

# **FIVE-YEAR FINANCIAL PLAN**

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

**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***

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### **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***

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### **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.

For most of FY 2018, FDA's user fee governance process leveraged the User Fee Council. FDA has since transitioned from that governance structure to a new model that leverages a new committee, which is referred to as the User Fee Financial Management Committee. The User Fee Financial Management Committee 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 User Fee Financial Management Committee 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 User Fee Financial Management Committee will receive policy guidance and strategic direction directly from the FDA's Executive Committee relative to how the Agency will forecast and react to industry trends, plan and manage its research agenda in support of the user fee programs, and forecast its user fee workload. The User Fee Financial Management Committee 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	<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 <b>a full application fee</b> 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 <b>one-half of a full fee</b> 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. Five-Year Forward View

### Discussion of Workload and Other Activities in PDUFA

In PDUFA VI, FDA is implementing numerous commitments made under the user fee agreement as well as new programs mandated by Congress in the FDARA. FDA is making significant progress implementing important PDUFA VI commitments, including 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.

During FY 2018, 75 applications were received and will be reviewed under the Program For Enhanced Review Transparency and Communication for NME NDAs and Original BLAs (the Program), which include new molecular drug applications (NME NDAs) and original biologics license applications (BLAs). FDA noted a large increase in the number of Original Priority NMEs and BLAs (104 percent) and Priority NDA and BLA Efficacy Supplements (114 percent) in FY 2018 compared to the most recent five-year average.

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 during the first year of PDUFA VI with 8363 commercial investigational new drugs (IND) that had activity and 3492 formal meeting requests from sponsors. 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 and on-time approvals. 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, 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 (Cures), which facilitates development of PDUFA regenerative medicine products. FDA looks forward to the remaining years of PDUFA VI being a period of strong innovation in drug development.

FDA is continuing to strive 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 Cures. FDA has utilized user fee resources to establish a new scientific staffing function and to establish 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 Cures.

### **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, maximize efficiency by simplifying the administration of user fees, and enhance 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 include:

- Increasing 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<sup>1</sup> 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.

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 4 years is to ensure there is sufficient capacity to

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<sup>1</sup> 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.

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. 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 more targeted human resource and financial needs. This capability will help FDA ensure it has the resources it needs when they are required to be able to deliver on all performance commitments.

In addition, once the foundational resource capacity planning capability and the modernized time reporting approach are in place, FDA will have the ability, through a process defined in statute that will include a third-party evaluation and review of public comment, to implement a capacity planning adjustment methodology for PDUFA. This methodology will adjust the annual target revenue amount to account for the resources required to respond to sustained changes in program workload. The new methodology is expected to be implemented for the setting of PDUFA fees for FY 2021, therefore 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 in 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 the third quarter of 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 user fee structure changes under PDUFA VI.

### **Working Capital Fund/Cost Allocation**

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***

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This section provides an overview of the projected financial outlook for PDUFA through the FY 2018 – 2022 authorization 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	Actual	Estimate	Estimate	Estimate	Estimate
Target Revenue	Note 1	\$911,346,000	\$911,346,000	\$1,010,322,000	\$1,059,786,000	\$1,101,218,000	\$1,141,402,000
Cash Collections		\$911,346,000	\$908,077,723	\$1,010,322,000	\$1,059,786,000	\$1,101,218,000	\$1,141,402,000
Recoveries	Note 2	\$0	\$13,149,599	\$10,000,000	\$10,000,000	\$10,000,000	\$10,000,000
Carryover Available for Use, Beginning of Year		\$232,969,623 <sup>†</sup>	\$232,969,623	\$125,372,944 <sup>†</sup>	\$102,422,710	\$103,888,514	\$103,440,188
<b>Total Budgetary Resources</b>		<b>\$1,144,315,623</b>	<b>\$1,154,196,945</b>	<b>\$1,145,694,944</b>	<b>\$1,172,208,710</b>	<b>\$1,215,106,514</b>	<b>\$1,254,842,188</b>

