FY 2018 PDUFA
FINANCIAL REPORT

REQUIRED BY THE

PRESCRIPTION DRUG USER FEE ACT

FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Executive Summary

The Prescription Drug User Fee Act of 1992 (PDUFA), as amended, requires the Food and Drug Administration (FDA or the Agency) to report annually on the financial aspects of PDUFA implementation. This is the first report under the sixth authorization of PDUFA (PDUFA VI) and covers fiscal year (FY) 2018.

PDUFA specifies that the following three legal conditions must be satisfied each year for FDA to collect and spend PDUFA user fees:

1. FDA's overall Salaries and Expenses Appropriation (excluding user fees and rent payments to the General Services Administration (GSA)) must be equal to, or greater than, FDA's FY 1997 Salaries and Expenses Appropriation (excluding user fees) multiplied by the adjustment factor.

2. The fee amounts FDA may collect must be provided in appropriation acts.

3. FDA must spend at least as much from appropriated funds (excluding user fees) for the review of human drug applications as it spent in FY 1997, multiplied by the adjustment factor.

FDA met the three legal conditions in FY 2018, and this report explains how these legal conditions were satisfied. The statements and tables in the report provide data on prescription drug user fee collections, expenditures, and carryover balances, as well as comparative data from prior years.

In FY 2018, FDA had net collections of $908 million in prescription drug user fees, spent $1.06 billion in user fees for the human drug review process, and carried a cumulative balance of $209.2 million forward for future fiscal years.

PDUFA user fees and non-user fee appropriations in FY 2018 supported 4,394 full-time equivalents (FTEs), including salaries and operational expenses, to support the process for the review of human drug applications. Detailed program accomplishments can be found in the FY 2018 PDUFA Performance Report.

Report Overview

A. Scope

This financial report addresses the implementation and use of prescription drug user fees by FDA during the period of October 1, 2017, through September 30, 2018. It presents the legal conditions that FDA must satisfy to collect and spend prescription drug user fees each year and documents how FDA determined that it met those requirements. In addition, this report presents summary statements of FY 2018 fee collections, carryover balances, obligations of user fees, and total costs of the process for the review of human drug applications from both PDUFA fees and non-user fee appropriations.

B. Report Requirements

In accordance with section 736(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), FDA will publish an annual financial report on the implementation of the authority for user fees during such fiscal year and the use by FDA of the fees collected for such fiscal year. The purpose of this report is to meet these requirements.

FDA is required to submit the financial report to Congress no later than 120 days after the end of each fiscal year (September 30). Additional details on what is required to be included in this report are included in **Appendix A**.

Management Discussion

C. Organization Background

FDA is responsible for protecting public health by 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, and meet established quality standards.
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 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 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 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.

D. 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 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, and authorizes continued funding for FDA from FY 2018 through FY 2022 to support program operations, evaluation, and improvement. PDUFA VI promises 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 include application fees and program fees with a greater proportion of the target revenue allocation assigned to program fees which provide a more predictable source of funding. It also modifies the program fee billing date to reduce the need for multiple billing cycles. The objectives of this simpler and more efficient fee structure are to increase the predictability of funding, reduce administrative burdens, and improve management of funding.

Exhibit 2 outlines the PDUFA VI fee structure.

Exhibit 2: PDUFA VI Fee Structure

Fee Type		Definition
Application	*With Clinical Data*	Human drug application for which clinical data (other than bioavailability or bioequivalence studies) with respect to safety or effectiveness are required for approval is assessed **a full application fee** when the application is submitted.
	Without Clinical Data	Human drug application for which clinical data (other than bioavailability or bioequivalence studies) with respect to safety or effectiveness are not required for approval is assessed **one-half of a full fee** when the application is submitted.
Program		Prescription drug product program fees are assessed annually for covered prescription drug products. The program fees are assessed for each such drug product that is identified in a drug application approved as of October 1st of such fiscal year.

The statute specifies how the fees must be calculated each fiscal year, including annual adjustments that must be made for inflation, capacity planning, additional dollar amounts, additional direct costs, and operating reserve. The fee amounts are published in the Federal Register each year, typically at the beginning of August (PDUFA User Fee Rates Archive).

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

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

E. Legal Conditions

The FD&C Act, as amended by PDUFA, specifies that three legal conditions must be satisfied each year for FDA to collect and spend prescription drug user fees. **Exhibit 3** describes those legal conditions and provides a brief explanation as to how those legal conditions were met.

Exhibit 3: PDUFA Legal Conditions

Legal Condition #	Details	
1	Description	The first condition requires that FDA's FY 2018 Salaries and Expenses Appropriation (excluding user fees and rent payments to GSA) be greater than or equal to FDA's Salaries and Expenses Appropriation (excluding user fees and rent payments to GSA) for FY 1997 multiplied by the adjustment factor for inflation.
	Met By	In FY 2018, FDA's appropriation for salaries and expenses was $2,782,370,000 excluding user fees and rent payments to GSA. FDA's FY 1997 Salaries and Expenses Appropriation, excluding user fees and rent, was $1,252,121,136 after applying the FY 2018 adjustment factor. Therefore, the first legal condition was satisfied.
2	Description	The fee amounts FDA may collect for each fiscal year must be specified in that year's user fee appropriation acts.
	Met By	The President signed the Consolidated Appropriations Act, 2018 (Public Law 115-141), on March 23, 2018. It specified that $911,346,000 shall be derived from prescription drug user fees, and that prescription drug user fees collected in excess of this amount, if any, are appropriated for FDA. Therefore, the second legal condition was satisfied.
3	Description	The third condition requires a minimum spending from appropriations, excluding user fees, on the PDUFA program. The minimum spending from appropriations is the amount that FDA spent on the PDUFA program in FY 1997, multiplied by the adjustment factor.
	Met By	The specified minimum level for FY 2018 is $225,939,032. In FY 2018, FDA obligated $309,563,812 from appropriations (exclusive of user fees) for the review of human drug applications. Because FDA spent more than the specified minimum amount in FY 2018, the third legal condition was satisfied.

The legal conditions as stated in FD&C Act and details on the adjustment factor are included in **Appendix D**.

