FY 2016 AGDUFA FINANCIAL REPORT

REQUIRED BY THE

ANIMAL GENERIC DRUG USER FEE ACT OF 2008

AS AMENDED

FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

EXECUTIVE SUMMARY

The Animal Generic Drug User Fee Act of 2008 (AGDUFA), as amended, requires the Food and Drug Administration (FDA or the Agency) to report annually to Congress on the financial aspects of its implementation of AGDUFA. This report covers activities for fiscal year (FY) 2016.

AGDUFA, as amended, specifies that the following three legal conditions must be satisfied each fiscal year in order for FDA to collect and spend AGDUFA user fees:

1. FDA's overall Salaries and Expenses Appropriation, excluding fees, must meet or exceed FDA's overall FY 2003 Salaries and Expenses Appropriation, excluding fees and multiplied by the adjustment factor.

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

3. FDA must spend at least as much from appropriations for the review of generic new animal drug applications as it spent in FY 2008, multiplied by the adjustment factor.

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 FY 2016 generic new animal drug user fee collections, expenditures, and carryover balances, as well as comparative data from earlier periods.

In FY 2016, FDA had net collections of $8.85 million in generic new animal drug user fees, spent $8.91 million in user fees for the generic new animal drug review process, and carried a cash balance of $11.84 million forward for future fiscal years.

In FY 2016, AGDUFA user fees and non-user fee appropriations supported 71 full-time equivalents, including salaries and operational expenses to support the process for the review of generic new animal drug applications. Detailed program accomplishments can be found in the FY 2016 AGDUFA Performance Report.

In FY 2017, FDA will spend user fees to continue enhancing the generic new animal drug review process, focusing on improving the efficiency, quality, and predictability of the program. Some challenges FDA faces in 2017 include implementing a two-phased Chemistry, Manufacturing and Controls technical and review process; creating a question-based review process for bioequivalence studies; increasing communication and transparency with industry through timely meetings; and responding to an increase in submissions while continuing to meet the performance goals.

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1: BACKGROUND

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Animal Generic Drug User Fee Act (AGDUFA), authorizes the Food and Drug Administration (FDA or the Agency) to collect fees from the animal pharmaceutical industry to supplement non-user fee appropriations spent on FDA's generic new animal drug review process. FDA spends fee revenues and non-user fee appropriations to hire, support, and maintain personnel for the review of generic new animal drug applications to help ensure that safe and effective generic new animal drug products reach the American public.

AGDUFA (Title II, Public Law 110-316) was enacted on August 14, 2008, and authorized the animal generic drug user fee program for 5 years from FY 2009 through FY 2013 (AGDUFA I). On June 13, 2013, the program was reauthorized for an additional 5 years from FY 2014 through FY 2018 by the Animal Generic Drug User Fee Amendments of 2013 (AGDUFA II, Title II, Public Law 113-14).

Under AGDUFA II, three types of user fees are established: (1) fees for certain types of abbreviated applications for generic new animal drugs (25 percent of estimated revenue); (2) annual fees for certain generic new animal drug products (37.5 percent of estimated revenue); and (3) annual fees for certain sponsors of abbreviated applications for generic new animal drugs and/or investigational submissions for generic new animal drugs (37.5 percent of estimated revenue). When certain conditions are met, FDA will waive or reduce fees for generic new animal drugs intended solely to provide for a minor use or minor species indication.

The total annual fee revenue amount and amounts for each type of fee are set forth in the statute for AGDUFA, with provisions for workload adjustment. AGDUFA II authorizes FDA to set fees for each fiscal year so that the total revenue FDA plans to receive in each category is estimated to equal the statutory amount, after adjustments are made to reflect changes in review workload, if applicable. However, the workload adjustment cannot result in fee revenues for a fiscal year that are less than the fee revenues for that fiscal year as specified in the statute.

In August 2015, FDA set fees for FY 2016 in accordance with the amounts specified in AGDUFA II (see 80 FR 46012). FDA used the statutory revenue amounts for each category of fees in determining its fee revenue target for FY 2016. Fee revenues are adjusted each year after FY 2014 to reflect changes in review workload, if applicable. In FY 2016, the fee revenues were adjusted by 30.6305 percent to account for increased workload. Additional adjustments to the statutory fee revenue amounts for FY 2016 for inflation were not necessary because inflation adjustments were built into the statutory fee revenue totals for each of the 5 years of AGDUFA II.

AGDUFA II requires FDA to submit a financial report to Congress within 120 days after the end of each fiscal year. This financial report addresses the collection and use of generic new animal drug user fees by FDA during the period of October 1, 2015, through September 30, 2016. The report presents the legal conditions that must be satisfied for FDA to collect and spend generic new animal drug user fees each year and shows how FDA determined that it met those requirements. In addition, the report presents statements related to FY 2016 user fee collections, carryover balances, obligations of user fees, and total costs of the process for the review of generic new animal drug applications paid from user fees and non-user fee appropriations.