Obligations	Notes	FY 2018		FY 2019	FY 2020	FY 2021	FY 2022
		Estimate	Actual	Estimate	Estimate	Estimate	Estimate
Total Payroll and Operating	Note 3	\$859,512,968	\$881,209,920	\$844,242,070	\$867,299,730	\$908,635,655	\$945,130,019
Total Rent	Note 4	\$64,632,000	\$49,964,883	\$65,278,320	\$65,931,103	\$66,590,414	\$67,256,319
Total Shared Services	Note 5	\$126,189,050	\$130,936,781	\$133,751,844	\$135,089,362	\$136,440,256	\$137,804,659
<b>Total Obligations</b>		<b>\$1,050,334,018</b>	<b>\$1,062,111,583</b>	<b>\$1,043,272,234</b>	<b>\$1,068,320,196</b>	<b>\$1,111,666,325</b>	<b>\$1,150,190,996</b>

Carryover	Notes	FY 2018		FY 2019	FY 2020	FY 2021	FY 2022
		Estimate	Actual	Estimate	Estimate	Estimate	Estimate
Total Carryover, End of Year		\$211,120,182	\$209,223,939	\$186,273,705	\$187,739,509	\$187,291,183	\$188,601,187
Carryover Unavailable for Use, End of Year		(\$83,850,995)	(\$83,850,995)	(\$83,850,995)	(\$83,850,995)	(\$83,850,995)	(\$83,850,995)
<b>Carryover Available for Use, End of Year</b>		<b>\$127,269,187</b>	<b>\$125,372,944</b>	<b>\$102,422,710</b>	<b>\$103,888,514</b>	<b>\$103,440,188</b>	<b>\$104,750,192</b>

Target Revenue has been rounded to the nearest thousand dollars

All other numbers have been rounded to the nearest dollar

<sup>†</sup>Indicates an actual amount

**Budgetary Resources:** The budgetary resources component of **Table 1** illustrates the FY 2018 actuals and the forecast for FY 2019 through FY 2022 for the sum of available user fee funding (i.e., the existing carryover balance available for use 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 are the actual amount collected during the fiscal year and are forecasted 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.

**Obligations:** The obligations component of **Table 1** shows the FY 2018 actual expenditure and planned annual expenditure for FY 2019 through 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 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 PDUFA funds at the end of each fiscal year are referred to as the “carryover balance” of **Table 1**. 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.

## 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**

Target Revenue	Notes	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
		Actual	Estimate	Estimate	Estimate	Estimate
Statutory Base		\$878,590,000	\$935,903,507	\$1,001,480,000	\$1,050,763,000	\$1,092,005,000
Inflation Adjustment		\$14,820,056	\$16,572,979	\$23,999,467	\$27,060,562	\$28,122,678
Capacity Planning Adjustment		\$22,415,658	\$27,685,634	\$8,329,713	\$8,754,891	\$9,098,517
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	\$0
Additional Direct Costs Adjustment	Note 8	\$8,730,000	\$8,842,303	\$9,022,587	\$9,213,173	\$9,406,204
<b>Target Revenue Total</b>	<b>Note 1</b>	<b>\$911,346,000</b>	<b>\$1,010,322,000</b>	<b>\$1,059,786,000</b>	<b>\$1,101,218,000</b>	<b>\$1,141,402,000</b>

Target Revenue has been rounded to the nearest thousand dollars

Budgetary Resources	Notes	FY 2018		FY 2019	FY 2020	FY 2021	FY 2022
		Estimate	Actual	Estimate	Estimate	Estimate	Estimate
Cash Collections		\$911,346,000	\$908,077,723	\$1,010,322,000	\$1,059,786,000	\$1,101,218,000	\$1,141,402,000
Recoveries	Note 2	\$0	\$13,149,599	\$10,000,000	\$10,000,000	\$10,000,000	\$10,000,000
Carryover Available for Use, Beginning of Year		\$232,969,623†	\$232,969,623	\$125,372,944†	\$102,422,710	\$103,888,514	\$103,440,188
<b>Total Budgetary Resources</b>		<b>\$1,144,315,623</b>	<b>\$1,154,196,945</b>	<b>\$1,145,694,944</b>	<b>\$1,172,208,710</b>	<b>\$1,215,106,514</b>	<b>\$1,254,842,188</b>

Numbers have been rounded to the nearest dollar

†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 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 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 was 1.6868 percent in FY 2018, and 1.7708 percent in FY 2019. The inflation adjustment for FY 2020 is estimated at 2.3964 percent; FY 2021 – FY 2022 is estimated at 2.5753 percent.

