FY 2016 PDUFA FINANCIAL REPORT

REQUIRED BY THE

PRESCRIPTION DRUG USER FEE ACT

AS AMENDED

FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

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 its implementation. This report covers fiscal year (FY) 2016.

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 fees, must equal or exceed FDA's overall FY 1997 Salaries and Expenses Appropriation, excluding fees and adjusted for inflation.

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

3. FDA must spend at least as much from appropriated funds for the review of human drug applications as it spent in FY 1997, adjusted for inflation.

FDA met the three legal conditions in FY 2016, 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 2016, FDA had net collections of $883.7 million in prescription drug user fees, spent $836.9 million in user fees for the human drug review process, and carried a cumulative balance of $409.8 million forward for future fiscal years.

PDUFA user fees and non-user fee appropriations in FY 2016 supported 4,125 full-time equivalents, including salaries and operational expenses, to support the review of human drug applications. Detailed program accomplishments can be found in the FY 2016 PDUFA Performance Report.

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1: BACKGROUND

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Prescription Drug User Fee Act (PDUFA), authorizes the Food and Drug Administration (FDA or the Agency) to collect fees from the pharmaceutical 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), and 2012 (PDUFA V) with the support of the pharmaceutical industry, public stakeholders, and the Administration.

Over time, PDUFA has been a tremendous success, creating a predictable, streamlined review process and dramatically reducing the average time to new drug approval. Today, almost 60 percent of new active substances approved in the world market are launched first in the United States. That is more than triple the rate approved first in the United States in the first year of PDUFA (1993). Success has been achieved, in large part, through earlier and enhanced communications between FDA and industry made possible by increased FDA resources funded through PDUFA user fees.

Since its creation, PDUFA has relied on the same user fee structure. Under PDUFA, application fees, establishment fees, and product fees are set to each contribute one-third of the total revenue amount in a fiscal year, though actual collections may vary from this formula. An application fee is collected when certain new drug applications (NDAs) or biologics license applications (BLAs) and supplements are submitted. Product fees are assessed for marketed products with certain exceptions. An establishment fee is assessed for each establishment listed in an approved human drug application as an establishment that manufacturers the prescription drug named in the application in final dosage form, and, if an establishment is listed in a human drug application by more than one applicant, the establishment fee is apportioned among all applicants whose prescription drug products are manufactured by the establishment during the fiscal year and assessed product fees. Product and establishment fees are due annually. The base fee revenue amount is set in the statute for PDUFA V, and it is then adjusted for annual changes in inflation and human drug review workload.

PDUFA requires FDA to submit a financial report to Congress no later than 120 days after the end of each fiscal year. This financial report addresses the implementation and use of prescription drug user fees by FDA during the period of October 1, 2015, through September 30, 2016. This report presents the legal conditions that FDA must satisfy to collect and spend prescription drug user fees each year and shows how FDA determined that it met those requirements. In addition, this report presents summary statements of FY 2016 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.

2: LEGAL CONDITIONS

PDUFA imposes three legal conditions that FDA must satisfy to collect and spend prescription drug user fees. A summary of how each of these legal conditions was satisfied in FY 2016 is below.

Legal Condition 1 – FDA's overall Salaries and Expenses Appropriation (excluding user fees and rental payments to the General Services Administration (GSA)) must meet or exceed FDA's FY 1997 Salaries and Expenses Appropriation (excluding user fees and rental payments to GSA), adjusted for inflation (see Adjustment Factor in Appendix 4.1). In FY 2016, FDA's appropriation for salaries and expenses was $2,542,625,000, excluding user fees and rent payments to GSA. FDA's FY 1997 Salaries and Expenses Appropriation excluding user fees and rent was $1,229,868,763 after applying the FY 2016 adjustment factor. Therefore, the first legal condition was satisfied.

Legal Condition 2 – The amount of user fees collected for each fiscal year must be provided in that year's appropriation act. The President signed the Consolidated Appropriations Act, 2016 (Public Law 114-113), on December 18, 2015. It specified that $851,481,000 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.

Legal Condition 3 – User fees may be collected and used only in years when FDA spends a specified minimum amount of appropriated funds (exclusive of user fees) for the review of human drug applications. This specified minimum is the amount FDA spent on the review of human drug applications from appropriations (exclusive of user fees) in FY 1997, adjusted for inflation (see Adjustment Factor in Appendix 4.1). The specified minimum level for FY 2016 is $221,923,702. In FY 2016, FDA obligated $320,942,599 from appropriations (exclusive of user fees) for the review of human drug applications. Because FDA spent more than the specified minimum amount in FY 2016, the third legal condition was satisfied.

References

Detailed explanations and calculations of how each of these legal conditions was satisfied in FY 2016 are described in section 4.1 – Appendix A.

3: FINANCIAL INFORMATION

3.1 – USER FEE COLLECTIONS

Introduction

PDUFA specifies that user fees shall be collected for prescription drug applications and annual fees shall be collected for establishments and products. The statute further specifies how the fees must be calculated each fiscal year, including annual adjustments that must be made for inflation and changes in workload.

User fee collections are reported in the year the fee was originally due (referred to as the "cohort year"). For example, a fee originally due in FY 2015, but received in FY 2016, is attributed to FY 2015 collections. Totals reported for each fiscal year are net of any refunds for the cohort year. To ensure the quality of the information provided in this financial report, FDA annually updates prior years' numbers.