2: LEGAL CONDITIONS

AGDUFA imposes three legal conditions that must be satisfied in each fiscal year for FDA to collect and spend generic new animal 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 overall Salaries and Expenses Appropriation (excluding user fees) must meet or exceed FDA's FY 2003 Salaries and Expenses Appropriation (excluding user fees), including an adjustment for inflation. In FY 2016, FDA's appropriation for salaries and expenses was $2,719,308,000 excluding user fees. FDA's FY 2003 Salaries and Expenses Appropriation, excluding user fees, was $1,799,035,086 after applying the adjustment factor. Therefore, the first legal condition was satisfied.

Legal Condition 2 – The amount of user fees collected for each fiscal year must be specified in that year's appropriation acts. The President signed the Consolidated Appropriations Act, 2016 (Public Law 114-113), on December 18, 2015. The Act specified that $9,705,000 shall be derived from generic new animal drug user fees, and that generic new animal drug user fees collected in excess of this amount are also 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 generic new animal drug applications. This specified minimum is the amount FDA spent on the review of generic new animal drug applications from appropriations (exclusive of user fees) in FY 2008, multiplied by an adjustment factor. The specified minimum level for FY 2016 is $6,261,514. In FY 2016, FDA obligated $6,300,520 from appropriations (exclusive of user fees) for the review of abbreviated applications for generic new animal drugs. Under AGDUFA, the condition is considered met if the total review expense funded by appropriations in any year is more than the amount that is 3 percent below the specified minimum. Because FDA spent more than the specified minimum amount from appropriations 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

AGDUFA specifies that user fees shall be collected for abbreviated applications for generic new animal drugs, and annual user fees shall be collected for products and sponsors. The statute also specifies the amount FDA is allowed to collect from each of these three fee categories, and how the fee rates should be adjusted in each fiscal year for increases in workload. Per the statute, waivers may be granted under certain circumstances. Under AGDUFA, fees collected and appropriated but not spent by the end of a fiscal year continue to remain available for FDA to spend in future 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 it 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 product and sponsor 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 will turn the debt over to the United States Treasury for further collection efforts.

Data

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

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

Fees Collected	FY 2015	FY 2016	Notes
Application Fees	$2,837,543	$1,399,800	
Product Fees	$3,544,500	$3,455,885	
Sponsor Fees	$3,599,998	$3,603,308	
Total Collections	**$9,982,041**	**$8,458,993**	A
Fees Receivable	**FY 2015**	**FY 2016**	**NOTES**
Product Fees	$8,500	$0	
Sponsor Fees	$40,450	$41,900	
Total Receivables	**$48,950**	**$41,900**	

Numbers have been rounded to the nearest dollar

Notes

A. In FY 2016, FDA received a net total of $394,943 that was attributed to FY 2015 collections. Therefore, FDA increased its FY 2015 fee collections of $9,587,098 reported last year to $9,982,041 as of September 30, 2016.

References

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

A further breakdown of fees paid in FY 2016 is provided in section 4.2 – Appendix B.

3.2 – USER FEE OBLIGATIONS

Introduction

AGDUFA fees may be expended only for costs necessary to support the "process for the review of abbreviated applications for generic new animal drugs," as defined in AGDUFA. For ease of reading, the "process for the review of abbreviated applications for generic new animal drugs" is referred to as the "AGDUFA program" in this report.

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 AGDUFA program.

Data

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

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

Object Class Expense Category	FY 2015	FY 2016
Personnel Compensation Benefits		
Full-time Permanent	$3,443,687	$4,190,067
Other than full-time permanent	$190,438	$233,826
Other personnel compensation	$58,753	$39,411
Military personnel	$26,161	$28,377
Special personal services payments	$0	$0
Civilian personnel benefits	$1,192,679	$1,502,218
Military personnel benefits	$13,923	$14,230
Benefits former personnel	$0	$0
Total Personnel Compensation and Benefits	**$4,925,641**	**$6,008,130**
Non-Pay Costs		
Travel & transportation of persons	$10,242	$29,079
Transportation of things	$0	$1,537
Rent payments to GSA	$158,549	$30,000
Rent payments to others	$425	$165

Object Class Expense Category	FY 2015	FY 2016
Communications, utilities & miscellaneous	$156	$252,582
Printing & reproduction	$23,700	$66
Other Contractual Services:		
Consulting services	$206,512	$259,671
Other services	$791,882	$1,560,049
Purchases of goods & services from Government accounts	$2,518,762	$148,864
Operations & maintenance of facilities	$6,400	$0
Research & development contracts	$0	$0
Operations & maintenance of equipment	$7,818	$31,519
Subsistence and support of persons	$0	$0
Supplies & materials	$10,219	$47,678
Equipment	$33,219	$542,467
Land & structure	$0	$0
Grants, subsidies, & contributions	$0	$0
Insurance claims & indemnities	$0	$0
Interest account	$0	$0
Receivables – collected	$0	$0
Total Non-Pay Costs	**$3,767,885**	**$2,903,677**
Total Obligations	**$8,693,525**	**$8,911,806**

Numbers have been rounded to the nearest dollar

References

Total program cost and full-time equivalents (FTEs) usage by year are shown in Tables 6 through 8.