F. Strategic Plan

FDA is focused on utilizing PDUFA user fee and budget authority resources to achieve the performance goals and program enhancements outlined in the PDUFA VI Commitment Letter, along with all applicable FDARA provisions. In addition to dedicating resources to ensure the program is sufficiently staffed to manage workload within agreed upon performance timelines, FDA also committed to achieve several key performance enhancements:

- Enhancing management of user fee resources
- Improving FDA hiring and retention of qualified scientific and medical review staff
- Improving information technology related to electronic submissions

Additional details regarding how FDA will meet these commitments can be found the Five-Year Forward View section of the PDUFA Five-Year Financial Plan.

G. Performance Summary

Performance Goals

FDA noted a large increase in the number of Original Priority NMEs and BLAs and Priority NDA and BLA Efficacy Supplements in FY 2018. Other submission types, notably Original Priority non-NME NDAs and Class 2 Resubmitted NDAs and BLAs, all showed substantial increases in workload in FY 2018. The marked trend of meeting management workload during PDUFA V continued into PDUFA VI. For instance, Type A meetings requested increased from 175 in FY 2017 to 223 in FY 2018. Due to the dramatic increase in volume of work, FDA struggled to meet all performance goals in this area.

During FY 2018, 75 applications were received and reviewed under the modified review program for NMEs and original BLAs. As of September 30, 2018, 28 of these applications had been reviewed and acted on, with all reviews completed on time. The remaining 47 applications are pending within their PDUFA goal dates.

As of September 30, 2018, FDA had completed 1,773 actions for the FY 2018 cohort. FDA is currently meeting or exceeding 11 of 12 review performance goals for FY 2018. With 1,239 submissions currently under review and still within the PDUFA goal date, FDA has the potential to meet or exceed 11 of 12 review performance goals for FY 2018. FDA missed the PDUFA goal date for 90 percent on time review of class 1 resubmission of original applications. Due to the low number of class 1 resubmission (i.e., nine total), missing the goal for a single application resulted in dropping below the PDUFA standard of 90 percent on time. FDA continues to strive to meet all PDUFA review goal dates.

FDA is currently meeting or exceeding 8 of 19 procedural and processing goals (i.e., meeting management, procedural responses, and procedural notifications) for the FY 2018 cohort. With 1,071 submissions currently under review and still within the PDUFA goal date, FDA has the potential to meet or exceed 8 of 19 procedural and processing goals for FY 2018, with 3 out of the remaining 11 goals that could exceed 85 percent on-time performance. FDA missed the following procedural goals related to formal meeting management: meeting request response for Type A and Type B End-of-Phase (EOP); meeting scheduling for Type A, B, B (EOP), and C; final written response only for Type A, Type B, Type B (EOP), and Type C; AND meeting preliminary response for Type B (EOP). Factors that contributed to missing the meeting management goals were the large volume of formal PDUFA meeting requests (3,492 requests), increasing workload in other user fee areas, and misunderstanding by frontline review staff for the new goal for the Type B(EOP) meeting preliminary comments.

Program Commitments

Overall, by the end of FY 2018, PDUFA met 36 commitments and missed 3 commitments. The missed commitments include the PDUFA hiring goal, the lack of timely posting of the quarter 1 hiring data for PDUFA, and the date for the Drug Development Tool/Biomarker public meeting being postponed. Regarding commitments achieved outside of program performance, PDUFA published or held:

- 6 guidances
- 5 public meetings
- 8 new or updated programs/processes
- 11 web, list, or database updates
- 2 implementation plans
- 2 public reports
- 2 new or updated internal documents

Details on these deliverables can be found in the FY 2018 PDUFA performance report on the PDUFA website.

During FY 2018, FDA continued the efforts toward a new drug development modernization plan that provides the structural framework necessary to advance the Cures/FDARA goals – and more closely align the scientific prospect of complex and innovative new products with methods and approaches that can best unlock these opportunities. The Center for Drug Evaluation and Research (CDER) proposed changes intended to free up resources so that our scientists and physicians have more time to focus on new drug development, particularly for unmet medical needs, and on the multiple efforts needed to make sure candidate drugs are developed and assessed properly, with appropriate input from external scientists, expert physicians, and patient communities.

Financial Information

This section provides an overview of the program financials for PDUFA for fiscal years 2017 and 2018. These financials include user fee revenue, obligations, carryover, non-user fee appropriations, and FTEs.

H. User Fee Program Financials

Table 1 represents a summary of the PDUFA financial position for FY 2017 and FY 2018. The financial notes referenced in this table can be found in **Appendix E**.

Table 1: Prescription Drug Collections, Obligations, and Carryover for Fiscal Years 2017 and 2018

Budgetary Resources	Notes	FY 2017	FY 2018
Target Revenue	Note 1	**$754,524,000**	**$911,346,000**
Total Carryover, Beginning of Year		$409,773,027	$350,108,200
Net Collections		$837,477,202	$908,077,723
Recoveries	Note 2	$8,130,200	$13,149,599
Total Budgetary Resources		**$1,255,380,429**	**$1,271,335,522**

Obligations	Notes	FY 2017	FY 2018
Total Payroll and Operating	Note 3	$725,470,181	$881,209,920
Total Rent	Note 4	$51,466,000	$49,964,883
Total Shared Services	Note 5	$128,336,048	$130,936,781
Total Obligations		**$905,272,229**	**$1,062,111,583**

Carryover	Notes	FY 2017	FY 2018
Total Carryover, End of Year		**$350,108,200**	**$209,223,939**

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

Budgetary Resources: The budgetary resources component of **Table 1** illustrates the sum of available user fee funding (i.e., the existing available carryover balance and additional user fee collections) that was used to fund obligations. The target revenue is the annual revenue amount established when fees for the fiscal year are set. Net collections is the amount collected during the fiscal year.

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

Obligations: The obligations component of **Table 1** shows the annual expenditure of PDUFA fee funds broken out into major expense categories. PDUFA fees may be expended only for costs to support the "process for the review of human drug applications," as defined in PDUFA. For more information on the allowable and excluded costs, see **Appendix B.**

Carryover: PDUFA fees are available until expended. This means that the fees that are collected, appropriated, and not obligated at the end of a fiscal year remain available to FDA for use in future fiscal years. The unobligated PDUFA funds at the end of each fiscal year are referred to 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, so FDA can continue performing human drug application reviews under the financial constraints.

I. User Fee Revenue

Table 2 outlines the annual target revenue amounts for FY 2018. The financial notes referenced in this table can be found in **Appendix E**.