Under PDUFA, fees collected and appropriated—but not spent by the end of a fiscal year—continue to remain available for FDA to spend in future years. However, an offset provision requires that if the sum of PDUFA fees collected for the first three fiscal years and estimated to be collected for the fourth fiscal year exceed the cumulative amount appropriated for the first four fiscal years, the excess must be offset in the fifth fiscal year (i.e., the excess must be subtracted from the amount of fees that FDA would otherwise be authorized to collect for FY 2017). An offset of $124,065,726 was taken when PDUFA fees were set for FY 2017.[1]

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

The receivables for FY 2015 and FY 2016 are from uncollected product and establishment fees. After 90 days of attempting to collect the delinquent debt, FDA turns these receivables over to the Program Support Center (PSC), Department of Health and Human Services, for further attempts at collection. After 120 days of outstanding debt, PSC turns the debt over to the United States Treasury for further collection efforts.

[1] FDA published FY 2017 prescription drug user fee rates in the *Federal Register* on July 28, 2016 (81 FR 49674), https://www.gpo.gov/fdsys/pkg/FR-2016-07-28/pdf/2016-17870.pdf

Data

Table 1 provides totals of user fees collected during the past 2 fiscal years and reflects the amount of open receivables.

TABLE 1: PRESCRIPTION DRUG USER FEE COLLECTIONS AND RECEIVABLES BY FEE SOURCE AS OF SEPTEMBER 30, 2016

Fees Collected	FY 2015	FY 2016	Notes
Application Fees	$297,964,800	$317,846,025	
Establishment Fees	$271,675,336	$273,657,122	
Product Fees	$279,464,685	$265,644,258	
Total Collections	**$849,104,821**	**$857,147,405**	A
Fees Receivable	**FY 2015**	**FY 2016**	**Notes**
Establishment Fees	$758,744	$1,862,916	
Product Fees	$548,475	$1,939,907	
Total Receivables	**$1,307,219**	**$3,802,824**	

Numbers have been rounded to the nearest dollar

Notes

A. In FY 2016, FDA received a net total of $27,177,400 that was attributed to FY 2015 collections. As a result, FDA increased its FY 2015 fee collections from $821,927,421 reported last year to $849,104,821 as of September 30, 2016. The increase in FY 2015 fee revenue was due to the collection of fees associated with the annual “clean up” billing issued after the close of the fiscal year for new product and establishment fees not assessed in August.

References

The balances carried over from year to year are described in section 3.3 – Carryover Balances.

Trending of historical fees paid and user fee rates are provided in section 4.2 – Appendix B.

3.2 – USER FEE OBLIGATIONS

Introduction

PDUFA fees may be expended only for costs necessary to support the "process for the review of human drug applications," as defined in PDUFA. For ease of reading, the "process for the review of human drug applications" is referred to as the "PDUFA program" in this report. For more information on the allowable and excluded costs, see section 4.3 – Appendix C.

Data

Table 2 provides a breakout of user fee obligations by expense category during the past 2 fiscal years.

Fluctuations in non-pay object class obligations are due to variations in programmatic operations from year-to-year, such as one-time costs associated with operations and maintenance of facilities and equipment. Thus, increases or decreases in specific non-pay categories do not necessarily indicate a trend in growth or reductions in those categories.

TABLE 2: PRESCRIPTION DRUG USER FEE OBLIGATIONS BY OBJECT CLASS EXPENSE CATEGORY BREAKDOWN AS OF SEPTEMBER 30, 2015 AND 2016

Object Class Expense Category	FY 2015	FY 2016
Personnel Compensation Benefits		
Full-time permanent	$253,569,853	$271,089,797
Other than full-time permanent	$39,952,307	$42,029,263
Other personnel compensation	$39,201,732	$44,330,504
Military personnel	$22,658,647	$24,838,950
Special personnel services payments	$74,871	$82,038
Civilian personnel benefits	$100,041,201	$109,367,751
Military personnel benefits	$11,940,951	$13,561,783
Benefits former personnel	$400,000	$13,526
Total Personnel Compensation and Benefits	**$467,839,561**	**$505,313,611**
Non-Pay Costs		
Travel & transportation of persons	$6,104,013	$7,571,725
Transportation of things	$42,851	$119,037
Rent payments to GSA	$27,390,280	$25,512,000
Rent payments to others	$129,508	$801,706
Communications, utilities, & miscellaneous	$68,577	$3,875,121
Printing & reproduction	$726,120	$12,435
Other Contractual Services:		

Object Class Expense Category	FY 2015	FY 2016
Consulting services	$7,931,206	$17,079,000
Other services	$119,156,328	$123,829,216
Purchases of goods & services from government accounts	$76,568,311	$70,351,072
Operations & maintenance of facilities	$18,102,687	$15,867,681
Research & development contracts	$12,246,672	$22,593,219
Operations & maintenance of equipment	$24,603,889	$13,913,427
Subsistence & support of persons	$0	$0
Supplies & materials	$8,301,867	$7,764,725
Equipment	$13,091,691	$10,374,776
Land & structure	$0	$0
Grants, subsidies, & contributions	$13,762,417	$11,896,344
Insurance claims & indemnities	$0	$0
Interest account	$0	$0
Receivables – collected	$0	$0
Total Non-Pay Costs	**$328,226,416**	**$331,561,485**
Total Obligations	**$796,065,980**	**$836,875,096**

Numbers have been rounded to the nearest dollar

References

Additional information on PDUFA program costs can be found in section 3.6 – Total PDUFA Program Costs.

Table 3 below (on next page) provides additional information on FDA's Information Technology (IT) obligations for the PDUFA program.

In Table 3, Center IT Systems are systems utilized by one specific Center. Common IT Systems are systems utilized by two or more Centers or organizational components. Development expenses represent expenses to develop new systems, or new features or functionalities in existing systems. Maintenance expenses represent ongoing costs to maintain existing systems.

