FY 2016 GDUFA FINANCIAL REPORT

REQUIRED BY THE

GENERIC DRUG USER FEE AMENDMENTS OF 2012

FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

EXECUTIVE SUMMARY

The Generic Drug User Fee Amendments of 2012 (GDUFA) require the Food and Drug Administration (FDA or the Agency) to report annually on the financial aspects of its implementation. Required under GDUFA, this report covers activities for fiscal year (FY) 2016. This is the fourth GDUFA Financial Report.

GDUFA specifies that the following three legal conditions must be satisfied each fiscal year in order for FDA to collect and spend human generic drug user fees:

1. FDA's total appropriations for salaries and expenses (excluding user fees) must be equal to, or greater than, FDA's FY 2009 appropriations for salaries and expenses (excluding user fees) multiplied by the adjustment factor.

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

3. FDA must allocate a minimum of $97,000,000 of appropriations (excluding user fees) multiplied by the adjustment factor, and these funds shall be available to defray the costs of human generic drug activities.

As it has in each year since the enactment of GDUFA, FDA met these three legal conditions in FY 2016, and this report explains how these legal conditions were satisfied. The statements and tables in the report also provide data on FY 2016 human generic drug user fee collections, expenditures, and carryover balances.

In FY 2016, FDA had net collections of $315.3 million in human generic drug user fees, spent $373.2 million of fee revenue on human generic drug activities, and carried a balance of $173.7 million forward for human generic drug activities in future fiscal years.

GDUFA fees and non-user fee appropriations in FY 2016 supported 1,765 full-time equivalents, including salaries and operational expenses to support human generic drug activities. Detailed program accomplishments can be found in the FY 2016 GDUFA Performance Report.

Pursuant to GDUFA's design, FDA has restructured the human generic drug program. The restructuring has prepared FDA to meet, starting in FY 2015, goal dates agreed upon in the GDUFA Commitment Letter.[1] The restructuring included the hiring and training of new staff, reorganizing the Office of Generic Drugs, establishing a new Office of Pharmaceutical Quality, replacing fragmented information technology systems with a new integrated system, and enhancing review and business processes.

Directly related to FDA's restructuring effort, in FY 2016 FDA met its backlog goal over a year ahead of the commitment and approved a human generic drug program record of 835 abbreviated new drug applications.[2] In FY 2017, FDA will spend user fees to continue modernizing the human generic drug program, as agreed to in the GDUFA Commitment Letter, by continuing to focus efforts on improving the efficiency, quality, and predictability of human generic drug activities. These efforts are more important than ever as FDA prepares to meet its primary challenge to review original applications within the shortest GDUFA goal dates, which will shrink from 15 months to 10 months in FY 2017.

[1] http://www.fda.gov/downloads/ForIndustry/UserFees/GenericDrugUserFees/UCM282505.pdf
[2] This number represents tentative and final approvals.

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1: BACKGROUND

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Generic Drug User Fee Amendments (GDUFA), authorizes the Food and Drug Administration (FDA or the Agency) to collect user fees from the human generic drug industry to supplement non-user fee appropriations spent on FDA's human generic drug activities. FDA spends user fee revenues and non-user fee appropriations to hire, support, and maintain resources allocated for the GDUFA program to ensure that safe and effective human generic drug products reach the American public more quickly.

GDUFA (Public Law 112-144, Title III) was authorized for 5 years, through FY 2017. It established fees for: (1) abbreviated new drug applications (ANDAs) in the backlog as of October 1, 2012 (assessed in FY 2013 only); (2) certain types of ANDAs and prior approval supplements (PASs) for human generic drug products; (3) generic drug finished dosage form (FDF) and active pharmaceutical ingredient (API) facilities; and (4) drug master files (DMFs) for APIs associated with human generic drug products (section 744B(a) of the FD&C Act).

GDUFA 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 human generic drug user fees by FDA for October 1, 2015, through September 30, 2016. This report discusses the legal conditions that must be satisfied for FDA to collect and spend human generic drug user fees each year. In addition, this report presents statements of FY 2016 fee collections, carryover balances, obligations, and the total costs of the GDUFA program paid from both user fees and non-user fee appropriations.

