER, CDRH, ORA, and HQ.

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 A** 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

The GSA charges rent to FDA for the Federal buildings that FDA occupies. This rent is charged at different rates depending on the type and location of the space provided. Since rent is an 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 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 square footage occupied by that Center.

Note 5. Shared Service Costs

FDA contains several shared service organizations, funded through the WCF, that provide support across the user fee programs. Several new organizations were funded by the WCF in FY 2021. The shared service organizations funded in FY 2021 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 the public health.
- **Division of Budget Execution and Control:** Initiates, monitors, and analyzes FDA budget resources. The Agency budget is comprised of several appropriation accounts including: Salaries and Expenses, Revolving Fund for Color Certification and other Services, Cooperative Research and Development Agreement, Contingency Fund, Building and Facilities, and Royalties.
- **Office of Finance, Budget, Acquisitions, and Planning:** Leads FDA's budget, acquisitions, and financial management functions while ensuring the financial integrity of FDA's resources.
- **Office of Security Operations:** Develops and implements the Agency-wide security policies and programs by providing leadership and guidance to managers and staff on all aspects of security. Administers vital security functions that contribute to the Agency's mission of protecting the public health by enhancing the safety and security of all personnel, facilities, and information.
- **Office of Laboratory Safety:** Reinforces FDA's expectations for safety and laboratory security, enhances communications among FDA 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 development and implementation of administrative policies, programs, and initiatives.
- **Office of Human Capital Management:** Provides Human Resource services which 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 the FDA to hire a talented and qualified workforce.
- **Office of Planning, Evaluation, and Risk Management:** Partners with FDA leaders to achieve organizational excellence by improving program performance, governance, operational efficiency, and risk management.

Note 6. Additional Dollar Amounts Adjustment

PDUFA VI specifies that additional direct costs be accounted for in target fee revenue amounts. For each of the fiscal years 2018 through 2022, additional dollar amounts for each fiscal year are as follows:

- $20,077,793 for FY 2018
- $21,317,472 for FY 2019
- $16,953,329 for FY 2020
- $5,426,896 for FY 2021
- $2,769,609 for FY 2022

Note 7. Operating Reserve Adjustment

To determine the 14-week cap on the operating reserve for FY 2022, the FY 2022 annual base revenue adjusted for inflation, capacity planning, and additional dollar amounts, $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 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 20212021 operating reserve was $225,724,631.[10]

Because the estimated end of year FY 2021 PDUFA operating reserve does not exceed the 14-week operating reserve for FY 2022, FDA did not reduce the FY 2022 PDUFA fee revenue. However, FDA applied an operating reserve adjustment to increase the fee revenue and fees for FY 2022. The statute authorizes FDA to raise the fee revenue by up to $84,300,781 ($310,025,412 minus $225,724,631) for the operating reserve adjustment. FDA exercised its discretion to make a smaller operating reserve adjustment of $39,402,923.

Note 8. Additional Direct Costs Adjustment

PDUFA VI specifies that $8,730,000 be added to other fee adjustments to account for additional direct costs in PDUFA VI starting with FY 2018. This additional direct cost adjustment is adjusted for inflation starting with FY 2019.

As a result of a geographical revision made by the Bureau of Labor and Statistics in January 2018, the Washington, DC-Baltimore index was discontinued and replaced with two separate indices (i.e., "Washington-Arlington-Alexandria" and "Baltimore-Columbia-Towson"). In order to continue applying a CPI which best reflects the geographic region in which FDA is located and which provides the most current data available, the Washington-Arlington-Alexandria index will be used in calculating the relevant adjustment factors for FY 2020 and subsequent years.

The Secretary shall, in addition to other adjustments, further increase the fee revenue and fees for:

- FY 2018, by $8,730,000; and
- FY 2019, by $8,730,000, multiplied by the CPI for urban consumers (Washington -Baltimore, DC–MD–VA–WV; Not Seasonally Adjusted; All Items; Annual Index) for the most recent year of available data, divided by such Index for 2016.
- FY 2020 and subsequent fiscal years, by $8,730,000, multiplied by—

[10] https://www.federalregister.gov/documents/2021/08/16/2021-17505/prescription-drug-user-fee-rates-for-fiscal-year-2022

- The CPI for urban consumers (Washington-Arlington-Alexandria, DC–MD–VA–WV; Not Seasonally Adjusted; All Items; Annual Index) for the most recent year of available data, divided by the CPI for urban consumers (Washington -Baltimore, DC–MD–VA–WV; Not Seasonally Adjusted; All Items; Annual Index) for 2016.

Note 9. Unappropriated Amounts

This is the amount that FDA collected in user fees in excess of the amount specified in appropriations acts prior to FY 2010. FDA's ability to access and obligate these collections remains uncertain. **Table 8** outlines the excess user fees by fiscal year.

Table 8: 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**

Note 10. 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.

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

Note 11. 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."