TABLE 3: FY 2016 PDUFA PROGRAM IT OBLIGATIONS BY IT EXPENSE CATEGORY AND FUNDING SOURCE AS OF SEPTEMBER 30, 2016

IT Expense Category	Non-User Fee Appropriations	PDUFA	Total	Development	Maintenance
Center IT Systems	$16,046,513	$18,458,543	$34,505,056	$13,543,098	$20,961,958
Common IT Systems	$54,417,110	$75,201,532	$129,618,643	$17,291,811	$112,326,831
Total Obligations	**$70,463,623**	**$93,660,076**	**$164,123,699**	**$30,834,910**	**$133,288,789**

Numbers have been rounded to the nearest dollar

3.3 – CARRYOVER BALANCES

Introduction

PDUFA fees collected, appropriated, and not obligated at the end of the fiscal year remain available to FDA in future fiscal years. These funds are referred to as "carryover balances."

Table 4 reflects the amount of fees collected net of any refunds or other adjustments that occurred during each fiscal year, for all cohort years combined, and the amount obligated during the fiscal year. The numbers do not include any accounts receivable. Therefore, the numbers for FY 2015 and FY 2016 are different from the numbers in Table 1 in section 3.1 – User Fee Collections, which reflect the total net collections for the cohort years only.

Obligations in Table 4 include any recoveries and deobligations from prior years, which may cause differences from Tables 2 and 8. In FY 2016, FDA recovered $619,652 in PDUFA deobligations.

Data

Table 4 captures FDA's carryover balances since the enactment of PDUFA in FY 1993.

The operations in FY 2016 resulted in a net increase of the carryover balance of $47,427,122 (from $362,345,905 at the end of FY 2015 to $409,773,027 at the end of FY 2016). The increase in carryover is due to higher-than-expected fee-paying applications received in FY 2016 and collections from the FY 2015 product and establishment clean-up billing.

TABLE 4: PRESCRIPTION DRUG USER FEE COLLECTIONS, OBLIGATIONS, AND CARRYOVER BALANCES BY FISCAL YEAR

Program	Fiscal Years	Beginning Carryover	Net Collection	Obligations	Year-End Carryover
PDUFA	1993-1997	$0	$328,768,265	$292,306,111	$36,462,154
PDUFA II	1998-2002	$36,462,154	$680,152,170	$693,931,100	$22,683,224
PDUFA III	2003-2007	$22,683,224	$1,435,876,426	$1,327,743,557	$130,816,093
PDUFA IV	2008-2012	$130,816,093	$2,848,504,459	$2,800,851,845	$178,468,707
PDUFA V	2013	$178,468,707	$728,595,772	$666,901,600	$240,162,879
	2014	$240,162,879	$796,660,672	$733,723,947	$303,099,604
	2015	$303,099,604	$855,312,281	$796,065,980	$362,345,905
	2016	$362,345,905	$883,682,566	$836,255,444	$409,773,027

Numbers have been rounded to the nearest dollar

3.4 – COLLECTIONS REALIZED

Introduction

The following information depicts collections realized by cohort year (the same as Total Collections in Table 1, section 3.1 – User Fee Collections), collection amounts specified in the appropriation acts, and offset amounts made when fees for FY 2007 and FY 2012 were set. An offset of $124,065,726 was taken when fees were set for FY 2017.

Data

Previous cohort-year collections realized in FY 2016 have been updated from last year's report. The update reflects net collections for each cohort year through September 30, 2016. Cohort year fees collected after September 30, 2016, will be reported in the FY 2017 Financial Report. Other variances between Table 4 and Table 5 are a result of unapplied collections at the end of the fiscal year. These collections will either be applied or refunded during FY 2017.

TABLE 5: PRESCRIPTION DRUG USER FEES COLLECTED, COLLECTION AMOUNTS SPECIFIED IN APPROPRIATION ACTS, AND EXCESS AMOUNTS AS OF SEPTEMBER 30, 2016

Fiscal Year	Collections Realized	Collection Amount Specified in Appropriation Acts	Amount in Excess of Collection Amount Specified in Appropriation Acts	Notes
1998	$117,849,016	$117,122,000	$727,016	
1999	$125,729,367	$132,273,000	-	
2000	$141,134,682	$145,434,000	-	
2001	$138,421,429	$149,273,000	-	
2002	$141,408,975	$161,716,000	-	
Total PDUFA II			**$727,016**	
2003	$218,302,684	$222,900,000	-	
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	
Total PDUFA III			**$38,139,693**	A
2008	$478,184,756	$459,412,000	$18,772,756	
2009	$531,876,530	$510,665,000	$21,211,530	
2010	$555,748,523	$578,162,000	($22,413,477)	
2011	$593,024,940	$667,057,000	($74,032,060)	
2012	$707,406,592	$702,172,000	$5,234,592	
Total PDUFA IV			**($51,226,659)**	A,B

Fiscal Year	Collections Realized	Collection Amount Specified in Appropriation Acts	Amount in Excess of Collection Amount Specified in Appropriation Acts	Notes
2013	$721,225,394	$718,669,000	$2,556,394	
2014	$805,649,146	$760,000,000	$45,649,146	
2015	$849,104,821	$798,000,000	$51,104,821	
2016	$857,147,405	$851,481,000	$5,666,405	
Total PDUFA V			**$104,976,766**	
Offset When Fees Were Set for FY 2017			**$124,065,726**	C

Numbers have been rounded to the nearest dollar

Notes

A. Collections exceeding amounts specified in appropriations acts through FY 2007 totaled $38,866,709. Excess collections offset under section 736(g)(4) of the FD&C Act when fees were set for FY 2007 totaled $7,957,922. Excess collections offset under section 736(g)(4) of the FD&C Act when fees were set for FY 2012 totaled $30,974,959.

B. FDA had excess collections in PDUFA IV in FY 2008 and FY 2009 totaling $39,984,286. However, overall FDA under-collected by $51,226,659 in FY 2008 – FY 2012.