2: LEGAL CONDITIONS

GDUFA imposes three legal conditions that must be satisfied for FDA to collect and spend human generic drug user fees. A summary of how each of these legal conditions was satisfied in FY 2016 is shown below.

Legal Condition 1 – FDA's total appropriations for salaries and expenses (excluding user fees) must be equal to or greater than FDA's FY 2009 appropriations for salaries and expenses (excluding user fees) multiplied by the adjustment factor. FDA's FY 2016 total appropriation for salaries and expenses (excluding user fees) was $2,719,308,000 whereas the FY 2009 salaries and expenses appropriation (excluding user fees) was $2,138,129,014 after applying the FY 2016 adjustment factor. Thus, the first legal condition was satisfied.

Legal Condition 2 – Fees authorized under GDUFA shall be collected and available in each fiscal year in an amount not to exceed that specified in appropriation acts for such fiscal year. The Consolidated Appropriations Act, 2016 (Public Law 114-113) which the President signed on December 18, 2015, made appropriations through September 30, 2016, for the salaries and expenses account of FDA. It specified that $318,363,000 shall be derived from human generic drug user fees, and that human generic drug user fees collected in excess of this amount, if any, are appropriated for FDA. Thus, the second legal condition was satisfied.

Legal Condition 3 – FDA must allocate a minimum of $97,000,000 of appropriations (excluding user fees) multiplied by the adjustment factor, and these funds shall be available to defray the costs of the GDUFA program. The specified minimum level for FY 2016 is $101,717,595. In FY 2016, FDA obligated $120,714,671, exclusive of user fees, for the GDUFA program. As 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

GDUFA specifies that user fees shall be collected for certain pending applications in the backlog as of October 1, 2012 (assessed in FY 2013 only), ANDAs, PASs, DMFs, and FDF and API facilities. The statute also specifies the amount FDA is allowed to collect each fiscal year and how the fee rates should be adjusted in subsequent fiscal years.

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, even if the fee is 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-year numbers.

The receivables for FY 2015 and FY 2016 are from uncollected backlog, DMF, application filing, and facility 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 the debt being outstanding, PSC turns the debt over to the United States Treasury for further collection efforts.

Data

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

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

Fees Collected	FY 2015	FY 2016	Notes
DMF Fees	$19,778,180	$22,297,172	
Application Filing Fees	$38,442,924	$74,206,567	
Facility Fees	$224,788,772	$219,621,327	
Total Collections	**$283,009,876**	**$316,125,066**	A
Fees Receivable	**FY 2015**	**FY 2016**	**Notes**
DMF Fees	$26,720	$48	
Application Filing Fees	$58,730	$442,738	
Facility Fees	$3,215,269	$3,322,048	
Total Receivables	**$3,300,719**	**$3,764,834**	

Numbers have been rounded to the nearest dollar

Notes

A. FY 2016 total fee collections increased by $33,115,190 over the previous fiscal year, primarily due to an 87-percent increase in application filing fee collections.

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

GDUFA fees may be expended only for costs necessary to support "human generic drug activities" as defined in GDUFA. For ease of reference, "human generic drug activities" are referred to as "the GDUFA program" in this report. For more information on the allowable and excluded costs, see section 4.3 – Appendix C.

Fluctuations in object class obligations are due to variations in programmatic operations from year to year. As a result, increases or decreases in specific categories do not necessarily indicate growth or reductions in the overall GDUFA program.

Data

Table 2 provides a breakout of user fee obligations by expense category during the past 2 fiscal years. Employee salaries and benefits accounted for over 48 percent of FY 2016 human generic drug user fee obligations, which was an increase of approximately 7 percent from FY 2015. This is a direct result of significant hiring that occurred to meet GDUFA goals (obligations for personal compensation increased 31 percent between FY 2015 and FY 2016).