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

Target Revenue	Notes	FY 2018
Base Amount		$878,590,000
Inflation Adjustment	Note 6	$14,820,056
Capacity Planning Adjustment	Note 7	$22,415,658
Additional Dollar Amounts	Note 8	$20,077,793
Operating Reserve Adjustment	Note 9	($33,287,582)
Additional Direct Costs Adjustment	Note 10	$8,730,000
Target Revenue Total	**Note 1**	**$911,346,925**

Base Amount/Target Revenue numbers have been rounded to the nearest thousand dollars.
All other numbers have been rounded to the nearest dollar.

The process for setting of the annual target revenue is defined in statute. The base amount for FY 2018 is specified in statute. Each year's base amount is adjusted for the following factors: inflation adjustment, capacity planning adjustment, additional dollar amounts. The amount may be adjusted, if necessary, to provide for sufficient operating reserves. Finally, the amount is adjusted to provide for additional direct costs to fund PDUFA VI initiatives. Please refer to the respective notes for more details and definition of each adjustment.

PDUFA provides for the assessment of the following: (1) Application fees are assessed on certain types of applications for the review of human drug and biological products; and (2) prescription drug program fees are assessed on certain approved products. User fee collections are recognized and reported in the year that the fee was originally due (referred to as the "cohort year"). Totals reported for each fiscal year are net of any refunds for the cohort year. To ensure the quality of the information provided in this financial report, FDA annually updates prior year numbers.

Cohort Year

The year in which user fee collections are originally due and reported. For example, a fee originally due in FY 2017, but received in FY 2018, is attributed to FY 2017 collections.

FDA issues invoices for program fees twice a year: in August for fees due on October 1, and in December after the close of the fiscal year for the new program fees not previously assessed.

Increase in Collections
The primary factor in the increase in collections was the increase in target revenue in PDUFA VI.

Under PDUFA, fees collected and appropriated but not spent by the end of the fiscal year, continue to remain available for FDA to spend in future years, as they are classified as no-year funding. The balance carried over from year to year is described in **Section K – User Fee Carryover**. An operating reserve adjustment exists to regulate the carryover user fee balance over time.

Table 3 outlines PDUFA collections by fee source and cohort year. Fee types changed from FY 2017 to FY 2018, so some fee types are no longer applicable. Refer to **Section D** for more background and information regarding these changes.

Table 3: Prescription Drug User Fee Collections by Fee Source for Cohort Years 2017 and 2018

Fees Collected	Cohort Year 2017			Cohort Year 2018		
	Estimated†	Actual	% Dif.	Estimated†	Actual	% Diff
Application Fees	$251,508,000	$300,936,500	16%	$182,269,200	$173,742,280	-5%
Establishment Fees	$251,508,000	$251,704,624	0%	N/A	N/A	N/A
Product Fees	$251,508,000	$262,682,748	4%	N/A	N/A	N/A
Program Fees	N/A	N/A	N/A	$729,076,800	$730,044,347	0%
Total Collections	**$754,524,000**	**$815,323,872**	**7%**	**$911,346,000**	**$903,786,627**	**-1%**

Fees Receivable	Actual	Actual
Application Fees	$1,019,050	$0
Establishment Fees	$1,024,414	N/A
Product Fees	$391,011	N/A
Program Fees	N/A	$4,202,721
Total Receivables	**$2,434,475**	**$4,202,721**

Numbers have been rounded to the nearest dollar.
†Estimated values were taken from the Prescription Drug User Fee Rates for Fiscal Year 2018.

J. User Fee Obligations

PDUFA fees may be expended only for costs to support the "process for the review of human drug applications," as defined in PDUFA. For more information on the allowable and excluded costs, see **Appendix B.**

Table 4 provides a comparison breakout of user fee obligations by expense category during the past 2 fiscal years. The financial notes can be found in **Appendix E**.

Table 4: Prescription Drug User Fee Obligations by Expense Category for Fiscal Years 2017 and 2018

User Fee Obligations	Notes	FY 2017	FY 2018
Payroll & Operating	Note 3		
CBER		$93,416,086	$129,543,398
CDER		$575,314,711	$688,935,477
CDRH		N/A	$786,091
ORA		$6,676,392	$7,733,467
HQ		$50,062,991	$54,211,488
Total Rent	Note 4	$51,466,000	$49,964,883
Total Shared Services	Note 5	$128,336,048	$130,936,781
Total Obligations		**$905,272,229**	**$1,062,111,583**

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.
- **Rent:** This is paid to the General Services Administrations for federal buildings that FDA occupies, as well as to non-federal sources for direct leases and services. Rental rates vary based on the type and location of the space provided.
- **Shared Services:** FDA has several shared service organizations that provide support across the user fee programs, such as human resources and IT.

In FY 2018, FDA made significant investments in the PDUFA program to ensure it is continuing to operate on a strong foundation, to deliver on its PDUFA VI commitments, and to modernize to meet evolving workload demands and scientific innovation. These investments were made in areas including pre-market review, post-market safety (including investments in the Sentinel Initiative), information technology, regulatory science, and additional staffing to support increased workload for regenerative medicine products. 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.

Capacity Planning Adjustment

FDA recognizes that revenue generated by the capacity planning adjustment will be allocated to and used by organizational review components engaged in direct review work so as to enhance resources and expand staff capacity and capability. FDA committed to documenting in this annual financial report how the revenue from this adjustment was utilized in FY 2018.[1]

The capacity planning adjustment, known prior to PDUFA VI as the workload adjustment, adjusts the annual target revenue amount to account for sustained increases in regulatory submissions. This helps

[1] See page 37 section II.A.4 of the the PDUFA VI Commitment Letter.

to ensure that FDA can expand its review capacity to meet additional workload demands, and thereby helps to ensure FDA can continue to maintain performance on its review timelines.

The capacity planning adjustment accounts for five types of regulatory review submissions: new drug applications/biologics license applications (NDAs/BLAs); commercial investigational new drugs (INDs) with activity; efficacy supplements; manufacturing supplements; and formal PDUFA industry meetings.[2,3] These submission types are then weighted based on the percentage of total PDUFA time in CDER and CBER spent on the review of each submission type.