C. Under PDUFA, if cumulative collections through FY 2015—including an estimate for FY 2016—exceed the fee revenues specified in appropriation acts during that period, FDA will lower the fee rates for FY 2017 by the cumulative amount that fees exceeded the amounts specified in appropriation acts during that period. An offset of $124,065,726 was taken when fees were set for FY 2017; this offset amount included an estimate for the FY 2016 clean-up billing, which is why the FY 2016 contribution to the offset calculation is larger than the value that appears in Table 5 under “amount collected in excess of the amount specified in appropriations acts,” which reflects actual collections as of September 30, 2016.

3.5 – RESERVES AND BALANCE AVAILABLE FOR ALLOCATION

Introduction

PDUFA's carryover balance in FY 2016 is $409,773,027. Anticipated claims on this balance are described below. After subtracting these claims, FDA's total remaining carryover balance is $280,707,301. The current status of FDA's ability to access and obligate some funds in the remaining carryover balance remains uncertain.

Data

Table 6 provides a summary of carryover balances as of September 30, 2016, and anticipated claims on those balances.

TABLE 6: SUMMARY STATEMENT OF PRESCRIPTION DRUG USER FEE CARRYOVER BALANCE AS OF SEPTEMBER 30, 2016

Status of Carryover Funds	Amount	Notes
Total Carryover Balance	$409,773,027	
Offset Taken for FY 2017	($124,065,726)	
Reserve for Refunds	($5,000,000)	A
Remaining Carryover Balance	**$280,707,301**	B

Numbers have been rounded to the nearest dollar

Notes

A. Prudent operations require that a reserve be kept aside for potential refunds. For that purpose, a total of $5,000,000 is being set aside.

B. The current status of FDA's ability to access and obligate collections in excess of the amount specified in the appropriation acts for fiscal years prior to FY 2010 remains uncertain. This unavailable balance is $78,850,995.

3.6 – TOTAL PDUFA PROGRAM COSTS

Introduction

There are four organizations that support the PDUFA program: the Center for Drug Evaluation and Research (CDER), the Center for Biologics Evaluation and Research (CBER), the Office of Regulatory Affairs (ORA), and FDA Headquarters (HQ). The PDUFA program is supported by user fee and non-user fee appropriations.

Data

Table 7 shows the costs (non-user fee appropriations and user fees) for the PDUFA program during the past 10 fiscal years by FDA organizational components (CDER, CBER, ORA, and HQ). The percentages spent in the various FDA components have remained essentially stable over time, with CDER at approximately 69 percent, CBER at approximately 20 percent, ORA at approximately 3 percent, and HQ at approximately 8 percent.

TABLE 7: PDUFA PROGRAM – HISTORICAL TREND OF TOTAL COSTS BY ORGANIZATION AS OF SEPTEMBER 30 OF EACH FISCAL YEAR

Fiscal Year	Total Spent	Spent by CDER	CDER %	Spent by CBER	CBER %	Spent by ORA	ORA %	Spent by HQ	HQ %
2007	$575,005,992	$385,939,977	67%	$122,871,873	21%	$25,860,072	5%	$40,334,070	7%
2008	$713,900,390	$493,748,819	69%	$145,080,623	20%	$27,811,039	4%	$47,259,909	7%
2009	$855,426,294	$585,414,578	68%	$170,363,705	20%	$36,509,080	4%	$63,138,931	8%
2010	$931,845,581	$640,509,784	69%	$176,353,112	19%	$34,968,204	4%	$80,014,481	8%
2011	$1,025,621,707	$719,677,685	70%	$199,895,537	20%	$37,783,238	4%	$68,265,247	6%
2012	$1,032,419,218	$714,461,517	69%	$201,589,189	20%	$37,186,485	4%	$79,182,027	7%
2013	$966,169,007	$661,662,397	68%	$191,204,309	20%	$31,508,236	3%	$81,794,065	9%
2014	$1,077,263,695	$732,426,835	68%	$225,907,603	21%	$34,166,935	3%	$84,762,322	8%
2015	$1,127,664,528	$779,711,530	69%	$235,182,801	21%	$30,716,326	3%	$82,053,871	7%
2016	$1,157,817,695	$801,353,416	69%	$228,314,238	20%	$40,513,807	3%	$87,636,234	8%

Numbers have been rounded to the nearest dollar

Table 8 provides the total amount spent on the PDUFA program for the last 10 years, and the dollar amount and percentages derived from user fee and non-user fee appropriations. The percentage attributable to PDUFA fees has increased over time, but has been essentially stable in recent years.

TABLE 8: PDUFA PROGRAM – HISTORICAL TREND OF TOTAL COSTS BY FUNDING SOURCE AS OF SEPTEMBER 30 OF EACH FISCAL YEAR

Fiscal Year	Total Spent	Spent from Appropriations	Appropriations Percent	Spent from PDUFA Fees	PDUFA Fee Percent
2007	$575,005,992	$254,576,372	44%	$320,429,620	56%
2008	$713,900,390	$263,113,555	37%	$450,786,835	63%
2009	$855,426,294	$343,374,894	40%	$512,051,400	60%
2010	$931,845,581	$358,587,181	38%	$573,258,400	62%
2011	$1,025,621,707	$397,795,307	39%	$627,826,400	61%
2012	$1,032,419,218	$395,490,417	38%	$636,928,801	62%
2013	$966,169,007	$299,267,407	31%	$666,901,600	69%
2014	$1,077,263,695	$343,539,748	32%	$733,723,947	68%
2015	$1,127,664,528	$331,598,549	29%	$796,065,980	71%
2016	$1,157,817,695	$320,942,599	28%	$836,875,096	72%

Numbers have been rounded to the nearest dollar

References

An expense category breakout of the FY 2015 and FY 2016 dollar amounts spent from PDUFA fees is provided in Table 2 of section 3.2 – User Fee Obligations.