TABLE 2: HUMAN GENERIC 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	$79,172,563	$101,240,741
Other than full-time permanent	$11,862,625	$17,516,502
Other personnel compensation	$4,628,937	$6,533,811
Military personnel	$8,861,503	$10,966,490
Special personnel services payments	$6,087	$4,274
Civilian personnel benefits	$28,725,500	$38,845,274
Military personnel benefits	$4,399,124	$5,530,017
Benefits former personnel	$0	$15,262
Total Personnel Compensation and Benefits	**$137,656,339**	**$180,652,370**
Non-Pay Costs		
Travel & transportation of persons	$4,269,094	$5,307,079
Transportation of things	$288,254	$314,794
Rent payments to GSA	$13,178,668	$14,705,000
Rent payments to others	$18,845	$341,211

Object Class Expense Category	FY 2015	FY 2016
Communications, utilities & miscellaneous	$2,678	$1,243,708
Printing & reproduction	$31,494	$16,152
Other contractual services:		
Consulting services	$7,243,975	$12,144,689
Other services	$87,945,159	$75,495,754
Purchases of goods & services from government accounts	$30,700,488	$30,312,030
Operations & maintenance of facilities	$3,303,486	$3,514,243
Research & development contracts	$3,841,489	$6,319,658
Operations & maintenance of equipment	$3,528,396	$6,348,624
Subsistence and support of persons	$0	$0
Supplies & materials	$3,351,137	$3,971,226
Equipment	$4,902,847	$10,692,213
Land & structure	$0	$0
Grants, subsidies, & contributions	$31,818,069	$21,609,659
Insurance claims & indemnities	$0	$0
Interest account	$0	$0
Receivables – collected	$0	$248,090
Total Non-Pay Costs	**$194,424,080**	**$192,584,129**
Total Obligations	**$332,080,419**	**$373,236,499**

Numbers have been rounded to the nearest dollar

References

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

3.3 – CARRYOVER BALANCES

Introduction

GDUFA 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, and are available solely for the GDUFA program. The operations in FY 2016 resulted in a net decrease of the carryover balance of $56,998,884 from $230,674,059 to $173,675,175 (25 percent). The decrease in carryover is due to FDA's hiring efforts is order to meet the increasing workload associated with the GDUFA program.

Table 3 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 3 include any recoveries and deobligations from prior years, which may cause differences from Tables 2 and 7. In FY 2016, FDA recovered $916,219 in GDUFA deobligations.

Data

Table 3 captures FDA's carryover balances since the enactment of GDUFA in FY 2013.

TABLE 3: HUMAN GENERIC DRUG USER FEE COLLECTIONS, OBLIGATIONS, AND CARRYOVER BALANCES BY FISCAL YEAR

Program	Fiscal Year	Beginning Carryover	Net Collection	Obligations	Year-End Carryover
GDUFA	2013	$0	$297,722,245	$121,280,100	$176,442,145
	2014	$176,442,145	$327,219,493	$226,128,860	$277,532,778
	2015	$277,532,778	$285,221,700	$332,080,419	$230,674,059
	2016	$230,674,059	$315,321,396	$372,320,280	$173,675,175

Numbers have been rounded to the nearest dollar

3.4 – COLLECTIONS REALIZED

Introduction

Under GDUFA, the total amount of user fees collected for a cohort year must be provided in appropriation acts. In FY 2016, the appropriations language enacted in Public Law 114-113 specified that $318,363,000 shall be derived from human generic drug user fees, and that human generic drug user fees collected in excess of this amount are also appropriated for FDA. The total amount of GDUFA fees collected for FY 2016 is available for allocation for the GDUFA program.

Data

Table 4 depicts fee collections realized during GDUFA by cohort year (the same as Total Collections in Table 1 section 3.1 – User Fee Collections), collection amounts specified in the appropriations acts, and any amounts in excess of the collection amount specified in the appropriations acts. Other variances between Table 3 and Table 4 are a result of unapplied collections at the end of the fiscal year. These collections will either be applied or refunded during FY 2017. For each of the last 2 years, collections realized were less than the amounts specified in the appropriations act.

