

FIVE-YEAR FINANCIAL PLAN

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

FOR THE

PRESCRIPTION DRUG USER FEE ACT PROGRAM

FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES



U.S. FOOD & DRUG
ADMINISTRATION

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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. 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 will only cover the five-years in the current reauthorization period.

Management Discussion

D. Organization Background

FDA is responsible for protecting public health by ensuring 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	Ensures the safety, purity, potency, and effectiveness of biological products including vaccines, 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 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 current user fee governance process leverages the User Fee Council (UFC) that 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 UFC is responsible for providing oversight support 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. In the near future, FDA expects to make enhancements to its existing governance structure based on recommendations from a third-party evaluation of PDUFA program resource management.

E. User Fee Background and Structure

Under PDUFA, FDA collects fees from drug manufacturers to fund the human drug review process. The Federal Food, Drug and Cosmetic (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.

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	<i>With Clinical Data</i>	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.
	<i>Without Clinical Data</i>	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, typically at the beginning of August ([PDUFA User Fee Rates Archive](#)).

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

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

F. Five-Year Forward View

Discussion of Workload and Other Activities in PDUFA

In its sixth authorization, PDUFA is a mature program relative to the other user fee programs. During PDUFA V, FDA implemented numerous commitments made under the user fee agreement as well as new programs mandated by Congress in the FDA Safety and Innovation Act. These included the review program for new molecular entity new drug applications (NME NDAs) and original biologics license applications (BLAs), patient-focused drug development, a structured framework for benefit-risk assessment, the breakthrough therapy program, and the qualified infectious disease product program. Some of these programs received funding and some did not. For those programs that were not accompanied by resources, FDA used existing resources to implement them.

Throughout PDUFA V, FDA’s workload for some of these new programs was higher than anticipated. An example of this is the breakthrough therapy program where over 70 designated products were in development and nearly 20 designated products were in review as of October 1, 2017. FDA assessed the breakthrough therapy workload during PDUFA V that was then used in the PDUFA VI discussions with industry and other stakeholders to secure new funding to continue supporting this successful program. By most measures, FDA continued to observe increasing workload throughout PDUFA V. In 2017, FDA saw workload increases in the following areas compared to the most recent five-year average:

- 57 NME NDAs and original BLAs received (10% increase)
- 106 non-NME NDAs (26% increase)
- 243 efficacy supplements (37% increase)

Many of these increases in application submissions have follow-on workload effects, such as increased pre-approval inspections, many of which require foreign travel. FDA's activity during drug development again reached new heights at the close of PDUFA V with 8083 commercial INDs that had activity and 3413 formal meeting requests from sponsors. In the five-year period between 2012 and 2017, FDA's formal meeting workload increased by 50%. While FDA and industry agreed on changes to meeting management during PDUFA VI, FDA recognizes that meetings between review staff and sponsors are critical interactions that facilitate efficient development programs. Therefore, FDA expects that this workload will continue to increase during PDUFA VI and is committed to enhancing the agency's ability to forecast changes in workload through a resource capacity planning function. Additional commitments made in PDUFA VI include an expansion of the patient-focused drug development program, enhancements to FDA's management of combination products, new programs related to complex innovative trial designs and model-informed drug development, and exploring the use of real world evidence for safety and efficacy determinations. FDA is also committed to the Regenerative Medicine Advanced Therapies (RMAT) program, designated by the 21st Century Cures Act, which facilitates development of PDUFA regenerative medicine products. FDA looks forward to the next five years of PDUFA VI being a period of strong innovation in drug development.

As PDUFA VI begins, FDA is also working to improve the Agency's ability to attract, hire, and retain the top scientific talent that is 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 21st Century Cures Act (Cures). FDA intends to utilize user fee resources, including the carryover balance, to launch the new scientific staffing function and to implement the additional compensation given to current and new staff under Cures.

Another use of FDA's carryover resources lies in CDER's ongoing examination of the new drugs regulatory program to ensure that it is well-positioned for future success. FDA intends to invest carryover resources to enhance new drug review operations. Within CBER, FDA's carryover resources are facilitating harmonization and streamlining of regulatory operations and enhancing application of information technology (IT) and data standards to facilitate regulatory review.

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 expected to improve the predictability of FDA funding, improving efficiency by simplifying the administration of user fees, and enhancing flexibility of financial mechanisms to improve management of PDUFA program funding. Some of the key changes to the fee structure and fee-setting mechanisms include:

- Increasing the proportion of the target revenue derived from the program fee (80%) compared to the application fee (20%), providing a more predictable source of fees.
- The application of an interim and final capacity planning adjustment, which is discussed in greater detail later in this section, to adjust the target revenue to keep pace with increases in program workload.
- The application of an operating reserve adjustment¹ 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

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.

weeks of operating expenses, which mitigates certain financial risks, such as under collections and a lapse in appropriations, while avoiding the accrual of higher carryover balances.