The development of the costs associated with the PDUFA program is described in more detail in section 4.4 – Appendix D.

3.7 – FULL-TIME EQUIVALENT

Introduction

Full-time equivalent (FTE) is a measure of a paid staff year devoted to the PDUFA program. In this table, an FTE does not represent an accounting of individual people, but rather an estimate of labor hours expended on PDUFA activities on an FTE basis.

Data

Table 9 presents total FTE levels, paid from user fee and non-user fee appropriations, which support the PDUFA program. The data covers the past 10 years and is arranged by FDA organizational components (CDER, CBER, ORA, and HQ). Staff in the consolidated shared services organization (facilities, procurement, IT services, etc.) is included in the FTE levels for the various components.

Due to a system upgrade that was in progress at the end of FY 2015, the typical data for that year's FTE calculations was unavailable. FDA had to estimate the breakdown for FY 2015 using an alternative methodology based on high-level FTEs. In FY 2016, after the system upgrade was complete, FDA was able to return to the normal methodology. This change in methodology has caused an overstatement of process FTEs for FY 2015. In addition, beginning in FY 2015, the calculation to determine the allocation of shared services FTEs among programs was amended to more accurately estimate labor hours expended on PDUFA activities. This recalculation includes the addition of the Office of Human Resources and a restructuring of the activities related to the Office of Information Management.

TABLE 9: HISTORICAL TREND OF TOTAL FTES UTILIZED BY ORGANIZATION AS OF SEPTEMBER 30 OF EACH FISCAL YEAR

Fiscal Year	CDER	CBER	ORA	HQ	Total
2007	1,809	574	163	191	2,738
2008	1,912	610	165	238	2,925
2009	2,344	658	217	307	3,526
2010	2,552	710	192	306	3,760
2011	2,666	722	198	291	3,877
2012	2,636	740	183	295	3,854
2013	2,450	748	166	290	3,655
2014	2,487	744	167	320	3,718
2015	2,927	765	138	308	4,138
2016	2,833	782	180	330	4,125

Numbers have been rounded to the nearest full FTE

4: APPENDICES

4.1 – APPENDIX A: 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 in detail and explains how FDA met these conditions in FY 2016. A summary of the legal conditions is provided in section 2 – Meeting the Legal Conditions in FY 2016.

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 2014, the October of the fiscal year preceding FY 2016, was 237.433. The CPI for October 1996 was 158.3. Dividing the CPI of October 2014 by the CPI of October 1996 yields an adjustment factor of 1.499893 (rounded to the sixth decimal place) for FY 2016.

Legal Condition 1

The first legal condition is found in section 736(f)(1) of the FD&C Act. It states that fees:

> [S]hall be refunded for a fiscal year beginning after FY 1997 unless appropriations for salaries and expenses of the Food and Drug Administration for such fiscal year (excluding the amount of fees appropriated for such fiscal year) are equal to or greater than the amount of appropriations for the salaries and expenses of the Food and Drug Administration for the fiscal year 1997 (excluding the amount of fees appropriated for such fiscal year) multiplied by the adjustment factor applicable to the fiscal year involved.

The first condition requires that FDA's FY 2016 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. FDA's Salaries and Expenses Appropriation (excluding user fees and rent payments to GSA) for FY 1997 was $819,971,000. Multiplying this amount by the adjustment factor of 1.499893 equals $1,229,868,763.

In FY 2016, Congress appropriated $2,542,625,000 to FDA for salaries and expenses, excluding user fees and rent payments to GSA. Because the FY 2016 Salaries and Expenses Appropriation is greater than the adjusted FY 1997 Salaries and Expenses Appropriation, $1,229,868,763, the first legal condition was met.

Legal Condition 2

The second legal condition is described in section 736(g)(2)(A)(i) of the FD&C Act and states that fees:

> [S]hall 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

On December 18, 2015, the President signed the Consolidated Appropriations Act, 2016, Public Law 114-113, which specified that $851,481,000 shall be derived from prescription drug user fees, and that prescription drug user fees collected in excess of this amount, if any, are also appropriated for FDA. Therefore, the second legal condition was met.

Legal Condition 3

The third legal condition is defined in section 736(g)(2)(A)(ii) of the FD&C Act; it states that fees:

> [S]hall 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.

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.

In FY 1997, the amount spent from appropriations on the PDUFA program was $147,959,689. After applying the adjustment factor of 1.499893 (rounded to sixth decimal place), the minimum appropriation spending level for the PDUFA program for FY 2016, excluding user fees, is $221,923,702.

In FY 2016, FDA obligated $320,942,599 from appropriations, exclusive of user fees, for the PDUFA program, which exceeds the specified minimum appropriation spending level. Therefore, the third legal condition was met.

4.2 – APPENDIX B: FEES, WAIVERS, AND EXEMPTIONS

PDUFA Fee History

PDUFA established three fee categories and set fee revenues for each category annually. Based on the statutory revenues and estimated numbers of fees that would be paid in each category, FDA published the FY 2016 fee rates for all categories in August 2015.[2] Table 10 provides a history of fee rates for the past 10 years.