TABLE 4: HUMAN GENERIC DRUG USER FEES COLLECTED, COLLECTION AMOUNTS SPECIFIED IN APPROPRIATIONS ACTS, AND EXCESS AMOUNTS AS OF SEPTEMBER 30, 2016

Fiscal Year	Collections Realized	Collection Amount Specified in Appropriations Act	Amount in Excess of Collection Specified in Appropriations Act
2013	$301,571,553	$299,000,000	$2,571,553
2014	$321,803,006	$305,996,000	$15,807,006
2015	$283,009,876	$312,116,000	-
2016	$316,125,066	$318,363,000	-

Numbers have been rounded to the nearest dollar

3.5 – RESERVES AND BALANCE AVAILABLE FOR ALLOCATION

Introduction

GDUFA's carryover balance in FY 2016 is $173,675,175. There are anticipated claims on this balance that are described below. After subtracting these claims, FDA's total remaining carryover balance is $168,675,175.

Data

Table 5 provides a summary of carryover balances as of September 30, 2016, and anticipated claims on those balances.

TABLE 5: SUMMARY STATEMENT OF HUMAN GENERIC DRUG USER FEE CARRYOVER BALANCE AS OF SEPTEMBER 30, 2016

Status of Carryover Funds	Amount	Notes
Total Carryover Balance	$173,675,175	
Reserve for Refunds	($5,000,000)	A
Remaining Carryover Balance	**$168,675,175**	

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.

3.6 – TOTAL GDUFA PROGRAM COSTS

Introduction

There are four organizations that support the GDUFA 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 GDUFA program is supported by both user fees and non-user fee appropriations.

Data

Table 6 shows the full cost (non-user fee appropriations and user fees) for the GDUFA program during the past 4 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 81 percent, ORA at approximately 12 percent, and HQ at approximately 7 percent.

TABLE 6: GDUFA 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 %
2013	$266,884,096	$215,983,391	81%	$169,574	0%	$33,801,677	13%	$16,929,455	6%
2014	$387,081,279	$319,051,167	83%	$737,326	0%	$42,406,255	11%	$24,886,531	6%
2015	$452,705,318	$367,926,837	81%	$547,864	0%	$57,572,841	13%	$26,657,776	6%
2016	$493,951,170	$398,335,502	81%	$619,055	0%	$62,189,458	12%	$32,807,154	7%

Numbers have been rounded to the nearest dollar

Table 7 provides the total amount spent on the GDUFA program for the last 4 fiscal years, and the dollar amount and percentage derived from fees and non-user fee appropriations. GDUFA fees have continued to increase as a percentage of total GDUFA program spending.

TABLE 7: GDUFA 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 GDUFA Fees	GDUFA Fee Percent
2013	$266,884,096	$145,603,996	55%	$121,280,100	45%
2014	$387,081,279	$160,952,419	42%	$226,128,860	58%
2015	$452,705,318	$120,624,899	27%	$332,080,419	73%
2016	$493,951,170	$120,714,671	24%	$373,236,499	76%

Numbers have been rounded to the nearest dollar

References

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

The development of the costs associated with the GDUFA 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 GDUFA program. In this table, an FTE does not represent an accounting of individual people, but rather an estimate of labor hours expended on GDUFA activities on an FTE basis.

Data

Table 8 presents total FTE levels that support the GDUFA program by FDA organizational components (CDER, CBER, ORA, and HQ) for the last 4 years, paid from both user fees and non-user fee appropriations. Staff in the consolidated shared services organization (facilities, procurement, Information Technology (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 GDUFA 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.

The number of FTEs utilized for the GDUFA program continued to grow in FY 2016 as the program strived to meet its challenging performance goals.

TABLE 8: HISTORICAL TREND OF TOTAL FTES UTILIZED BY ORGANIZATION AS OF SEPTEMBER 30 OF EACH FISCAL YEAR

Fiscal Year	CDER	CBER	ORA	HQ	Total
2013	623	1	170	58	852
2014	930	3	199	92	1,224
2015	1,064	2	231	100	1,397
2016	1,402	3	238	122	1,765

Numbers have been rounded to the nearest FTE

References

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

4: APPENDICES

4.1 – APPENDIX A: CONDITIONS FOR ASSESSMENT AND USE OF FEES

Introduction

The FD&C Act, as amended by GDUFA, specifies three legal conditions that must be met each fiscal year for FDA to collect and spend human generic drug user fees. This appendix provides detailed descriptions of these conditions and explanations of how FDA met these conditions in FY 2016. A summary of the legal conditions is provided in section 2 – Legal Conditions.