While FDA expects stable funding and operations in PDUFA VI, 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 next five years is to ensure there is sufficient capacity to manage the program workload, meet performance and procedural goals, and deliver on new 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. While it will take several years to establish and mature the resource capacity planning capability, it will provide the ability to better forecast workload and to translate forecasts into human resource and financial requirements. This capability will help FDA ensure it has the resources it needs when it needs them to be able to deliver on its performance commitments.

In addition, once the foundational resource capacity planning capability and the modernized time reporting approach are in place, FDA has the ability, through a process defined in statute that includes a third-party evaluation and review of public comment, to implement a capacity planning adjustment methodology for PDUFA. This methodology would adjust the annual target revenue amount to account for the resources required to respond to sustained changes in program workload. The earliest the new methodology is expected to be implemented is for the setting of PDUFA fees for FY 2021; the impact on fees and annual revenue amounts cannot be estimated at this time. In the near term, FDA and Industry agreed to an interim methodology that updates the PDUFA V workload adjustment methodology to adjust the target revenue for changes in workload.

FDA also made commitments in PDUFA VI to help enhance efficiency and transparency in the administration of PDUFA's financial resources. This includes a third-party evaluation of PDUFA program resource management during FY 2018 (currently in progress). It also includes the publishing of a five-year plan (this plan), to be updated annually. FDA will also hold an annual public meeting, the first to occur during FY 2019, 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 modernized user fee structure.

Working Capital Fund/Cost Allocation

FDA has stood up a Cost Allocation and Recovery framework to improve financial management of resources, including PDUFA, the Biosimilar User Fee Act (BsUFA) and the Generic Drug User Fee Amendments (GDUFA). Congress recently passed P.L. 115-141 which provides FDA with the authority to establish a Working Capital Fund (WCF) to finance Agency-wide centralized administrative services. Cost Allocation and Recovery and the WCF will benefit the financial management of Agency user fee funds by:

- Increasing transparency by defining administrative activities performed for Centers and Offices and allocating user fee costs based on Agency usage.
- Strengthening accountability by helping the Agency improve the tracking and management of administrative costs, including costs charged to user fees relative to 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 engagement in decision making relative to administrative costs, efficiency opportunities, recapitalization, and burden on all funding sources – including user fees.

In addition, the WCF authority would enhance efficient use of Agency user fees by specifying the collections that the Agency is authorized to credit to the fund and defining the fund’s authorized uses, including which funds may be expended (i.e., scope of services).

Financial Information

This section provides an overview of the projected financial outlook for PDUFA through the fiscal year 2018 – 2022 reauthorization period. These projections include user fee revenue, obligations, carryover, non-user fee appropriations requirements, and planned hiring. The forecasts included in this section are driven by the initiatives and goals as outlined in the Five-Year Forward View section of this plan.

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. Future updates to this plan will supplement the financial estimates with actual amounts received, obligated, and carried over for the past fiscal year. 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

Budgetary Resources	Notes	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
		Estimate	Estimate	Estimate	Estimate	Estimate
Target Revenue	Note 1	\$911,346,000 [†]	\$998,696,000	\$1,050,273,000	\$1,092,115,000	\$1,132,754,000
Cash Collections		\$911,346,000	\$998,696,000	\$1,050,273,000	\$1,092,115,000	\$1,132,754,000
Carryover Available for Use, Beginning of Year		\$232,969,623 [†]	\$127,269,187	\$103,928,295	\$85,200,078	\$69,015,761
Total Cash Available for Obligation		\$1,144,315,623	\$1,125,965,187	\$1,154,201,295	\$1,177,315,078	\$1,201,769,761

Obligations	Notes	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
		Estimate	Estimate	Estimate	Estimate	Estimate
Total Payroll and Operating	Note 2	\$859,512,968	\$829,307,630	\$874,344,663	\$911,696,197	\$952,473,609
Total Rent	Note 3	\$64,632,000	\$65,278,320	\$65,931,103	\$66,590,414	\$67,256,319
Total FDA Central	Note 4	\$48,503,591	\$48,988,627	\$49,478,514	\$49,973,299	\$50,473,032
Total Shared Services	Note 5	\$77,685,459	\$78,462,314	\$79,246,937	\$80,039,407	\$80,839,801
Total Obligations		\$1,050,334,018	\$1,022,036,891	\$1,069,001,218	\$1,108,299,317	\$1,151,042,760

Carryover	Notes	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
		Estimate	Estimate	Estimate	Estimate	Estimate
Total Carryover, End of Year		\$211,120,182	\$187,779,290	\$169,051,073	\$152,866,756	\$134,577,996
Carryover Unavailable for Use, End of Year		(\$83,850,995)	(\$83,850,995)	(\$83,850,995)	(\$83,850,995)	(\$83,850,995)
Carryover Available for Use, End of Year		\$127,269,187	\$103,928,295	\$85,200,078	\$69,015,761	\$50,727,001

Target Revenue has been rounded to the nearest thousand dollars

+ Indicates an actual amount

Budgetary Resources: The budgetary resources component of **Table 1** illustrates the forecast for the sum of available user fee funding (i.e., the existing available carryover balance and additional projected user fee collections) that will be used to fund obligations. The target revenue is the annual revenue amount established when fees for the fiscal year are set. Cash collections is the actual amount collected during the fiscal year. Cash collections is forecasted to be equal to the target revenue, and will be updated with actuals each year.