TABLE 10: TRENDS IN APPLICATION, ESTABLISHMENT, AND PRODUCT FEE RATES

Fiscal Year	Establishment Fee	Product Fee	Application Fee
2007	$313,100	$49,750	$896,200
2008	$392,700	$65,030	$1,178,000
2009	$425,600	$71,520	$1,247,200
2010	$457,200	$79,720	$1,405,500
2011	$497,200	$86,520	$1,542,000
2012	$520,100	$98,970	$1,841,500
2013	$526,500	$98,380	$1,958,800
2014	$554,600	$104,060	$2,169,100
2015	$569,200	$110,370	$2,335,200
2016	$585,200	$114,450	$2,374,200

[2] FDA published FY 2016 prescription drug user fee rates in the *Federal Register* on August 3, 2015 (80 FR 46028), https://www.gpo.gov/fdsys/pkg/FR-2015-08-03/pdf/2015-18914.pdf

PDUFA Fees Forecasted Versus Actual Fees Received

Table 11 depicts FDA's estimates of fee-paying units used in the *Federal Register* (FR) notices for setting PDUFA fees prospectively versus the actual number of fee-paying units received each year for the last 10 years. The application totals below represent full-application equivalents (FAEs).

A full application requiring clinical data counts as one FAE. An application not requiring clinical data counts as one-half of an FAE, as does a supplement requiring clinical data. An application that is withdrawn, or refused for filing, counts as one-fourth of an FAE if the applicant initially paid a full application fee, or one-eighth of an FAE if the applicant initially paid one-half of the full application fee amount.

FDA updates prior-year "actual numbers" annually after the clean-up billing process, which is why FY 2015 actual numbers are different in this year's financial report.

Fees collected in FY 2016 do not include clean-up billing in FY 2017. Therefore, these numbers will be updated in next year's financial report.

TABLE 11: TRENDS IN FORECASTED VS. ACTUAL FEE-PAYING APPLICATIONS, ESTABLISHMENTS, AND PRODUCTS

Fiscal Year	Forecasted vs. Actual	Establishment Fees	Product Fees	Application Fees
2007	FR	375	2,360	131
	Actual	416	2,381	134
2008	FR	390	2,355	130
	Actual	429	2,426	140
2009	FR	400	2,380	137
	Actual	418	2,347	140
2010	FR	415	2,380	135
	Actual	439	2,457	118
2011	FR	415	2,385	134
	Actual	457	2,451	101
2012	FR	450	2,365	127
	Actual	461	2,464	122
2013	FR	455	2,435	122
	Actual	476	2,401	120
2014	FR	455	2,425	116
	Actual	465	2,487	133
2015	FR	472	2,434	115
	Actual	477	2,532	128
2016	FR	485	2,480	120
	Actual	468	2,321	134

PDUFA Waiver and Exemption History

Fees may be waived or reduced under the waiver provisions of the statute. PDUFA directs FDA to waive or reduce fees in five different circumstances:

- when a waiver is necessary to protect the public health;
- when a fee is a significant barrier to innovation;
- when the fees paid exceed FDA's costs of reviewing a firm's prescription drug applications;
- when imposition of the fee creates an inequity between certain 505(b)(1) and 505(b)(2) prescription drug applications (this waiver provision was omitted in PDUFA III and subsequent reauthorizations); and
- when a sponsor withdraws a pending prescription drug application after FDA has filed it, but before FDA has performed substantial work on the marketing application.

Beginning in FY 1998, PDUFA II also provided a waiver, for certain small businesses, of the full application fee for the first application submitted. In addition, other exemptions from application fees were added beginning in FY 1998. These specific exemptions are automatic and do not require a waiver request. They include the following:

- prescription drug applications for designated orphan products (designated for rare diseases or conditions affecting fewer than 200,000 patients in the United States); and
- supplemental applications for pediatric use indications (statutorily repealed by section 5 of Public Law 107-109, effective January 4, 2002).

The increased number of exemptions required by PDUFA II reduced the number of fee-paying applications. Many of the application fee waiver requests FDA received through FY 1997 pertained to orphan products; since designated orphan products are now given automatic exemptions, the number of waiver requests for application fees has decreased substantially.

Beginning in FY 2008, PDUFA IV provided exemptions for product and establishment fees for certain approved orphan products (see 21 USC § 379h(k)).

Table 12 summarizes the waivers granted by FDA for PDUFA fees payable in the 10 most recent fiscal years. FDA annually updates these amounts to include fees collected subsequent to the prior PDUFA financial report.

TABLE 12: TOTAL WAIVERS AS OF SEPTEMBER 30, 2016

Waivers	Applications			Products		Establishments		Total Value of Waivers Approved
	Small Business Waivers	Miscellaneous Waivers (Includes PEPFAR[3])	Value of Waivers Approved	Waivers Approved	Value of Waivers Approved	Waivers Approved	Value of Waivers Approved	
FY 2007	14.0	14.0	$25,093,600	25.8	$1,283,844	13.1	$4,095,372	$30,472,816
FY 2008	26.0	21.0	$55,366,000	17.1	$1,112,130	7.8	$3,053,420	$59,531,550
FY 2009	17.0	10.0	$33,674,400	20.9	$1,494,443	2.9	$1,215,818	$36,384,660
FY 2010	21.4	13.1	$48,520,696	15.9	$1,265,807	5.7	$2,621,489	$52,407,992
FY 2011	16.5	8.5	$38,550,000	29.4	$2,541,739	4.7	$2,345,858	$43,437,596
FY 2012	17.0	5.0	$40,513,000	12.0	$1,187,640	7.3	$3,812,333	$45,512,973
FY 2013	11.5	10.5	$43,093,600	20.0	$1,967,600	6.6	$3,480,750	$48,541,950
FY 2014	16.5	5.0	$46,635,650	21.7	$2,262,682	8.8	$4,898,967	$53,797,298
FY 2015	22.0	4.0	$60,715,200	23.0	$2,538,510	8.4	$4,782,610	$68,036,320
FY 2016	10.5	9.0	$46,296,900	1.0	$114,450	0.2	$97,533	$46,508,883

Numbers have been rounded to the nearest dollar

[3] PEPFAR refers to applications excluded from fees under the President's Emergency Plan for AIDS Relief.