- **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 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 was 2.509 percent in FY 2018, and 2.9067 percent in FY 2019. The capacity planning adjustment for FY 2020 – FY 2022 is estimated at 0.8123 percent.

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 5 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 carryover unavailable for use. 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 end of year FY 2019 PDUFA operating reserve does not exceed the 14-week operating reserve for FY 2019, FDA did not reduce the FY 2019 PDUFA target fee revenue. 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 2019 is \$8,842,303.

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, additional dollar amount adjustments, operating reserve adjustments, and additional direct costs. See **Note 1** for a diagram of this process.

Fee rates are established each year so that 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		Cohort Year 2019	Cohort Year 2020	Cohort Year 2021	Cohort Year 2022
	Estimate	Actual	Estimate	Estimate	Estimate	Estimate
Application Fees	\$182,269,200	\$180,757,325	\$202,064,400	\$211,957,200	\$220,243,600	\$228,280,400
Program Fees	\$729,076,800	\$723,029,302	\$808,257,600	\$847,828,800	\$880,974,400	\$913,121,600
<b>Total Cash Collections</b>	<b>\$911,346,000</b>	<b>\$903,786,627</b>	<b>\$1,010,322,000</b>	<b>\$1,059,786,000</b>	<b>\$1,101,218,000</b>	<b>\$1,141,402,000</b>

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. 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	Actual	Estimate	Estimate	Estimate	Estimate
Payroll & Operating	Note 3						
CBER		\$134,345,871	\$129,543,398	\$133,147,244	\$136,234,641	\$141,237,332	\$146,379,543
CDER		\$655,258,274	\$688,935,477	\$641,479,230	\$670,583,126	\$702,933,383	\$734,170,189
CDRH		\$1,292,304	\$786,091	\$2,630,174	\$3,990,769	\$4,125,016	\$4,264,200
ORA		\$8,307,191	\$7,733,467	\$8,498,654	\$8,630,125	\$8,895,537	\$9,170,525
HQ		\$60,309,328	\$54,211,488	\$58,486,768	\$47,861,070	\$51,444,387	\$51,046,563
Total Rent	Note 4	\$64,632,000	\$49,964,883	\$65,278,320	\$65,931,103	\$66,590,414	\$67,256,319
Total Shared Services	Note 5	\$126,189,050	\$130,936,781	\$133,751,844	\$135,089,362	\$136,440,256	\$137,804,659
<b>Total Obligations</b>		<b>\$1,050,334,018</b>	<b>\$1,062,111,583</b>	<b>\$1,043,272,234</b>	<b>\$1,068,320,196</b>	<b>\$1,111,666,325</b>	<b>\$1,150,190,996</b>

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. Rent is charged at different rates depending on the type and location of the space provided. The future year amounts, for the purposes of this plan, are assumed to have an increase of 1 percent yearly.