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.

Obligations: The obligations component of **Table 1** shows the planned 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 VI.

Carryover: PDUFA fees are available until expended. This means that the 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. The unobligated fee funds at the end of each fiscal year are referred to 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 of fee amounts and the risk of a lapse in appropriations.

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 collection 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 update 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

Target Revenue	Notes	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
		Actual	Estimate	Estimate	Estimate	Estimate
Base Amount		\$878,590,000	\$935,904,000	\$989,793,000	\$1,041,193,000	\$1,082,855,000
Inflation Adjustment		\$14,820,056	\$18,580,502	\$19,650,360	\$20,670,805	\$21,497,920
Capacity Planning Adjustment		\$22,415,658	\$13,990,595	\$14,796,168	\$15,564,534	\$16,187,329
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)	\$ -	\$ -	\$ -	\$ -
Additional Direct Costs Adjustment	Note 8	\$8,730,000	\$8,903,317	\$9,080,074	\$9,260,341	\$9,444,186
Target Revenue Total	Note 1	\$911,346,000	\$998,696,000	\$1,050,273,000	\$1,092,115,000	\$1,132,754,000

Base Amount and Target Revenue numbers have been rounded to the nearest thousand dollars

Budgetary Resources	Notes	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
		Estimate	Estimate	Estimate	Estimate	Estimate
Cash Collections		\$911,346,000	\$998,696,000	\$1,050,273,000	\$1,092,115,000	\$1,132,754,000
Carryover Available for Use, Beginning of Year		\$232,969,623 [†]	\$127,269,187	\$103,928,295	\$85,200,078	\$69,015,761
Total Cash Available for Obligation		\$1,144,315,623	\$1,125,965,187	\$1,154,201,295	\$1,177,315,078	\$1,201,769,761

[†] Indicates an actual amount

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

- Inflation Adjustment:** The inflation adjustment adjusts 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 inflation adjustment for future years, for the purposes of this plan, is estimated by using the Federal Reserve Bank of Cleveland's CPI projections, as well as historical averages of the changes in FDA's average salary and benefits amounts.

The actual inflation adjustment utilized in FY 2018 was 1.6868%. The average inflation adjustment for FY 2019 – FY 2022 is estimated at 1.9853%.

- 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 statute, include: the number of new drug and biological license applications, 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(end of phase (EoP)), C, and Written Response Only).

The current capacity planning adjustment is referred to in statute as the “interim” methodology; this is because the authorizing statute provides a procedure to develop a new methodology for this adjustment. This includes a third-party assessment of options to be published for public comment no later than the end of FY 2020. Following review of public comment, FDA is to adopt a capacity planning methodology that will be effective beginning with the first fiscal year for which fees are set after the methodology is established. For the purposes of this current plan, FDA estimates the capacity planning adjustment amount for FY 2021 and FY 2022 as remaining consistent with previous years, though the methodology will be updated as appropriate.

For the purposes of this plan, FDA utilizes time series forecasting methods to develop estimates for the future year capacity planning adjustment amounts. This provides an estimated amount to support planning, but the accuracy of these estimates from year to year is uncertain. FDA will update its projections each year as new data become available.

The actual capacity planning adjustment utilized in FY 2018 was 2.509%. The capacity planning adjustment for FY 2019 – FY 2022 is estimated at 1.4658%.

FDA notes that, operationally, a lag in time will exist from the time the capacity planning adjustment for the next fiscal year is calculated to the time that the new positions to be funded by the adjustment are onboarded. As such, it should be expected that a portion of the capacity planning adjustment funds may either be used for temporary operating expenses, or may contribute temporarily to the carryover balance.

- **Additional Dollar Amounts:** PDUFA VI provides for the hiring of 230 new positions to support workload associated with initiatives established or expanded by PDUFA VI. These 230 new positions are scheduled to be hired over the five years of PDUFA VI. The dollar amounts for the new positions committed to being hired each year are specified in statute.
- **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 available and unavailable carryover. 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 \$33,287,582. The current plan does not anticipate the need to utilize the operating reserve adjustment in the remaining years of PDUFA VI. However, circumstances may change and FDA will re-assess its outlook on the operating reserve adjustment in each annual update to this plan.

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

The amount for FY 2018 is \$8,730,000.