Adjustment Factor

In order to compare and determine whether the legal conditions are satisfied, FDA must calculate and incorporate adjustment factors (defined in section 744A(3) of the FD&C Act, as amended by GDUFA) in the assessments of the first and third conditions. The FD&C Act states:

> The term 'adjustment factor' means a factor applicable to a fiscal year that 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 2011.

The Consumer Price Index (CPI) for October 2014, the October of the fiscal year preceding FY 2016, was 237.433. The CPI for October 2011 was 226.421. Dividing the CPI of October 2014 by the CPI of October 2011 yields an adjustment factor of 1.048635 (rounded to the sixth decimal place) for FY 2016.

Legal Condition 1

The first legal condition, defined in section 744B(h)(1) of the FD&C Act states that fees:

> Shall be refunded for a fiscal year beginning after fiscal year 2012, 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 fiscal year 2009 (excluding the amount of fees appropriated for such a fiscal year) multiplied by the adjustment factor (as defined in section 744A) applicable to the fiscal year involved.

The first condition requires that FDA's FY 2016 salaries and expenses appropriation (excluding user fees) be equal to or greater than FDA's FY 2009 salaries and expenses appropriation (excluding user fees), multiplied by the adjustment factor. FDA's FY 2009 salaries and expenses appropriation (excluding user fees) was $2,038,964,000. Multiplying this amount by the adjustment factor of 1.048635 equals $2,138,129,014.

In FY 2016, Congress appropriated $2,719,308,000 to FDA for salaries and expenses, (excluding user fees). Since the FY 2016 salaries and expenses non-user fee appropriation is greater than the adjusted FY 2009 salaries and expenses appropriation of $2,138,129,014, the first legal condition was satisfied.

Legal Condition 2

The second legal condition, defined in section 744B(i)(2)(A)(i) of the FD&C Act, states that fees:

> 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.

The Consolidated Appropriations Act, 2016 (Public Law 114-113), which the President signed on December 18, 2015, made appropriations for FDA salaries and expenses, through September 30, 2016. It specified that $318,363,000 shall be derived from human generic drug user fees, and that human generic drug user fees collected in excess of this amount are also appropriated for FDA. Thus, the second legal condition was satisfied.

Legal Condition 3

The third legal condition, defined in section 744B(i)(2)(A)(ii) of the FD&C Act states that fees:

> Shall be available for a fiscal year beginning after fiscal year 2012 to defray the costs of human generic drug activities (including such costs for an additional number of full-time equivalent positions in the Department of Health and Human Services to be engaged in such activities), only if the Secretary allocates for such purpose an amount for such fiscal year (excluding amounts from fees collected under this section) no less than $97,000,000 multiplied by the adjustment factor defined in section 744A(3) applicable to the fiscal year involved.

The third condition requires a minimum spending from appropriations (excluding user fees) on the GDUFA program. For FY 2016, FDA's minimum spending from appropriations (excluding user fees) is set at $97,000,000 multiplied by the adjustment factor of 1.048635, which yields a minimum non-user fee appropriation spending of $101,717,595. Further, FDA is considered to have met this spending requirement even if it underspends this amount by up to 10 percent without any financial penalty (see section 744B(i)(2)(B)).

In FY 2016, FDA obligated $120,714,671 from appropriations (excluding user fees) for the GDUFA program, which exceeds the specified minimum appropriation spending level. Therefore, the third legal condition was met.

4.2 – APPENDIX B: FEES RATES AND FEE PAYING SUBMISSION TRENDS

GDUFA Fee History

GDUFA directs FDA to collect revenue from four fee categories: ANDAs in the backlog as of October 1, 2012; DMFs; facilities, and applications (ANDA and PAS). This requires FDA to establish user fee rates by fee category, application type, location, and business operation as specified in the statute. FDA published the following fee rates based on statutory target revenues and estimates of fee-paying submissions.