In FY 2018, the capacity planning adjustment resulted in an increase to the target revenue of 2.51 percent, equivalent to $22,415,658. This increase is driven by the fact that the counts of elements for 2017 (year ending June 30) are at or near the highest levels since the first incorporation of the workload adjuster in 2003. The NDA/BLA count in 2017 is equal to the highest annual number since the advent of the workload adjuster. Active commercial INDs, efficacy supplements, and meetings/written response only (WROs) are higher in 2017 than in any previous year recorded in the workload adjuster (note: Meetings/WROs are only counted back to 2014 while the other elements are counted back to 2003). The manufacturing supplement count is approximately 2 percent below the highest number recorded in the history of the workload adjuster. Comparing 2017 to 2014, the first year included in the average in the adjustment, NDA/BLAs are 12 percent higher, active commercial INDs are 10 percent higher, efficacy supplements are 25 percent higher, manufacturing supplements are 15 percent higher, and meetings scheduled and WROs are 27 percent higher. This significant and across-the-board increase in submission activity is the driver of the $22,415,658 upward adjustment to the fee revenue amount.

FDA split the allocation of this $22.4M to CDER and CBER based on the submission drivers in the capacity planning adjustment. This resulted in an allocation of $20.1M to CDER and $2.3M to CBER.

CDER utilized its capacity planning adjustment allocation to increase the staffing ceiling for its Office of New Drugs, the central focus of review activity for the aspects of the PDUFA program within CDER's realm of responsibility.

CBER utilized its capacity planning adjustment allocation to add new staff positions to support pre-market review in the Office of Vaccines Research and Review, the Office of Tissues and Advanced Therapy, the Office of Biostatistics and Epidemiology, and the Office of Compliance and Biologics Quality based on their review workload demand.

For historical context, **Table 5** provides the total amount spent by FDA and by each FDA organization on the PDUFA program for the past 5 years.

[2] See the fee-setting Federal Register notice published on September 14, 2017.

[3] Note: The number of PDUFA industry meetings scheduled was added to the adjustment for the first time in PDUFA VI. This was in recognition of the significant and growing demand for meeting with industry, which typically involve a substantial scientific review and often necessitates the input of senior management.

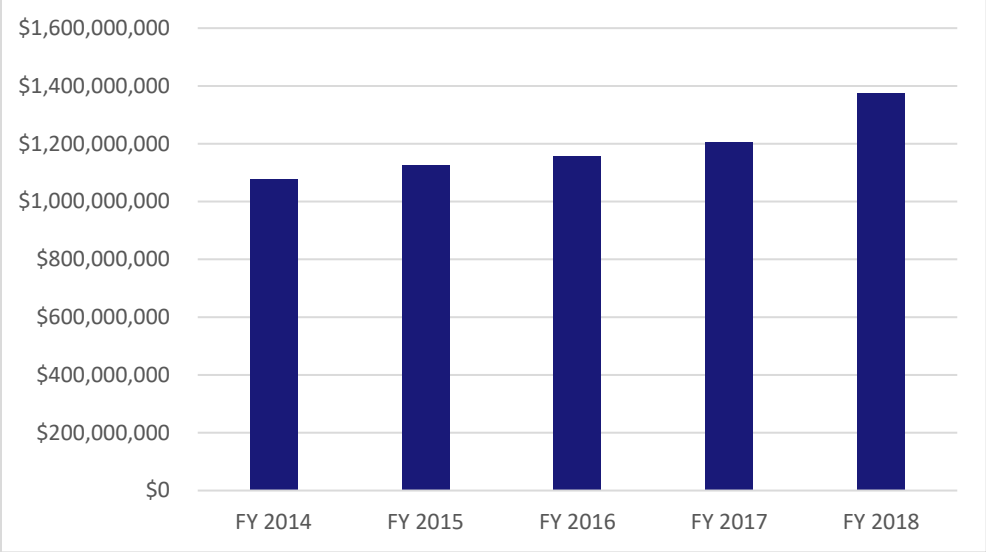
Table 5: PDUFA Program – Historical Trend of Total Costs by Organization as of September 30 of Each Fiscal Year

Costs		FY 2014	FY 2015	FY 2016	FY 2017	FY 2018
Total Spent		$1,077,263,695	$1,127,664,528	$1,157,817,695	$1,206,657,268	$1,374,508,527
CBER	Spent	$225,907,603	$235,182,801	$228,314,238	$231,880,788	$268,624,105
	Percent	21%	21%	20%	19%	20%
CDER	Spent	$732,426,835	$779,711,530	$801,353,416	$833,856,973	$954,062,652
	Percent	68%	69%	69%	69%	69%
CDRH	Spent	$0	$0	$0	$0	$4,260,126
	Percent	0%	0%	0%	0%	0%
ORA	Spent	$34,166,935	$30,716,326	$40,513,807	$44,814,804	$40,956,402
	Percent	3%	3%	3%	4%	3%
HQ	Spent	$84,762,322	$82,053,871	$87,636,234	$96,104,703	$106,605,242
	Percent	8%	7%	8%	8%	8%

Numbers have been rounded to the nearest dollar.

Exhibit 4 below provides an illustration of historical PDUFA costs.

Exhibit 4: Historic Total Costs by Fiscal Year



As demonstrated by this graph, there has been a steady increase in program needs in the past 5 years during PDUFA V, with obligations growing at an average rate of 6 percent. This includes the additional dollar amounts provided each year (see above) to provide for hiring of new positions that are capitalized into the subsequent year's base. Additionally, the inflation adjustment helps maintain the program's purchasing power and has run at a consistent rate of close to 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.

K. User Fee Carryover

PDUFA fees collected, appropriated, and not obligated at the end of the fiscal year remain available to support the PDUFA program in future fiscal years. This balance is referred to as the PDUFA carryover.

Maintaining an appropriate level of carryover enables FDA to mitigate financial risks to the program, including, for example, the risk of under collecting fees and the risk of a lapse in appropriations. FDA considers maintaining a carryover balance of between 8 to 10 weeks as a reasonable range to mitigate these risks. FDA does, however, weigh those risks against strategic programmatic needs that may take precedence, causing the balance to 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 preclude FDA from obligating the carryover funds.
- **Carryover Available for Use** – This value represents carryover funds that are not subject to any claims or restrictions and are therefore available for obligation.

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

Table 6 provides PDUFA carryover balances at the end of FY 2017 and FY 2018. The financial notes can be found in **Appendix E**.