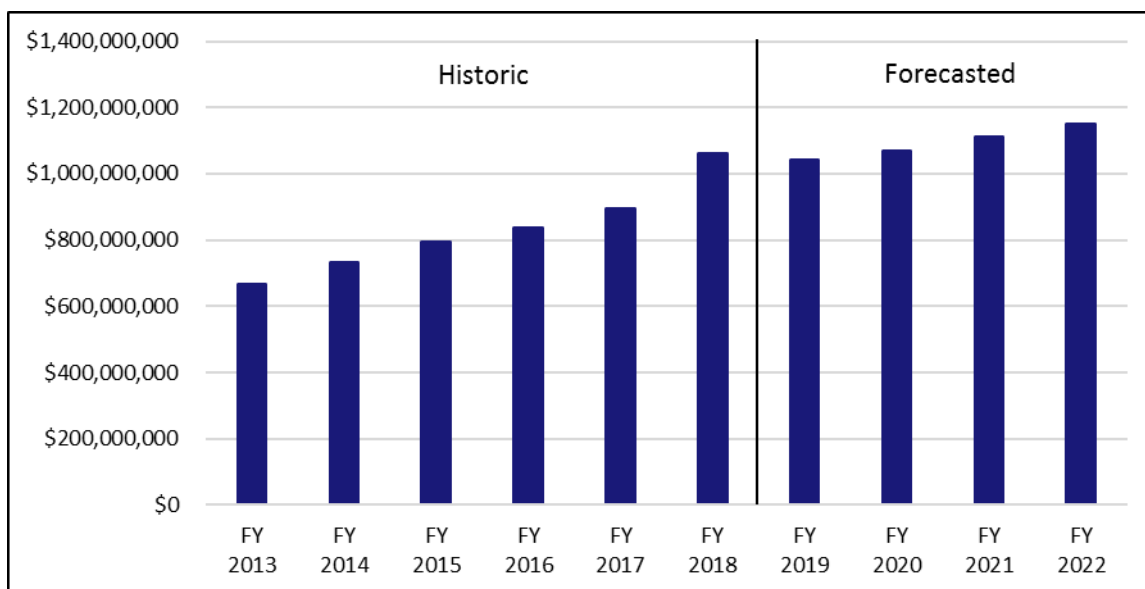
- Shared Services:** FDA has several shared service organizations that provide support across the user fee programs, such as human resources and IT. Shared services at FDA are located within the WCF. The future year amounts, for the purposes of this plan, are assumed to have an increase of 1 percent yearly. Yearly costs are determined by the Cost Allocation and Recovery framework discussed previously. In FY 2019, the WCF absorbed FDA Central as well as several other offices that were previously located within HQ. This change is responsible for the variance in HQ and Shared Services from the original plan, published in FY 2018, for FY 2019 and beyond. **Note 5** provides a full list of the what is contained in the WCF.

Variations occurred between the original FY 2018 plan and the actuals in some areas:

- CDER Obligations:** In FY 2018, FDA made significant investments in the PDUFA program to ensure it can continue to operate on a strong foundation, to deliver on its PDUFA VI commitments, and to modernize to meet evolving workload demands and scientific innovation. Many of these investments were funded through CDER’s budget, including investments in post-market safety (including Sentinel), information technology to support the program, and regulatory science. Additional investments supported activities including the long-term design and implementation of the resource capacity planning capability and the modernization of time reporting, and support for the modernization of CDER’s Office of New Drugs. These investments contributed to CDER’s actual payroll and operating exceeding the amount estimated.
- Shared Services Obligations:** Actual Shared Services obligations in FY 2018 were higher than estimates due to in-year transfers from the Centers to FDA Central. These types of transfers are normal and cause fluctuations to FDA Central every year.
- Rent:** The variances in rent actuals for FY 2018 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.

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 **Exhibit 3**, there has been a steady increase in program needs in the past 6 years with obligations growing at an average rate of 8 percent.

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 percent 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 percent 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 VI<sup>2</sup>, suggest adjustment increases at a lower annual rate on average than during PDUFA V.

The anomaly in this trend is FY 2018 with a growth of 18 percent from FY 2017. FDA invested carryover resources available for use to support a number of priority initiatives for the PDUFA program. Much of these FY 2018 investments are expected to provide benefits across the 5 years of PDUFA VI. Use of FDA's carryover resources lies in CDER's ongoing examination and modernization 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.

## 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 fees and the risk of a lapse in appropriations. FDA considers maintaining a carryover balance of between 8 – 10 weeks, which includes carryover unavailable for use, 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 cash collections minus net obligations. This is shown in **Table 1** above.