Table 13 summarizes orphan exemptions from PDUFA fees payable in the 10 most recent fiscal years. It includes exempt orphan application fees in FY 2016. To ensure the quality of the information provided in this financial report, FDA annually updates numbers from prior years as appropriate.

TABLE 13: TOTAL ORPHAN EXEMPTIONS AS OF SEPTEMBER 30, 2016

Exemptions	Applications		Products		Establishments		Total Value of Exemptions
	Exempt Orphan Application Fees	Value of Exemptions	Exempt	Value of Exemptions	Exempt Orphan Establishment Fees	Value of Exemptions	
FY 2007	21.3	$19,044,250	-	-	-	-	$19,044,250
FY 2008	27.8	$32,689,500	14.0	$910,420	5.2	$2,056,963	$35,656,883
FY 2009	23.8	$29,621,000	16.0	$1,144,320	7.4	$3,169,869	$33,935,189
FY 2010	21.8	$30,569,625	28.0	$2,232,160	11.5	$5,252,314	$38,054,099
FY 2011	33.0	$50,886,000	33.0	$2,855,160	16.0	$7,976,082	$61,717,242
FY 2012	36.6	$67,306,825	30.0	$2,969,100	12.1	$6,311,414	$76,587,339
FY 2013	35.1	$68,802,850	51.0	$5,017,380	18.2	$9,591,953	$83,412,183
FY 2014	38.5	$83,510,350	38.0	$3,954,280	16.3	$9,050,702	$96,515,332
FY 2015	60.0	$140,112,000	30.0	$3,311,100	15.7	$8,918,795	$152,341,895
FY 2016	48.5	$115,148,700	26.0	$2,975,700	12.6	$7,367,083	$125,491,483

Numbers have been rounded to the nearest dollar

4.3 – APPENDIX C: ALLOWABLE AND EXCLUDED COSTS FOR THE PDUFA PROGRAM

Introduction

Section 735 of the FD&C Act as amended defines the "process for the review of human drug applications" and the costs that may be included in that process, collectively referred to as the "PDUFA program" in this document. Fees may only be spent for activities that are included in this definition, although fee-generating activities are only a small subset of the activities that are included in this definition. The Agency identifies those activities that are applicable to the PDUFA program in this appendix. In Appendix D, the Agency describes how the costs for the PDUFA program are developed, based on the allowable activities identified in this appendix.

PDUFA Program Costs

Included Activities

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:

- All investigational new drug review activities, including amendments;
- All review activities for NDAs and BLAs, including supplements and amendments;
- Regulation and policy development activities related to the review of human drug applications;
- Development of product standards for products subject to review and evaluation;
- Meetings between FDA and the sponsor of a covered application or supplement;
- Review of labeling prior to approval of a covered application or supplement and the review of the initial pre-launch advertising;
- Review of post-marketing studies and clinical trials that have been agreed to by sponsors as a condition for approval;
- Inspections of facilities undertaken as part of the review of pending applications or supplements;
- Lot release activities for covered biological products;
- Assay development and validation to ensure batch-to-batch consistency and reliability for covered biological products;
- Monitoring of clinical and other research conducted in connection with the review of human drug applications;
- User Fee Act implementation activities;

- Research related to the human drug review process; and

- Postmarket 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 postmarket safety activities).

All user-fee-related costs represented by the above activities are collectively referred to in this report as costs for the PDUFA program.

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:

A. officers and employees of FDA, contractors of FDA, advisory committees, and costs related to such officers, employees, committees, and contracts;

B. management of information, and the acquisition, maintenance, and repair of computer resources;

C. leasing, maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, scientific equipment, and other necessary materials and supplies; and

D. 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.

Excluded Products and Activities

The PDUFA program excludes costs related to the following:

Excluded Products

- Generic drugs

- Over-the-counter drugs not associated with an NDA or NDA supplement

- Large-volume parenteral drug products approved before September 1, 1992

- Allergenic extract products

- Whole blood or a blood component for transfusion

- In vitro diagnostic biologic products

- Certain drugs derived from bovine blood

Excluded Activities

- Enforcement policy development not related to sections 505(o) and (p) of the FD&C Act
- Post-approval compliance activities not related to the enforcement of sections 505(o) and (p) of the FD&C Act
- Advertising review activities once marketing of the product has begun
- Inspections unrelated to the review of covered applications, unless undertaken for the enforcement of sections 505(o) and (p) of the FD&C Act
- Research unrelated to the human drug review process

4.4 – APPENDIX D: DEVELOPMENT OF COSTS FOR THE PDUFA PROGRAM

General Methodology

The costs associated with the PDUFA program are based on obligations attributed to CDER, CBER, ORA, and HQ. These organizations correspond to the cost categories presented as follows:

Cost Category	FDA Organization
Costs for the Review of NDAs, BLAs, and Supplements	CDER
Costs for the Review of NDAs, BLAs, and Supplements	CBER
Field Inspection and Investigation Costs	ORA
Agency General and Administrative Costs	HQ

The costs for each component are shown in Table 7. They were derived using time-reporting systems in CDER, CBER, and ORA, and were calculated for HQ as described in more detail in this appendix. Using the definitions of costs and activities included in the PDUFA program, as explained in the discussion in Appendix C, the cost categories within each organization listed above were identified as parts of the human drug application review process.

Center Costs

Costs of the PDUFA program are tracked for each organizational component in CDER and CBER, usually at the division level. Most FDA components involved in the PDUFA program perform a mixture of activities—some within the scope of the PDUFA program and some not. FDA groups its organizational components into three categories:

- Direct review and laboratory
- Indirect review and support
- Center-wide costs

The allocation of costs for each category is discussed below.