Table 6: PDUFA Carryover for Fiscal Years 2017 and 2018

Carryover	Notes	FY 2017	FY 2018
Total Carryover, End of Year		$350,108,200	$209,223,939
Unappropriated amounts	Note 11	($78,850,995)	($78,850,995)
Refunds	Note 12	($5,000,000)	($5,000,000)
Operating Reserve Adjustment	Note 9	($33,287,582)	$0
Carryover Unavailable for Use, End of Year		($117,138,577)	($83,850,995)
Carryover Available for Use, End of Year		**$232,969,623**	**$125,372,944**

Numbers have been rounded to the nearest dollar.

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

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

- **Operating Reserve Adjustment** – Should a negative operating reserve adjustment be necessary, FDA 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.

The operations in FY 2018 resulted in a net decrease of the carryover balance of $140,884,261, from $350,108,200 at the end of FY 2017 to $209,223,939 at the end of FY 2018. For details on how the carryover was spent, please see Section J.

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

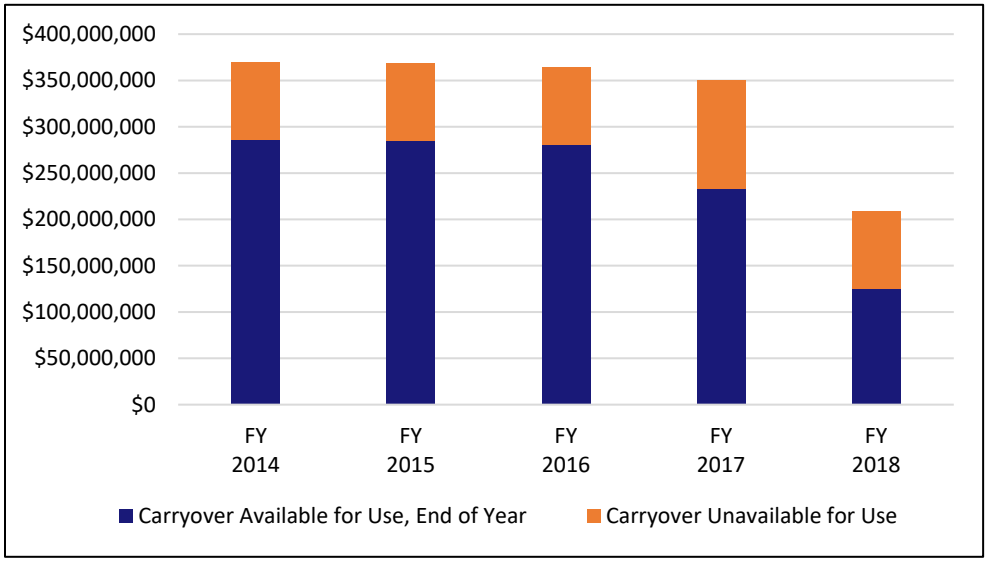
Table 7: Historical Prescription Drug User Fee Collections, Obligations, and Carryover Balances by Reauthorization Period

Carryover	Notes	PDUFA	PDUFA II	PDUFA III	PDUFA IV	PDUFA V	PDUFA VI
		FY 1993 1997	FY 1998 2002	FY 2003 2007	FY 2008 2012	FY 2013 2017	FY 2018
Total Carryover, Beginning of Year		$0	$36,462,154	$22,683,224	$130,816,093	$178,468,707	$350,108,200
Net Collections		$328,768,265	$680,152,170	$1,435,876,426	$2,848,504,459	$4,101,728,493	$908,077,723
Recoveries	Note 2	$0	$0	$0	$0	$8,749,852	$13,149,599
Total Obligations		($292,306,111)	($693,931,100)	($1,327,743,557)	($2,800,851,845)	($3,938,838,852)	($1,062,111,583)
Total Carryover, End of Year		$36,462,154	$22,683,224	$130,816,093	$178,468,707	$350,108,200	$209,223,939

Numbers have been rounded to the nearest dollar.

Exhibit 5 provides a historical perspective on the carryover for the last 5 years. As exhibited by the graph, carryover had previously trended upward. In FY 2018, FDA made the investments described above in order to manage the carryover balance. This is illustrated by the decrease in the carryover amount for this past fiscal year.

Exhibit 5: Historical Carryover by Fiscal Year



L. Non-User Fee Appropriations

For FDA to obligate user fees collected under PDUFA, a certain amount of non-user fee appropriations must be spent on the process for the review of human drug applications during that fiscal year. This is sometimes referred to as a "non-user fee spending trigger."[4] The spending trigger was $222,302,183 for FY 2017 and $225,939,032 for FY 2018.

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 13** for more details on the adjustment factor.

Table 8 provides the total amount spent on the PDUFA program for the past 5 years, and the dollar amount and percentages derived from user fee and non-user fee appropriations. The percentages attributable to PDUFA fees have increased over time.

Table 8: Historical Prescription Drug User Fee Obligations by Funding Source
As of September 30 of Each Fiscal Year

Obligations		FY 2014	FY 2015	FY 2016	FY 2017	FY 2018
Total Obligated		$1,077,263,695	$1,127,664,529	$1,157,817,695	$1,206,657,269	$1,374,508,527
Non-User Fee Appropriations	Total	$343,539,748	$331,598,549	$320,942,599	$301,385,040	$312,396,943
	Percent	32%	29%	28%	25%	23%
User Fee Revenue	Total	$733,723,947	$796,065,980	$836,875,096	$905,272,229	$1,062,111,583
	Percent	68%	71%	72%	75%	77%

Numbers have been rounded to the nearest dollar.

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

M. Full Time Equivalents (FTEs)

FTE employment or staff year, as defined by Office of Management and Budget (OMB) Circular A-11, section 85, means the total number of regular straight-time hours—not including overtime or holiday hours—worked by employees, divided by the number of compensable hours applicable to each fiscal year. Annual leave, sick leave, compensatory time off, and other approved leave categories are considered "hours worked" for purposes of defining FTE employment.

As it relates to PDUFA specifically, FTEs are referred to as "Process FTEs." This is how FDA measures a paid staff year devoted to the PDUFA program. In the table below, an FTE does not represent an accounting of individual people, but rather an estimate of labor hours expended on PDUFA activities. Funding is distributed to Centers based on the workload to support payroll to accomplish the program goals.