TABLE 9: TRENDS IN APPLICATION, DMF, AND FACILITY FEES[3]

Fiscal Year	Backlog Fee	DMF Fee	Domestic FDF Facility Fee	Foreign FDF Facility Fee	Domestic API Facility Fee	Foreign API Facility Fee	ANDA Fee	PAS Fee
2013	$17,434	$21,340	$175,389	$190,389	$26,458	$41,458	$51,520	$25,760
2014	N/A	$31,460	$220,152	$235,152	$34,515	$49,515	$63,860	$31,930
2015	N/A	$26,720	$247,717	$262,717	$41,926	$56,926	$58,730	$29,370
2016	N/A	$42,170	$243,905	$258,905	$40,867	$55,867	$76,030	$38,020

GDUFA Forecasted Versus Actual Fee-Paying Submissions

Table 10 depicts FDA's estimates of fee-paying units used in the *Federal Register* (FR) notices for setting GDUFA fees prospectively versus the actual number of fee-paying units received each year.

TABLE 10: TRENDS IN FORECASTED VS. ACTUAL FEE-PAYING APPLICATION, DMF, AND FACILITY FEES

Fiscal Year	Forecasted vs. Actual	Backlog Applications	DMFs	Domestic FDF Facilities	Foreign FDF Facilities	Domestic API Facilities	Foreign API Facilities	Applications
2013	FR	2,868	700	325	433	122	763	1,160
	Actual	2,851	1,808	283	324	124	901	1,143
2014	FR	N/A	583	315	433	128	775	1,149
	Actual	N/A	793	288	369	125	692	1,724
2015	FR	N/A	701	271	410	103	692	1,276
	Actual	N/A	740	299	399	126	715	655

[3] FDA published FY 2016 human generic drug user fee rates on August 3, 2015, in the *Federal Register* https://www.gpo.gov/fdsys/pkg/FR-2015-08-03/pdf/2015-18915.pdf

Fiscal Year	Forecasted vs. Actual	Backlog Applications	DMFs	Domestic FDF Facilities	Foreign FDF Facilities	Domestic API Facilities	Foreign API Facilities	Applications
2016	FR	N/A	453	283	422	105	721	1,005
	Actual	N/A	529	298	396	114	709	976

4.3 – APPENDIX C: INCLUDED AND EXCLUDED COSTS FOR THE GDUFA PROGRAM

Introduction

Section 744A of the FD&C Act, as amended by GDUFA, defines the term "human generic drug activities" and the costs that may be included in that process, collectively referred to as the GDUFA program in this document. Fees may be spent only for activities that are included in this definition. FDA identifies those activities and resources that are applicable to the GDUFA program in this appendix. In Appendix D, FDA describes how the costs for the GDUFA program are developed, based on the allowable activities identified below.

GDUFA Program Costs

Included Activities

Section 744A(8) of the FD&C Act defines in general, the term "human generic drug activities" as the activities associated with generic drugs and inspection of facilities associated with generic drugs. In summary, costs related to the following have been attributed to human generic drug activities:

A. The activities necessary for the review of generic drug submissions, including review of DMFs referenced in such submissions.

B. The issuance of—

    i. approval letters which approve ANDAs or prior approval supplements to such applications.

    ii. complete response letters which set forth in detail the specific deficiencies in such applications and, where appropriate, the actions necessary to place such applications in condition for approval.

C. The issuance of letters related to Type II active pharmaceutical ingredient DMFs which:

    i. set forth in detail, the specific deficiencies in such submissions, and where appropriate, the actions necessary to resolve those deficiencies; or

    ii. document that no deficiencies need to be addressed.