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

**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**.

**Table 5: PDUFA Carryover by Fiscal Year**

Carryover	Notes	FY 2018		FY 2019	FY 2020	FY 2021	FY 2022
		Estimate	Actual	Estimate	Estimate	Estimate	Estimate
<b>Total Carryover, End of Year</b>		<b>\$211,120,182</b>	<b>\$209,223,939</b>	<b>\$186,273,705</b>	<b>\$187,739,509</b>	<b>\$187,291,183</b>	<b>\$188,601,187</b>
Unappropriated amounts	Note 9	(\$78,850,995)	(\$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)	(\$5,000,000)
Operating Reserve Adjustment	Note 7	\$0	\$0	\$0	\$0	\$0	\$0
<b>Carryover Unavailable for Use, End of Year</b>		<b>(\$83,850,995)</b>	<b>(\$83,850,995)</b>	<b>(\$83,850,995)</b>	<b>(\$83,850,995)</b>	<b>(\$83,850,995)</b>	<b>(\$83,850,995)</b>
<b>Carryover Available for Use, End of Year</b>		<b>\$127,269,187</b>	<b>\$125,372,944</b>	<b>\$102,422,710</b>	<b>\$103,888,514</b>	<b>\$103,440,188</b>	<b>\$104,750,192</b>

Numbers have been rounded to the nearest dollar

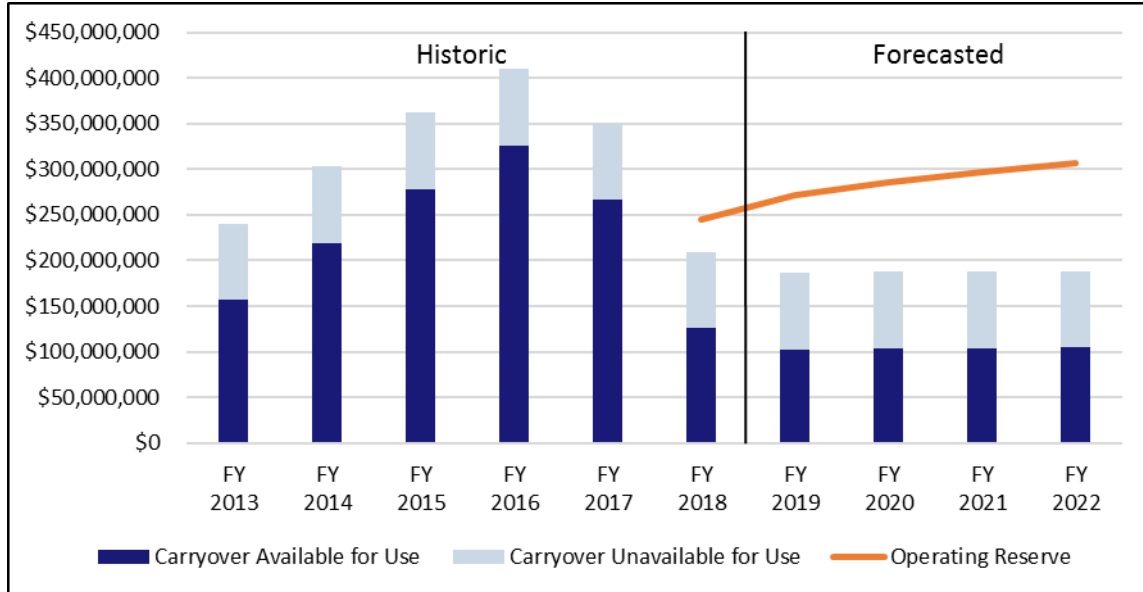
To determine how much carryover is available for obligation at the end of a fiscal year, the following factors must be considered:

- **Total Carryover, End of Year** – This is the total amount of unobligated funds at the end of the fiscal year. This balance dropped from its original target due to an increase in spending and a slight decline in anticipated collections.
- **Carryover Unavailable for Use, End of Year** – As noted above, this value includes unobligated funds subject to any claims or restrictions on fees collected. This includes:
  - **Unappropriated Amounts** – FDA’s PDUFA carryover balance includes \$78,850,995 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, the appropriations language was changed to ensure that all fee collections would be considered appropriated. In the absence of an appropriation for this \$78,850,995, FDA’s ability to obligate these funds remains uncertain. 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 are estimated to be \$10 million annually. Additional details on recoveries are included in **Note 2**.