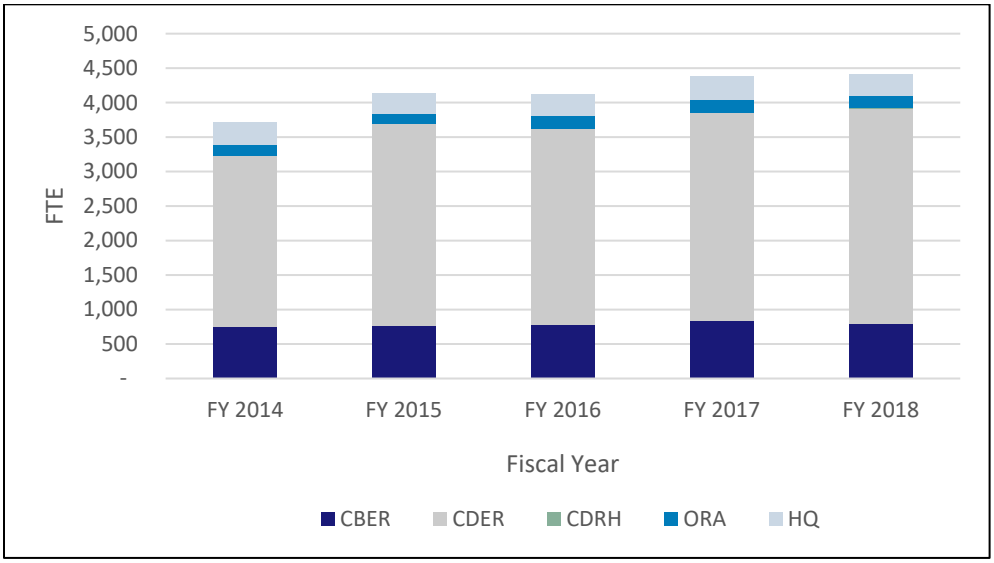
Table 9 presents total Process FTE levels, paid from user fee and non-user fee appropriations, that support the PDUFA program. The data covers the past 5 years and is arranged by FDA organizational components (CDER, CBER, CDRH, ORA, and HQ). Staff in the consolidated shared services organizations (e.g.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

Table 9: Historical Trend of Total Process FTEs Utilized by Organization as of September 30 of Each Fiscal Year

Fiscal Year	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018
CBER	744	765	782	833	791
CDER	2,487	2,927	2,833	3,016	3,111
CDRH	N/A	N/A	N/A	N/A	25
ORA	167	138	180	192	168
HQ	320	308	330	343	318
Total	**3,718**	**4,138**	**4,125**	**4,384**	**4,412**

Exhibit 6 provides the historical trend of FTE distribution and levels across FDA organizations for the past 5 years. There is a steady increase in FTEs, but the distribution has remained relatively the same.

Exhibit 6: Historical Total Process FTE Levels by FDA Organization



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 10** presents the hiring targets for these new positions for FY 2018 for PDUFA VI.

Table 10: PDUFA VI Target Versus Actual New Hires for Fiscal Year 2018

Organization	Target New Hires	Actual New Hires
CDER	45	37
CBER	16	16
Other FDA	10	10
Total Hires	**71**	**63**

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,*[5] that impact PDUFA hiring. Addressing these systemic level issues will take time, and FDA does not expect to see significant improvement in hiring early in PDUFA VI. 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.

Management Assurance

N. Internal Controls

The Federal Managers' Financial Integrity Act (FMFIA) of 1982 is intended to strengthen internal controls and accounting systems. 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 control 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

[5] https://www.fda.gov/media/108866/download

assessment, and FMFIA requires the head of each executive agency to report annually to the President and Congress on the effectiveness of the internal controls and any identified material weaknesses in those controls. FDA's FY 2018 Assurance Statement already submitted to HHS, 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 HHS guidelines, FDA has a robust internal control program, including integrated controls throughout processes. The Agency also 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 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. It is governed by the ERM Council, which is chaired by the Chief Operating Officer and the CDER Deputy Director for Operations.

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, 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, budgetary resources, and related notes are 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 corrective action plans 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, which cover the importance of internal controls, timely deficiency remediation, and roles and responsibilities.

O. Risks and Challenges

Financial Risks and Mitigation

As is the case with all financial programs, there are certain financial risks and challenges that exist with FDA's user fee programs. These risks and challenges can vary from program to program, with some being in FDA's control and some out of FDAs control. An example of a shared financial risk across all user fee programs is that FDA cannot obligate funds in advance of receiving the funds, either through appropriated user fee collections or non-user fee appropriations. FDA can only assume what the Agency's total appropriation will be in any given year. As a result, FDA has some risk of missing important performance goals, or failing to meet the non-user fee spending trigger for the fiscal year if that total appropriation comes in considerably lower than anticipated. Below is a listing of foreseeable risks associated with the collections and obligations of funds for which FDA has identified contingency plans in order to move forward in the best 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, 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 since non-user fee fund levels are often uncertain for a good portion of the fiscal year. With Continuing Resolutions (CR) becoming more prevalent, FDA has been required to spend at or slightly below levels from the prior authorized fiscal year during the CR period, thus limiting its ability to spend the non-user fee appropriations from the onset.

- **Lapse in Non-User Fee Appropriations:** 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 11** for additional details.

- **Under Collecting and Over Collecting Fees:** If FDA does not receive the estimated number of industry submissions, there may be an excess or deficit in targeted revenue. When FDA under collects user fees, it leverages its carryover balance to maintain continuity in operations. When FDA over collects, the carryover may increase without additional planned expenditures being identified to obligate those funds 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 Financial Management Committee 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 Integrated Budget and Acquisition Planning System (IBAPS) to enable greater and more timely insight into budget activity across the Agency. IBAPS improves the accuracy and availability of budget and acquisition information that enables FDA to better plan, forecast, track, and analyze the data to make 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.