D. Inspections related to generic drugs.

E. Monitoring of research conducted in connection with the review of generic drug submissions and DMFs.

F. Postmarket safety activities with respect to drugs approved under abbreviated new drug applications or supplements, including the following activities:

    i. Collecting, developing, and reviewing safety information on approved drugs including adverse event reports.

ii. Developing and using improved adverse-event data collection systems, including information technology systems.

iii. Developing and using improved analytical tools to assess potential safety problems including access to external databases.

iv. 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) insofar as those activities relate to abbreviated new drug applications.

v. Carrying out section 505(k)(5)(relating to adverse-event reports and postmarket safety activities).

G. Regulatory science activities related to generic drugs.

All user-fee-related costs represented by the above activities are collectively referred to in this report as human generic drug activities or the GDUFA program.

Section 744A(11) of the FD&C Act defines the term “resources allocated for human generic drug activities” as expenses for the following:

A. Officers and employees of the Food and Drug Administration, contractors of the Food and Drug Administration, advisory committees, and costs related to such officers, employees, committees, and to contracts with such contractors;

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 subsection (a) and accounting for resources allocated for the review of abbreviated new drug applications and supplements and inspections related to the generic drugs.

Excluded Activities

The GDUFA Program excludes from the term “human generic drug activities” costs related to the following:

A. All activities necessary for the review of new drug applications (NDAs), biologic license applications (BLAs), and investigational new drugs (INDs) for drugs that will not be approved under ANDAs.

B. The issuance of correspondence unrelated to abbreviated new drug submissions or prior approval supplements.

C. Inspections unrelated to human generic drugs.

D. Monitoring of research unrelated to human generic drug submissions and DMFs.

E. Post-market safety activities apart from those drugs approved under ANDAs or supplements.

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

General Methodology

The costs associated with the GDUFA 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 ANDA, PAS, and DMF Submissions	CDER and CBER
Field Inspection and Investigation Costs	ORA
Agency General and Administrative Costs	HQ

The costs for each component are shown in Table 6. 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 GDUFA program, as explained in the discussion in Appendix C, the cost categories within each organization listed above were identified as parts of the human generic drug review process.

Center Costs

Costs of the GDUFA program are tracked for each organizational component in CDER and CBER, usually at the division level. Most FDA components involved in the GDUFA program perform a mixture of activities – some within the scope of the GDUFA 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 eight weeks (two weeks per quarter) each fiscal year in activity-based time reporting systems. The activities in the systems differentiate between the nature of the activity, so that time reported can be separated into allowable and excluded activities as defined by GDUFA. The average percentage of time reported on the GDUFA 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 GDUFA program in FY 2016.

Indirect Review and Support

Indirect review and support components provide the infrastructure for the human generic drug activities. In CDER, these components include the Office of the Center Director, the Office of Management, the Office of Communications, and 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 GDUFA program is equivalent to the proportion of time Center employees in direct review and laboratory components spend on the GDUFA program. Thus the average percentage of time expended on the GDUFA program 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 GDUFA program. That percentage is either a specific amount that 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 GDUFA 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 GDUFA program.

Table 11 summarizes the calculation of ORA costs for the GDUFA 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 GDUFA program by the average salary and benefits cost in ORA to arrive at ORA salary and benefit costs for work within the scope of the GDUFA program.

The Agency then allocates ORA obligations for operations and other costs to the GDUFA program based upon the ratio of user fee related FTEs to total ORA FTEs.

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

TABLE 11: ORA COSTS FOR THE GDUFA PROGRAM AS OF SEPTEMBER 30, 2015 AND 2016

Cost Component	FY 2015	FY 2016
FTE Utilized	210	213
ORA Average Salary and Benefits	$124,714	$124,404
Total Salary and Benefits	$26,234,765	$26,498,052
Operating and Other Costs[4]	$31,338,076	$35,691,406
Total	**$57,572,841**	**$62,189,458**

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 GDUFA 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 GDUFA 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 GDUFA program in CDER, CBER, and ORA to derive the applicable Agency general and administrative costs.

Using this methodology, FDA dedicated $32,807,154 in general and administrative costs to the GDUFA program in FY 2016. The costs are total costs obligated from non-user fee appropriations and user fees. FDA strives to maintain a low overhead cost for the GDUFA program. General and administrative costs are approximately 7 percent of the FY 2016 GDUFA program costs.