**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 noted in FY 2018 version, FDA planned to substantially reduce the amount of the carryover in PDUFA VI to a target operating reserve level of around 10 weeks. FDA initiated its plan in FY 2018 and reduced the carryover by over \$100 million through strategic investments in the program as discussed in the obligations section of this plan. The carryover available for use is now within an 8 – 10 weeks of operating reserve levels.

**Carryover Reduction**

Carryover available for use is expected to be reduced from \$125,372,944 at the end of FY 2018 to \$104,750,192 at the end of FY 2022.

Since the 2018 version, FDA increased the outyear carryover estimates to reflect a targeted reduction in operating spending and included an estimate for recoveries. FDA will continue to monitor the balance, and the factors that influence it, to ensure that the Agency stays within a reasonable range of operating reserves to mitigate risks, such as collection shortfalls or lapses in appropriations. FDA may have to adjust its spending plan in the future to meet this goal.

## 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”.<sup>3</sup> **Table 6** presents actual non-user fee spending trigger for FY 2018 and FY 2019 and the forecasted non-user fee spending triggers for FY 2020 through 2022.

<sup>3</sup> 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.



**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	Estimate	Estimate	Estimate
\$225,939,032	\$230,550,787	\$236,366,343	\$240,164,468	\$243,996,032

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 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, 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 and the actual hiring for FY 2018.

**Table 7: Target New Hires by Organization for PDUFA VI**

Organization	2018		2019	2020	2021	2022
	Target	Actual	Target	Target	Target	Target
CDER	45	37	61	45	17	9
CBER	16	16	8	7	1	0
Other FDA	10	10	5	6	0	0
<b>Total Hires</b>	<b>71</b>	<b>63</b>	<b>74</b>	<b>58</b>	<b>18</b>	<b>9</b>

FDA missed the FY 2018 new hire target by eight hires, all within CDER. FDA acknowledges there are systemic issues with the Agency's hiring process, as noted in the report, *Initial Assessment of FDA Hiring and Retention – A Path Forward*<sup>4</sup>, that impact PDUFA hiring. Addressing these systemic level issues will take time. Despite these challenges, FDA was still able to hire the majority of FY 2018 target positions and did fill the remaining eight positions by March 30, 2019.

FDA also notes it is competing with the private sector in a tight labor market for medical and pharmaceutical professionals. Government compensation lags behind private sector benefits for many of the occupations needed for the PDUFA program. These factors, in addition to hiring system issues, contributed to FDA missing the FY 2018 planned hires.

<sup>4</sup> <https://www.fda.gov/media/108866/download>

# **Management Assurance**

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## **M. Internal Controls**

The Federal Managers' Financial Integrity Act (FMFIA) of 1982 is intended to strengthen internal controls and accounting systems. Office of Management and Budget (OMB) 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 controls to achieve the objectives of:

1. Effective and efficient operations,
2. Reliable financial 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 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) 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 to the President and the Congress on the effectiveness of the internal controls and any identified material weaknesses in those controls. FDA's FY 2018 Assurance Statement that was submitted to HHS, found no material weaknesses or financial system nonconformances.

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, overseeing the FMFIA and A-123 assessments, and fostering 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 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 updated its enterprise risk profile and facilitated risk response planning for five 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 continues to align and integrate core ERM methodologies with those of 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. 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, and 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 HHS system requirements.

FDA is also a participant in the annual audit of the consolidated financial statements of HHS, including the consolidated balance sheet, 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 2018 audit found that the financial statements present fairly, in all material respects, the consolidated financial position of HHS as of September 30, 2018 and 2017, and its consolidated net cost, changes in net position, and budgetary resources are in accordance with U.S. generally accepted accounting principles.