The base amount for FY 2018 is specified in statute. The base amount 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.

Fee rates are established each year so that revenues from application fees provide 20% of the total revenue, and prescription drug program fees provide 80% of the total revenue. **Table 3** presents the forecasted total annual collections by fee type.

Table 3: PDUFA VI Collections

Fee Type	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	Estimate	Estimate	Estimate	Estimate	Estimate
Application Fees	\$182,269,200	\$199,739,200	\$210,054,600	\$218,423,000	\$226,550,800
Program Fees	\$729,076,800	\$798,956,800	\$840,218,400	\$873,692,000	\$906,203,200
Total Cash Collections	\$911,346,000	\$998,696,000	\$1,050,273,000	\$1,092,115,000	\$1,132,754,000

Numbers have been rounded to the nearest hundred dollars

I. User Fee Obligations

Table 4 provides a breakout of planned user fee obligations by expense category for the five years represented in this plan. The annual updates to this plan will provide actual amounts for the preceding fiscal year, as well updated planned amounts for the remaining fiscal years. 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	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
		Estimate	Estimate	Estimate	Estimate	Estimate
Total Cash Available for Obligations		\$1,144,315,623	\$1,125,965,187	\$1,154,201,295	\$1,177,315,078	\$1,201,769,761
Payroll & Operating	Note 2					
CBER		\$134,345,871	\$133,873,563	\$139,177,612	\$143,608,390	\$148,610,395
CDER		\$655,258,274	\$621,710,074	\$666,503,944	\$697,311,396	\$731,071,961
CDRH		\$1,292,304	\$2,626,785	\$4,017,810	\$4,118,231	\$4,220,046
ORA		\$8,307,191	\$8,534,194	\$8,798,185	\$9,086,059	\$9,377,929
HQ		\$60,309,328	\$62,563,014	\$55,847,113	\$57,572,122	\$59,193,278
Total Rent	Note 3	\$64,632,000	\$65,278,320	\$65,931,103	\$66,590,414	\$67,256,319
Total FDA Central	Note 4	\$48,503,591	\$48,988,627	\$49,478,514	\$49,973,299	\$50,473,032
Total Shared Services	Note 5	\$77,685,459	\$78,462,314	\$79,246,937	\$80,039,407	\$80,839,801
Total Obligations		\$1,050,334,019	\$1,022,036,891	\$1,069,001,218	\$1,108,299,317	\$1,151,042,760

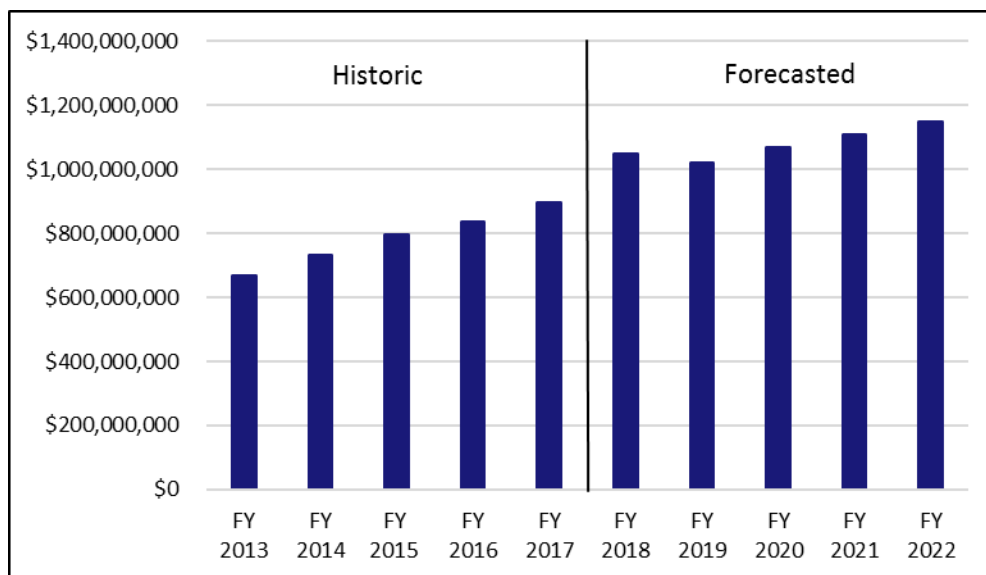
Total obligations include payroll and operating, rent, central, and shared services costs. The details of each component of total obligations is as follows:

- **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, science and research activities, and management and administrative functions that support the PDUFA program.
- **Rent:** This is paid to the General Services Administrations for the Federal buildings that FDA occupies, as well as directly to non-Federal sources for direct leases and services. This rent is charged at different rates depending on the type and location of the space provided.
- **Central:** The Central Account pays 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.
- **Shared Services:** FDA contains a number of shared service organizations that provide support across the user fee programs, such as human resources and IT.