Appendices

A. Reporting Requirements

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

Requirement	Details
FDARA, Title I., Section 103	Extends through FY 2022 requirements for financial reports and consultation by the FDA on reauthorization of PDUFA fees.
FDARA, Title IX, Section 903	Revises requirements for performance reports under user fee provisions for prescription drugs, medical devices, generic drugs, and biosimilars, including to require quarterly publication of information regarding certain guidance documents and meetings. Annual performance reports must include: (1) an analysis of changes in the number of FTEs hired under user fee agreements and the number funded under the FDA budget, (2) an analysis of changes in user fee revenue amounts and review costs, and (3) the number of employees in specified FDA offices for whom time reporting is required and the number for whom it is not required.
FD&C Act Section 736B(b)	Requires that a fiscal report, beginning with fiscal year 2018, is submitted no later than 120 days after the end of each fiscal year for which fees are collected. This report should include information on the implementation and use of fees collected that fiscal year.
PDUFA Reauthorization Goals and Procedure FY 2018 through 2022, Title 2, Section A, Number 4	FDA will document in the annual financial report how the workload adjuster and resource capacity adjustment fee revenues are being utilized.
PDUFA Reauthorization Goals and Procedure FY 2018 through 2022, Title VI, Section B	FDA will include in the annual PDUFA Financial Report information on the Agency's progress in the hiring of new staff used to support the new initiatives as identified in Section III.

B. Allowable and Excluded Costs for the PDUFA Program

Section 735(6) of the FD&C Act defines in general terms the activities that are included in the "process for the review of human drug applications." In summary, costs related to the following activities have been attributed to the "process for the review of human drug applications" under this definition:

Included Activities	
1. All investigational new drug review activities, including amendments; 2. All review activities for new drug applications (NDAs) and biologic license applications (BLAs), including supplements and amendments; 3. Regulation and policy development activities related to the review of human drug applications; 4. Development of product standards for products subject to review and evaluation; 5. Meetings between FDA and the sponsor of a covered application or supplement; 6. Review of labeling prior to approval of a covered application or supplement and the review of the initial pre-launch advertising; 7. Review of post-marketing studies and clinical trials that have been agreed to by sponsors as a condition for approval; 8. Inspections of facilities undertaken as part of the review of pending applications or supplements; 9. Lot release activities for covered biological products; 10. Assay development and validation to ensure batch-to-batch consistency and reliability for covered biological products;	11. Monitoring of clinical and other research conducted in connection with the review of human drug applications; 12. User Fee Act implementation activities; 13. Research related to the human drug review process; and 14. Post-market safety activities with respect to drugs approved under human drug applications or supplements, including the following activities: collecting, developing, and reviewing safety information on approved drugs, including adverse event reports; developing and using improved adverse event data-collection systems, including information technology systems; developing and using improved analytical tools to assess potential safety problems, including access to external databases; implementing and enforcing section 505(o) (relating to post-approval studies and clinical trials and labeling changes) and section 505(p) (relating to risk evaluation and mitigation strategies); and carrying out section 505(k)(5) (relating to adverse event reports and post-market safety activities).

Section 735(7) of the FD&C Act defines the "costs of resources allocated for the process for the review of human drug applications" as the expenses incurred in connection with this process for the following:

Included Expenses
1. Officers and employees of FDA, contractors of FDA, advisory committees, and costs related to such officers, employees, committees, and contracts; 2. Management of information, and the acquisition, maintenance, and repair of computer resources; 3. Leasing, maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, scientific equipment, and other necessary materials and supplies; and 4. Collecting user fees under section 736 of the FD&C Act and accounting for resources allocated for the review of human drug applications and supplements.

The PDUFA program excludes costs related to the following:

Excluded Products	Excluded Activities
1. Generic drugs 2. Over-the-counter drugs not associated with an NDA or NDA supplement 3. Large-volume parenteral drug products approved before September 1, 1992 4. Allergenic extract products 5. Whole blood or a blood component for transfusion 6. In vitro diagnostic biologic products 7. Certain drugs derived from bovine blood	1. Enforcement policy development not related to sections 505(o) and (p) of the FD&C Act 2. Post-approval compliance activities not related to the enforcement of sections 505(o) and (p) of the FD&C Act 3. Advertising review activities once marketing of the product has begun 4. Inspections unrelated to the review of covered applications, unless undertaken for the enforcement of sections 505(o) and (p) of the FD&C Act 5. Research unrelated to the human drug review process

C. User Fee Program History

PDUFA was enacted in 1992 to enable FDA to collect fees from drug manufacturers to support funding for the new drug approval process to speed application review without compromising the agency's high standards for new drug safety, efficacy, and quality. The FD&C Act, as amended by PDUFA, authorizes FDA to collect fees from industry to supplement non-user fee appropriations spent on FDA's human drug review process. FDA spends PDUFA fee revenues and non-user fee appropriations to hire, support, and maintain personnel for the review of human drug applications to help ensure that safe, effective, and high-quality prescription drugs are available to the American public.

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

D. Conditions for Assessment and Use of Fees

Introduction

The FD&C Act, as amended by PDUFA, specifies three legal conditions that must be met each fiscal year for FDA to collect and spend prescription drug user fees. This appendix describes these conditions and the applicable adjustment factor, as listed in the FD&C Act.

Adjustment Factor

To determine whether the legal conditions are satisfied, FDA must calculate and incorporate adjustment factors (defined in section 735(8) of the FD&C Act as amended) in the assessments of the first and third conditions. The FD&C Act states:

> The term 'adjustment factor' applicable to a fiscal year is the Consumer Price Index for all urban consumers (all items, United States city average) for October of the preceding fiscal year divided by such Index for October 1996.

The Consumer Price Index (CPI) for October 2016, the October of the fiscal year preceding FY 2018, was 241.729. The CPI for October 1996 was 158.3. Dividing the CPI of October 2016 by the CPI of October 1996 yields an adjustment factor of 1.527031 (rounded to the sixth decimal place) for FY 2018.