FDA has also implemented other internal controls including a continuous monitoring program to oversee the timely implementation of corrective action for deficiencies identified through 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, 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 spending trigger for the fiscal year if the 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 spending trigger requirements, and difficulties with hiring. To minimize this risk, FDA is enhancing its planning and execution around the hiring of new staff and contract actions. By putting more emphasis on the initial planning of initiatives, 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 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:** 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 lapse in

appropriations. 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 in which to obligate those funds. 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 Financial Management Committee and other FDA senior leaders determine how to mitigate any instances when user fee revenue differs significantly from 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. This system 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. Recent history with efforts to hire staff indicates that the Agency may experience challenges in meeting certain of the PDUFA VI commitments. 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"> <li>1. All investigational new drug review activities, including amendments;</li> <li>2. All review activities for new drug applications (NDAs) and biologic license applications (BLAs), including supplements and amendments;</li> <li>3. Regulation and policy development activities related to the review of human drug applications;</li> <li>4. Development of product standards for products subject to review and evaluation;</li> <li>5. Meetings between FDA and the sponsor of a covered application or supplement;</li> <li>6. Review of labeling prior to approval of a covered application or supplement and the review of the initial pre-launch advertising;</li> <li>7. Review of post-marketing studies and clinical trials that have been agreed to by sponsors as a condition for approval;</li> <li>8. Inspections of facilities undertaken as part of the review of pending applications or supplements;</li> <li>9. Lot release activities for covered biological products;</li> <li>10. Assay development and validation to ensure batch-to-batch consistency and reliability for covered biological products;</li> </ol>	<ol style="list-style-type: none"> <li>11. Monitoring of clinical and other research conducted in connection with the review of human drug applications;</li> <li>12. User Fee Act implementation activities;</li> <li>13. Research related to the human drug review process; and</li> <li>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).</li> </ol>

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"> <li>1. Officers and employees of FDA, contractors of FDA, advisory committees, and costs related to such officers, employees, committees, and contracts;</li> <li>2. Management of information, and the acquisition, maintenance, and repair of computer resources;</li> <li>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</li> <li>4. Collecting user fees under section 736 of the FD&amp;C Act and accounting for resources allocated for the review of human drug applications and supplements.</li> </ol>

The PDUFA program excludes costs related to the following:

Excluded Products	Excluded Activities
<ol style="list-style-type: none"> <li>1. Generic drugs</li> <li>2. Over-the-counter drugs not associated with an NDA or NDA supplement</li> <li>3. Large-volume parenteral drug products approved before September 1, 1992</li> <li>4. Allergenic extract products</li> <li>5. Whole blood or a blood component for transfusion</li> <li>6. In vitro diagnostic biologic products</li> <li>7. Certain drugs derived from bovine blood</li> </ol>	<ol style="list-style-type: none"> <li>1. Enforcement policy development not related to sections 505(o) and (p) of the FD&amp;C Act</li> <li>2. Post-approval compliance activities not related to the enforcement of sections 505(o) and (p) of the FD&amp;C Act</li> <li>3. Advertising review activities once marketing of the product has begun</li> <li>4. Inspections unrelated to the review of covered applications, unless undertaken for the enforcement of sections 505(o) and (p) of the FD&amp;C Act</li> <li>5. Research unrelated to the human drug review process</li> </ol>

## 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 FD&C Act, as amended by PDUFA, authorizes the FDA to collect fees from industry to supplement non-user fee appropriations spent on FDA’s human drug review process. FDA spends PDUFA fee revenues and non-user fee appropriations to hire, support, and maintain personnel for the review of human drug applications to help ensure that safe, effective, and high-quality prescription drugs are available to the American public.