Rent, FDA Central, and Shared Services projections are informed by prior year actuals. The future year amounts, for the purposes of this plan, are assumed to have an increase of 1% yearly. Yearly costs are determined by the Cost Allocation and Recovery framework discussed previously.

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

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



As demonstrated by this graph, there has been a steady increase in program needs in the past five years during PDUFA V with obligations growing at an average rate of 8%.

This trend is projected to continue through PDUFA VI and is driven by a few structural factors. This includes the additional dollar amounts provided each year (see above) to provide for hiring of new positions that are capitalized into subsequent year's base. Additionally, the inflation adjustment helps maintain the programs purchasing power and has run at a consistent rate of close to 2% since the start of PDUFA V. The capacity planning adjustment (known as the workload adjuster prior to PDUFA VI) has demonstrated consistent increases in the submissions and activity it measures averaging at about 3%

per year. FDA projects the submissions driving the adjustment to continue to trend upward, though at a somewhat slower rate overall; this plus the structural changes made to the capacity planning adjustment in PDUFA VI² suggest adjustment increases at a lower annual rate on average than during PDUFA V.

The anomaly in this trend is FY 2018 with an expected growth of 16% from FY 2017. FDA is investing available carryover resources to support a number of priority initiatives in support of the PDUFA program. Much of these FY 2018 investments are expected to provide benefits across the five years of PDUFA VI. There is more discussion of these investments in the Five-Year Forward section of this plan.

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. 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 of fee amounts and the risk of a lapse in appropriations. FDA considers maintaining a carryover balance of between 10 to 14 weeks as a reasonable range to mitigate these risks. FDA does however weigh those risks against strategic programmatic needs which may take precedence, causing the balance to dip below this range.

As noted above, the statute establishes a cap of 14 weeks of 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 carryover balance includes two categories:

- **Carryover Unavailable for Use** – This value represents carryover funds subject to claims or restrictions that precludes 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 5 provides projections of PDUFA carryover balances at the end of each fiscal year. Forecasted estimates will be updated with actual amounts in future Five-Year Financial Plan annual updates. The financial notes can be found in **Appendix C**.

² The weighting factor applied to the adjustment changes in PDUFA VI. Previously, the weighting factor summed to 100%; effectively adjusting 100% of costs. In PDUFA VI, the weighting factor only adjusts for the relative time invested on the input included in the adjustment by CDER in CBER. In FY 2018, the weight factor equaled 56%.

Table 5: PDUFA Carryover by Fiscal Year

Carryover	Notes	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
		Estimate	Estimate	Estimate	Estimate	Estimate
Total Carryover, End of Year		\$211,120,182	\$187,779,290	\$169,051,073	\$152,866,756	\$134,577,996
Unappropriated amounts	Note 9	(\$78,850,995)	(\$78,850,995)	(\$78,850,995)	(\$78,850,995)	(\$78,850,995)
Refunds	Note 10	(\$5,000,000)	(\$5,000,000)	(\$5,000,000)	(\$5,000,000)	(\$5,000,000)
Operating Reserve Adjustment	Note 7	\$-	\$-	\$-	\$-	\$-
Carryover Unavailable for Use, End of Year		(\$83,850,995)	(\$83,850,995)	(\$83,850,995)	(\$83,850,995)	(\$83,850,995)
Carryover Available for Use, End of Year		\$127,269,187	\$103,928,295	\$85,200,078	\$69,015,761	\$50,727,001

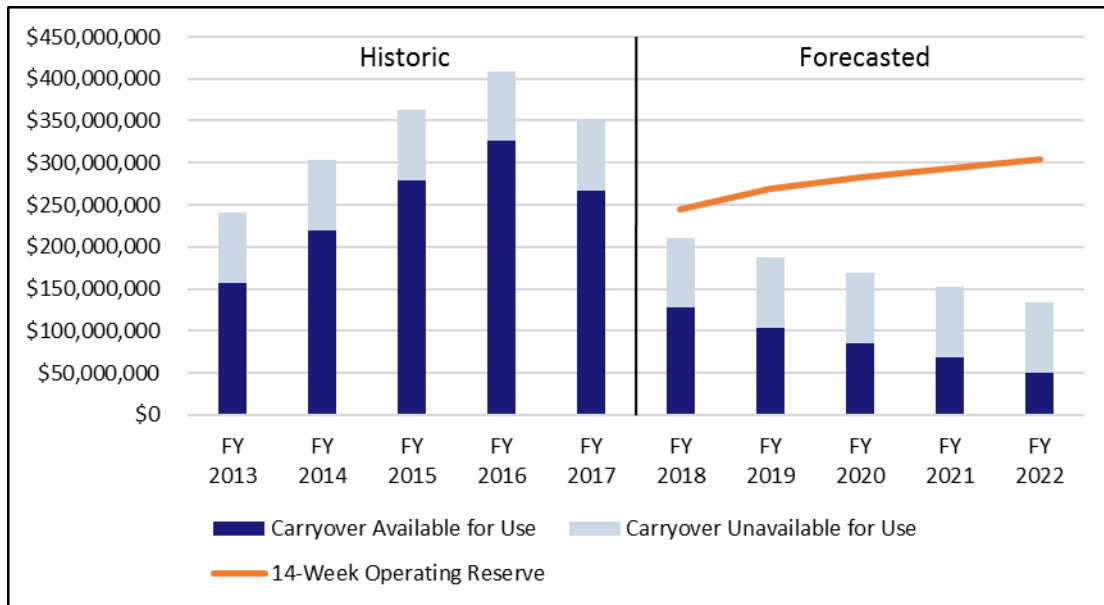
To determine how much carryover is available for obligation at the end of a fiscal year, the following factors must be considered:

- **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 \$79,000,000 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 this \$79,000,000, FDA cannot obligate these funds and maintains them in the carryover reserve. See **Note 9** 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 10** for additional details.
 - **Operating Reserve Adjustment**– Should a negative operating reserve adjustment be applied, FDA reduces the target revenue amount by the operating reserve adjustment. It then reserves 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.

For the purposes of this plan, future year recoveries have not been estimated. Additional details on recoveries are included in **Note 11**.

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

Exhibit 4: Historic and Forecasted Carryover by Fiscal Year



As illustrated, FDA plans to substantially reduce the amount of carryover in PDUFA VI. The operating reserve adjustment will be a mitigation tool to ensure carryover does not exceed the 14-week operating levels. In PDUFA V, carryover exceeded the 14-week operating levels at 22% in FY 2013 to up to 75% in FY 2016. Looking forward into PDUFA VI, FDA plans to maintain the operating reserve levels at around 10 weeks. As a result, carryover will be burned down accordingly over the five-year period.

Carryover Reduction

Available carryover is expected to be reduced from \$127,269,187 in FY 2018 to \$50,727,001 in FY 2022. That is a reduction of 60% over the course of PDUFA VI.

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 budget authority (BA) spending trigger”.³ **Table 6** presents the forecasted non-user fee BA spending triggers for PDUFA VI.

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

FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Actual	Estimate	Estimate	Estimate	Estimate
\$225,939,032	\$230,550,787	\$233,536,614	\$236,716,120	\$239,795,457

³ Fees 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.

The non-user fee BA 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 12** for more details on the adjustment factor.

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

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 over the five years of PDUFA VI.

Table 7: Target New Hires by Organization for PDUFA VI

Organization	2018	2019	2020	2021	2022
CDER	43	57	45	17	9
CBER	16	8	7	1	0
Other FDA	12	9	6	0	0
Total FTE	71	74	58	18	9

The capacity planning adjustment allows FDA to hire more staff to account for growing review needs. FDA will document the use of the funds from this adjustment in the annual financial report.

Management Assurance

M. Internal Controls

The Federal Managers' Financial Integrity Act (FMFIA) of 1982 is intended to strengthen internal controls and accounting systems. The Office of Management and Budget's Circular No. A-123, *Management's Responsibility for Internal Control and Enterprise Risk Management* (OMB A-123), implements the requirements of the FMFIA. The FMFIA requires that management establish and maintain effective internal control to achieve the objectives of:

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

DHHS provides guidance to its operating divisions (OpDivs) to implement FMFIA through its FMFIA Guidelines. OpDivs, including FDA, are responsible for developing and maintaining a cost-effective internal control and compliance program that includes programmatic and operational controls, as well as controls over financial reporting, and supports sound financial management. The Government Accountability Office (GAO) *Standards for Internal Control in the Federal Government* (Green Book) state, "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 to the President and the Congress on the effectiveness of the

internal controls and any identified material weaknesses in those controls. FDA's FY 2017 Assurance Statement that was submitted to DHHS, found no material weaknesses or financial system nonconformances.

Additionally, FDA has established a Senior Assessment Team (SAT) as the governance body responsible for providing oversight and accountability for FDA's internal control over financial reporting, including overseeing the FMFIA and A-123 assessments, and to foster an environment that promotes strong internal control. The SAT is chaired by the FDA Chief Financial Officer (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.

In accordance with FMFIA, OMB A-123, the Green Book, and the HHS Guidelines, FDA has a robust internal control program, including integrated controls throughout processes, and conducts an annual assessment of its internal control activities. In addition, FDA has an Enterprise Risk Management (ERM) Program, which began in earnest in FY 2016 and is integrated with FDA's FMFIA efforts. Under the ERM program, FDA has refreshed the enterprise risk profile and facilitated risk response planning for 5 priority enterprise risks. To accomplish this, Centers and Offices are engaged through senior leadership interviews, as well as working groups and problem-solving sessions. Further, FDA has established an ERM Community of Practice, and piloted integration with internal controls. FDA's ERM program has facilitated cross-Center and Office collaboration to identify and manage risks.