Direct Review and Laboratory

Employees in all components of CDER and CBER, other than those noted below as Center indirect review and support components, are required to report their time for a total of 8 weeks (2 weeks per quarter) each fiscal year in activity-based time reporting systems. The activities in the systems allow identification of the nature of the activity so that time reported can be separated into allowable and excluded activities as defined by PDUFA.

The average percentage of time reported on the PDUFA program in CDER and CBER is applied to all costs incurred for the entire fiscal year in those Centers. This method provides an estimate of each Center's costs incurred while conducting the PDUFA program in FY 2016.

Indirect Review and Support

Indirect review and support components provide the infrastructure for the review process. In CDER, these components include the Office of the Center Director, the Office of Management, the Office of Communications, portions of the Office of Executive Programs, and the Office of Strategic Programs. In CBER, these components include portions of the Office of the Center Director, Office of Management, and the Office of Communications, Outreach and Development. Most employees of these components do not report their time.

FDA assumes the time of management and administrative personnel supporting the PDUFA program is equivalent to the proportion of time Center employees in direct review and laboratory components spend on human drug review activities. Thus, the average percentage of time expended on human drug review activities for all direct review and laboratory components in FY 2016 was applied to all costs incurred for the entire fiscal year by the indirect review and support components.

Center-Wide Costs

A number of Center-wide and Agency-wide expenses are paid from the central accounts of the Center or of FDA rather than from funds allocated to a specific Center or division or office within the Center. These costs include rent, telecommunications and utility costs, some computer equipment and support costs, and costs of the Office of Shared Services, which supports all FDA programs and activities. A percentage of these Center and FDA-wide costs are chargeable to the PDUFA program. That percentage is a specific amount that either is supported by independent documentation or is the amount of time reported for allowable activities (direct and indirect) in the Center, as a percentage of total time reported for all Center direct and indirect activities.

As in prior years, resources expended in FY 2016 by the Office of Shared Services in supporting the PDUFA program are reported as if they were incurred in CDER, CBER, ORA, or HQ.

Field Inspection and Investigation Costs

ORA incurs all field inspection, investigation, and laboratory analyses costs. ORA costs are incurred in both district offices (the “field”) and headquarters offices, which are tracked in the Field Accomplishment and Compliance Tracking System (FACTS). FACTS is a time and activity tracking system that captures time spent in a variety of categories, including pre-approval inspections of manufacturing facilities, investigations of clinical studies, and analytical testing of samples, which are all part of the PDUFA program.

Table 14 summarizes the calculation of ORA costs for the PDUFA program for FY 2015 and FY 2016.

Total direct hours reported in FACTS are used to calculate the total number of FTEs required by ORA to perform these activities. In addition to the direct time, an allocation of support time is also included to represent the work done by ORA administrative and management personnel.

The Agency multiplies the total number of FTEs used in the PDUFA program by the average salary and benefits cost in ORA to arrive at ORA salary and benefit costs for work that is within the scope of the PDUFA program.

The Agency then allocates ORA obligations for operations and other costs to the human drug review activities based upon the ratio of user fee related FTEs to total ORA FTEs.

ORA costs for the PDUFA program described below include costs paid from non-user fee appropriations and costs paid from fee revenues.

TABLE 14: ORA COSTS OF THE PDUFA PROGRAM AS OF SEPTEMBER 30, 2015 AND 2016

Cost Component	FY 2015	FY 2016
FTE Utilized	125	157
ORA Average Salary and Benefits	$124,714	$124,404
Total Salary and Benefits	$15,570,436	$19,531,428
Operating and Other Costs[4]	$15,145,890	$20,982,379
Total	**$30,716,326**	**$40,513,807**

Numbers have been rounded to the nearest dollar

[4] Other costs are central, GSA, rent, rent-related, and Shared Services costs that are applicable to the PDUFA program.

Agency General and Administrative Costs

The Agency general and administrative costs include all costs incurred in FDA's HQ that are attributable to the Office of the Commissioner and all other FDA headquarters components that are not Centers or ORA. For the purpose of these calculations, HQ is considered to comprise the following offices:

- Immediate Office of the Commissioner
- Office of the Counselor to the Commissioner
- Office of Policy, Planning, Legislation, and Analysis
- Office of External Affairs
- Office of the Executive Secretariat
- Office of the Chief Counsel
- Office of Minority Health
- Office of Women's Health
- Office of the Chief Scientist (excluding the National Center for Toxicological Research)
- Office of Operations
- Office of Foods and Veterinary Medicine (excluding the Center for Food Safety and Applied Nutrition and the Center for Veterinary Medicine)
- Office of Medical Products and Tobacco (excluding CDER, CBER, the Center for Devices and Radiological Health, and the Center for Tobacco Products)
- Office of Global Regulatory Operations and Policy (excluding ORA)

In summary, the HQ costs include all of FDA except for the six product-oriented Centers, ORA, and the National Center for Toxicological Research.

The HQ costs applicable to the PDUFA program were calculated using a method prescribed by the Division of Cost Determination Management, Office of Finance, Office of the Secretary, Department of Health and Human Services. The method uses the percentage derived by dividing total HQ costs by the total FDA salary expenses (excluding benefits) after subtracting the salary expense (excluding benefits) from HQ. That percentage is then multiplied by the total salaries (excluding benefits) applicable to the PDUFA program in CDER, CBER, and ORA to derive the applicable Agency general and administrative costs.

Using this methodology, FDA dedicated $87,636,234 in general and administrative costs to the PDUFA program in FY 2016. The costs are total costs obligated from appropriations and user fees. FDA strives to maintain a low overhead cost for the PDUFA program. General and administrative costs are approximately 8 percent of the FY 2016 PDUFA program costs.