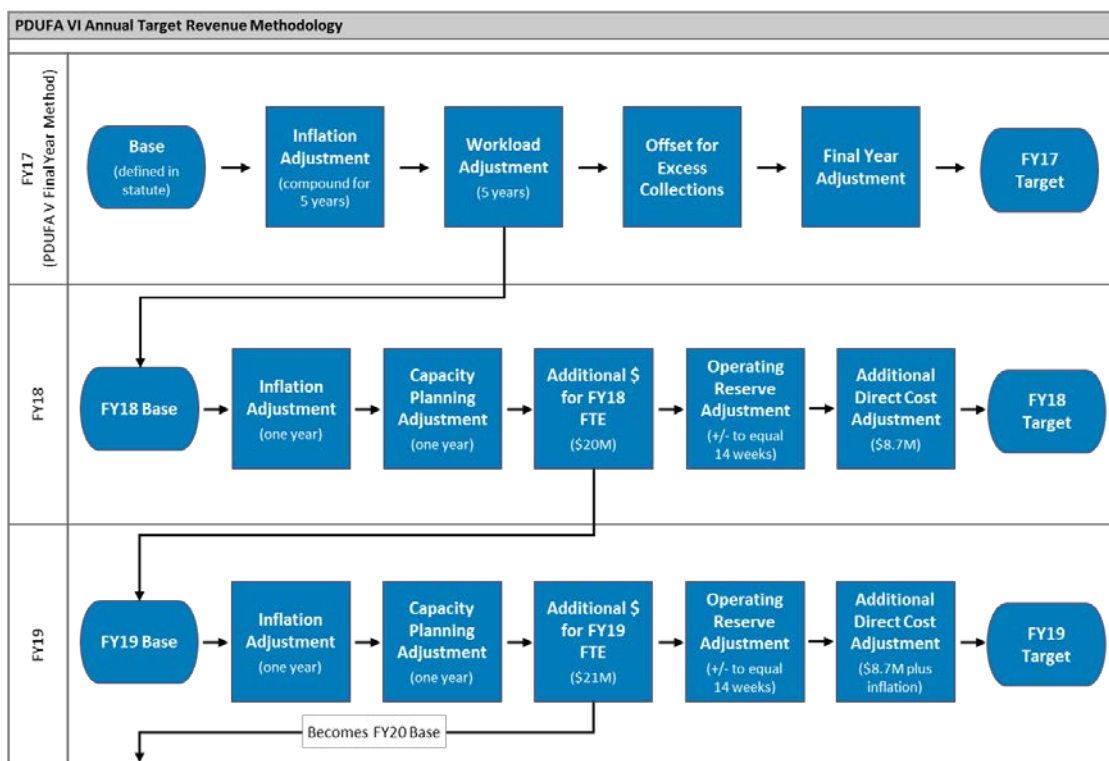
PDUFA was reauthorized in 1997 (PDUFA II), 2002 (PDUFA III), 2007 (PDUFA IV), 2012 (PDUFA V), and in 2017 (PDUFA VI) with the support of industry, other stakeholders, Congress, and the Administration. Over time, PDUFA has been a success, creating a predictable, streamlined review process and dramatically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

## C. Financial Notes

### Note 1. Annual Target Revenue Methodology

The flowchart in **Exhibit 5** is 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 number of employees that must be housed.

#### **Note 5. Shared Service Costs**

FDA contains several shared service organizations, located with the WCF, that provide support across the user fee programs. Several new organizations joined the WCF in FY 2019. The shared service organizations in FY 2019 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 (ERIC):** Provides support to all FDA employees 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 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.
- **Alternative Dispute Resolution (ADR):** Provides an alternative resource to existing administrative processes and assists in addressing work-related issues.
- **Division of Budget Execution and Control (DBEC):** 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.
- **Division of Ethics and Integrity (DEI):** Protects the integrity of FDA's programs and operations by promoting an ethical culture and ensuring compliance with applicable federal ethics laws.
- **Management Analysis Services Staff (MASS):** Provides organizational expertise and policy advice, consultation and support to ensure an efficient Agency structure that delivers on the FDA mission.
- **Office of External Affairs – History:** Provides research, documentation, and preservation of significant FDA historical resources, as well as serving as historian for the Agency.
- **Office of Security Operations (OSO):** 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.



- **Paperwork Reduction Act (PRA):** FDA's PRA staff acts as the liaison between FDA Centers, HHS, and OMB on all information collection matters.

#### **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 2019, the FY 2019 annual base revenue adjusted for inflation and capacity planning, \$980,162,120, is divided by 52, and then multiplied by 14. The 14-week cap on the operating reserve amount for FY 2019 is \$263,889,802.

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 end of year FY 2018 operating reserve was \$235,128,646.

Because the estimated end of year FY 2019 PDUFA operating reserve does not exceed the 14-week operating reserve for FY 2019, FDA did not reduce the FY 2019 PDUFA target fee revenue.

#### **Note 8. Additional Direct Costs Adjustment**

PDUFA VI specifies that \$8,730,000 be added in addition 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—
  - 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, 2018**

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
<b>Total</b>			<b>\$78,850,995</b>

### 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. 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."