FDA's internal control program includes an evaluation of controls over reporting, charge card compliance, improper payments, and financial systems compliance. One of the cycle memos included in the assessment scope includes internal controls over reporting for the reimbursable activity process, specifically focused on the Accounts Receivable and Payment process associated with the User Fee programs. This includes controls over reconciliation performance, aging, write-offs, the interface between the User Fee System and the Unified Financial Management System. As an FDA-owned system, FDA's User Fee System is compliant with HHS requirements and requirements of the Federal Financial Management Improvement Act (FFMIA) of 1996. In addition, FDA's Integrated Budget and Acquisition Planning System (IBAPS) meets FDA and DHHS system requirements.

FDA is also a participant in the annual audit of the consolidated financial statements of DHHS, including the consolidated balance sheets, the related consolidated statement of net costs and changes in net position, the combined statement of budgetary resources, and the related notes to the financial statements. The FY 2017 audit found that the financial statements present fairly, in all material respects, the consolidated financial position of DHHS as of September 30, 2017 and 2016, and its consolidated net cost, changes in net position, and budgetary resources for the years then ended in accordance with U.S. generally accepted accounting principles.

FDA has also implemented other internal control procedures including a Continuous Monitoring Program to oversee the timely implementation of any Corrective Action Plans (CAPs) for deficiencies identified through any of its control assessments. This Continuous Monitoring Program allows for management oversight of targeted remediation efforts and strengthening of internal controls. In addition, FDA offers annual internal control training sessions annually, which cover the importance of internal controls, timely deficiency remediation, and roles and responsibilities.

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 BA 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 interest of the program.

- **Under-Executing Planned Spend:** Historically, PDUFA budgetary resources have been under-spent due to the uncertainty of revenue (user fee and non-user fee), non-user fee BA spending trigger requirements, and difficulties with hiring, especially in the first year of a reauthorization period as new and expanded initiatives are being implemented. To minimize this risk, FDA is enhancing its planning and execution around the hiring of new staff and contract actions in this first year of the reauthorization. By putting more emphasis on the initial planning of initiatives in the first year of the five-year cycle, FDA predicts that there will be less variance while comparing planned allocations to 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 as non-user fee fund levels are often uncertain for much 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:** In PDUFA VI, FDA can maintain up to 14 weeks of an operating reserve so it can continue program operations in the event of a shutdown. In practice, FDA has less than 14 weeks of operating reserve because of the unappropriated amounts that are unavailable for use. See **Note 9** 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 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 User Fee Council and other FDA senior leaders determine how to mitigate any instances when user fee revenue is off forecasted estimates.

In addition to these mitigation strategies, FDA implemented the 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

FDA has committed to improving hiring and retention of scientific staff as described in the PDUFA VI commitment letter. As initiatives associated with these commitments span the course of PDUFA VI, the benefits expected from these initiatives will not be immediate, and thus, FDA may experience delays in hiring staff for the PDUFA program. Thus, there may be an impact on the planned versus actual spending in the payroll and operating forecasts in this plan.

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	
<ol style="list-style-type: none"> 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; 	<ol style="list-style-type: none"> 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
<ol style="list-style-type: none"> 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
<ol style="list-style-type: none"> 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 	<ol style="list-style-type: none"> 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

PDUFA was a law passed by the United States Congress in 1992 which allowed FDA to collect fees from drug manufacturers to fund the new drug approval process. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by PDUFA, authorizes the Food and Drug Administration (FDA or the Agency) 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.