Legal Conditions

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

Exhibit 7: Legal Conditions

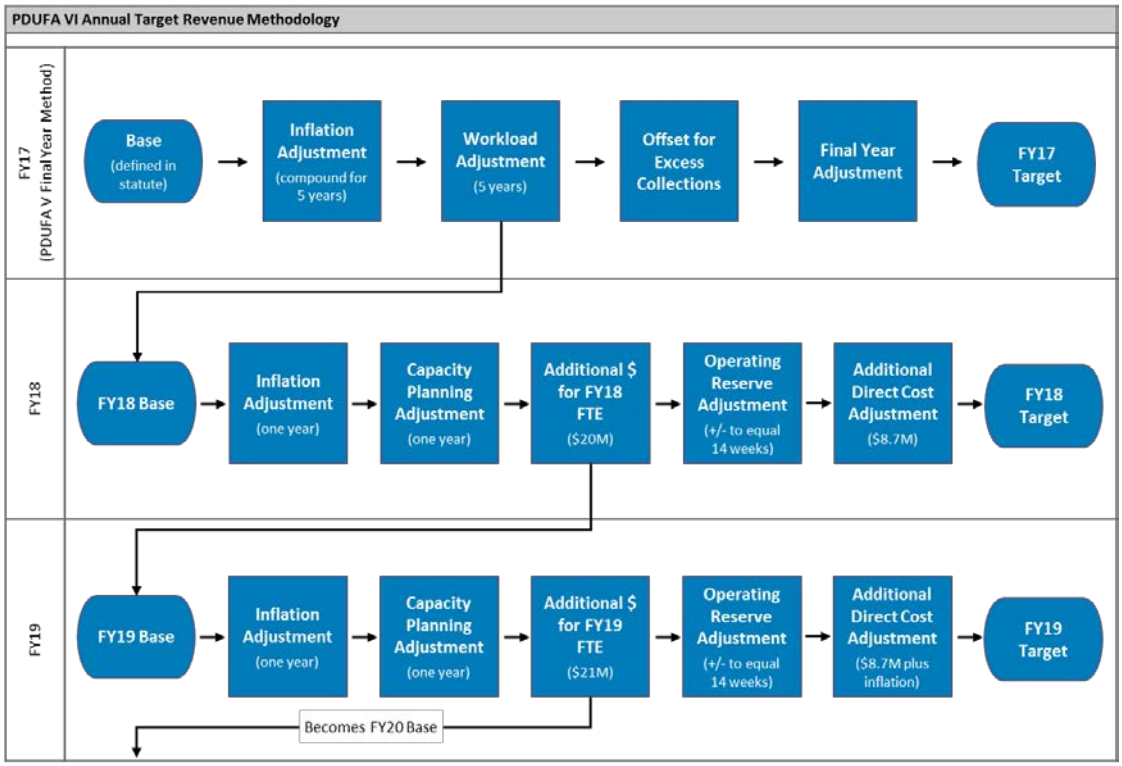
Legal Condition #	FD&C Act Section	Details
1	736(f)(1)	Fees under subsection (a) shall be refunded for a fiscal year beginning after fiscal year 1997 unless appropriations for salaries and expenses of the Food and Drug Administration for such fiscal year (excluding the amount of fees appropriated for such fiscal year) are equal to or greater than the amount of appropriations for the salaries and expenses of the Food and Drug Administration for the fiscal year 1997 (excluding the amount of fees appropriated for such fiscal year) multiplied by the adjustment factor applicable to the fiscal year involved.
2	736(g)(2)(A)(i)	The fees authorized by this section—(i) subject to subparagraph (C), shall be collected and available in each fiscal year in an amount not to exceed the amount specified in appropriation Acts, or otherwise made available for obligation, for such fiscal year.
3	736(g)(2)(A)(ii)	The fees authorized by this section— (ii) shall be available to defray increases in the costs of the resources allocated for the process for the review of human drug applications (including increases in such costs for an additional number of full-time equivalent positions in the Department of Health and Human Services to be engaged in such process) over such costs, excluding costs paid from fees collected under this section, for fiscal year 1997 multiplied by the adjustment factor.

E. Financial Notes

Note 1. Annual Target Revenue Methodology

Exhibit 8 is a flowchart which outlines the PDUFA VI Annual Target Revenue Methodology.

Exhibit 8: 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. These costs relate to how much of the PDUFA revenue is going toward payroll and operating expenses.

For payroll, employees are required to report their time in an activity-based reporting system, which allows FDA to identify activities that user fees can be used to support. See **Appendix B** for a listing of those activities. For operating activities (e.g., contracting services), funds are allocated based on the proportion to which those activities support the PDUFA program. If an operating activity solely supports PDUFA, it will be fully funded by the program. If the operating activity is shared, PDUFA will fund the activity in proportion to how it is used by the program as compared to other programs.

Note 4. Rent Costs

The General Services Administration (GSA) charges rent to FDA for the federal buildings that FDA occupies. Rental rates vary based 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 that provide support across the user fee programs. The shared service organizations include:

- **FDA Central**: Provides for Center-wide and Agency-wide services such as telecommunications, training, printing, mail and document management, IT systems, employee health units, and other support and miscellaneous services.
- **Employee Resource & Information Center (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. 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 utilized in FY 2018 was 1.6868 percent.

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

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

The inputs included in the adjustment, as prescribed in 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.

The capacity planning adjustment utilized in FY 2018 was 2.509 percent.

Note 8. Additional Dollar Amounts Adjustment

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. For fiscal year 2018, the additional dollar amount is $20,077,793.

Note 9. 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 11**) count towards the 14-week carryover cap.

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.

For the purpose of calculating the FY 2018 fees, the Additional Dollar Amounts Adjustment for FY 2018 (see Note 8) of $20,077,793, was not included in the determination of the 14-week operating reserve amount. However, it was included to determine the FY 2018 total target revenue amount of $935,903,507 (see Note 1) prior to the operating reserve and additional direct cost adjustments. 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 10. Additional Direct Costs Adjustment

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

Note 11. Unappropriated Amounts

This is the amount that FDA collected in user fees in excess of the amount specified in appropriations acts prior to FY 2010. FDA's ability to access and obligate these collections remains uncertain. **Table 11** outlines the excess user fees by fiscal year.

Table 11: Prescription Drug User Fees Collected, Collection Amounts Specified in Appropriation Acts, and Excess Amounts as of September 30, 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
Total			**$78,850,995**

Numbers have been rounded to the nearest dollar.

Note 12. Refunds

If an application is withdrawn after it is filed, FDA may refund the fee or a portion of the fee if no substantial work was performed on the application after the application was withdrawn.

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 13. Minimum Non-User Fee Appropriations Adjustment Factor

FDA must calculate and incorporate adjustment factors (defined in section 735(8) of the FD&C Act as amended). The FD&C Act states, "the term 'adjustment factor' applicable to a fiscal year is the Consumer Price Index for all urban consumers (all items, United States city average) for October of the preceding fiscal year divided by such Index for October 1996."