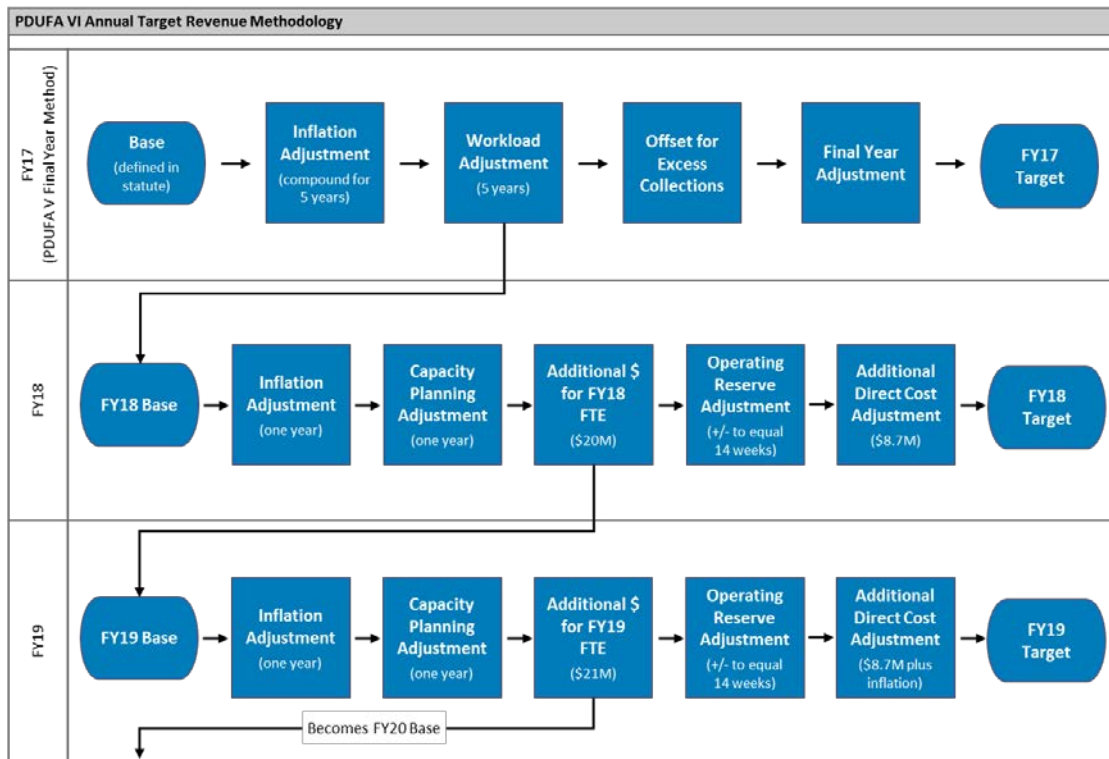
PDUFA was reauthorized in 1997 (PDUFA II), 2002 (PDUFA III), 2007 (PDUFA IV), 2012 (PDUFA V), and in 2017 (PDUFA VI) with the support of industry, other stakeholders, Congress, and the Administration. Over time, PDUFA has been a success, creating a predictable, streamlined review process and dramatically reducing the average time to new drug approval. PDUFA VI continues to support drug development oversight and marketing application review for the new drugs regulatory program.

C. Financial Notes

Note 1. Annual Target Revenue Methodology

The flowchart in **Exhibit 5** is delineating the PDUFA VI Annual Target Revenue Methodology.

Exhibit 5: PDUFA VI Annual Target Revenue Methodology



Note 2. 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. 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 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 3. Rent Costs

The General Services Administration (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 directly 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 number of employees that must be housed.

Note 4. FDA Central Costs

The Central Account pays 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. Like rent, the amount of central account support FDA pays is directly related to the number of employees that must be serviced. Each Center pays its portion based on the number of employees working in the PDUFA program.

Note 5. Shared Service Costs

FDA contains a number of shared service organizations that provide support across the user fee programs. The shared service organizations include:

- **Employee Resource & Information Center (ERIC):** Provides support to all FDA users requesting administrative, IT, facilities, human resources, and other employee services.
- **Employee Safety & Environmental Management (ESEM):** Provides safety, health, and environmental compliance for all FDA employees.
- **Office of Acquisitions and Grants Services (OAGS):** Manages contracts, grants, and other agreements.
- **Office of External Affairs (OEA):** Provides the development, coordination, and dissemination of FDA communications and outreach to the news media and various stakeholders.
- **Office of Equal Employment Opportunity (OEEO):** 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 (OFEMS):** Provides FDA employees with office and laboratory facilities.
- **Office of Financial Management (OFM):** Provides financial managerial services and policy guidance.
- **Office of Human Resources (OHR):** Supports workforce relations, client services, executive resources, accountability programs, policy and program development, and systems data and management.
- **Office of Information Management and Technology (OIMT):** 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.

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 2018, the FY 2018 annual base revenue adjusted for inflation and capacity planning, \$915,825,714, is divided by 52, and then multiplied by 14. The 14-week cap on the operating reserve amount for FY 2018 is \$246,568,461.

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 2017 operating reserve was \$279,856,044.

Because the estimated end of year FY 2017 PDUFA operating reserve exceeded the 14-week operating reserve for FY 2018, FDA reduced the FY 2018 PDUFA fee revenue of \$935,903,507 by \$33,287,582, resulting in an adjusted fee revenue of \$902,615,925, prior to the adjustment for additional direct costs.

Note 8. Additional Direct Costs Adjustment

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

- FY 2018, by \$8,730,000; and
- FY 2019 and subsequent fiscal years, by \$8,730,000, multiplied by the Consumer Price Index 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.

PDUFA VI specifies that \$8,730,000 be added in addition to the operating reserve adjustment to account for additional direct costs in PDUFA VI starting in FY 2018. This additional direct cost adjustment will be adjusted for inflation each year beginning in FY 2019.

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, 2017

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. 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.

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

Note 11. Recoveries

Recoveries account for funds returned to the Agency in the form of deobligations of prior year obligations.

Note 12. 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.”