Allowable and excluded costs are described in section 4.3 – Appendix C.

3.3 – CARRYOVER BALANCES

Introduction

AGDUFA fees collected, appropriated, and not obligated at the end of a fiscal year remain available to FDA for use in future fiscal years. These funds are referred to as carryover balances. The operations in FY 2016 resulted in a net decrease of the carryover balance of $54,498, which resulted in a year-end carryover balance of $11,843,993.

Data

Table 3 captures FDA's carryover balances at the beginning and end of the 5-year authorization period for AGDUFA I and for each fiscal year to date under AGDUFA II.

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 in this table 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 $3,320 in AGDUFA deobligations.

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

Program	Fiscal Years	Beginning Carryover	Net Collection	Obligations	Year-End Carryover
AGDUFA I	2009-2013	$0	$29,641,950	$21,095,151	$8,546,799
AGDUFA II	2014	$8,546,799	$8,088,825	$6,158,667	$10,476,957
	2015	$10,476,957	$10,115,060	$8,693,526	$11,898,491
	2016	$11,898,491	$8,853,989	$8,908,486	$11,843,993

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 potential offset when fees for FY 2018 are set. By statute, there will be no offsets made for excess collections until fee setting for FY 2018, the last year under the AGDUFA II authorization.

Under AGDUFA, if cumulative collections through FY 2016, including an estimate for FY 2017, exceed the fee revenues specified in appropriation acts during that period, FDA will lower the fee rates for FY 2018 by the cumulative amount that fees exceeded the amount specified in appropriation acts during that period. The current balance for a potential offset is $2,852,962.

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 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.

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

Fiscal Year	Collections Realized	Collection Amount Specified in Appropriations Act	Amount in Excess of Collection Amount Specified in Appropriations Act
2009	$5,099,071	$4,831,000	$268,071
2010	$4,392,209	$5,106,000	($713,791)
2011	$4,969,909	$5,397,000	($427,091)
2012	$7,801,640	$5,706,000	$2,095,640
2013	$7,765,430	$6,031,000	$1,734,430
Total AGDUFA I			**$2,957,259**
2014	$8,388,928	$7,328,000	$1,060,928
2015	$9,982,041	$6,944,000	$3,038,041
2016	$8,458,993	$9,705,000	($1,246,007)
Total AGDUFA II			**$2,852,962**
Net Balance for Potential Offset When Fees are Set for FY 2018			$2,852,962

Numbers have been rounded to the nearest dollar

3.5 – RESERVES AND BALANCE AVAILABLE FOR ALLOCATION

Introduction

AGDUFA's carryover balance in FY 2016 is $11,843,993. Anticipated claims on this balance are described below. After subtracting these claims, FDA's total remaining carryover balance is $4,327,319.

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 ANIMAL GENERIC DRUG USER FEE CARRYOVER BALANCE AS OF SEPTEMBER 30, 2016

Status of Carryover Funds	Amount	Notes
Total Carryover Balance	$11,843,993	
Reserve for Refunds	($100,000)	A
Reserve for Collections Deemed Unavailable due to Lack of Appropriations	($2,363,711)	B
Potential Offset in FY 2018	($2,852,962)	
3-Month Operating Reserve	($2,200,000)	C
Remaining Carryover Balance	**$4,327,319**	

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 $100,000 is being set aside.

B. $2,363,711 collected in excess of appropriations during AGDUFA I ($268,071 in FY 2009 and $2,095,640 in FY 2012) are deemed unavailable for obligation.

C. AGDUFA II authorizes FDA to have up to 3 months of available carryover balance at the end of FY 2018 in order to sustain operations for the first 3 months of FY 2019. FDA will estimate the amount of carryover balance it expects to have available for obligation in August 2017, when fees are set for FY 2018. If carryover balances are less than the amount FDA needs to fund 3 months of operations in 2019, FDA may add up to the full shortfall amount to the fee revenues when fees for FY 2018 are set in August 2017. At the end of FY 2016 the amount of carryover needed to sustain operations for 3 months was $2,200,000. This amount is currently covered by the balance available to FDA.

3.6 – TOTAL AGDUFA PROGRAM COSTS

Introduction

There are three FDA organizational components that contribute to the AGDUFA program: the Center for Veterinary Medicine (CVM), the Office of Regulatory Affairs (ORA), and FDA Headquarters (HQ). The AGDUFA program is supported by both user fees and non-user fee appropriations.

Data

Table 6 shows the costs for the AGDUFA program (non-user fee appropriations and user fees) during the past 8 fiscal years by FDA organizational component. The table displays data for CVM, ORA, and HQ. The percentage spent in the various FDA components has remained essentially stable over time.

TABLE 6: AGDUFA PROGRAM – HISTORICAL TREND OF TOTAL COSTS BY CENTER AS OF SEPTEMBER 30 OF EACH FISCAL YEAR

Fiscal Year	Total Spent	Spent by CVM	CVM %	Spent by ORA	ORA %	Spent by HQ	HQ %
2009	$9,830,437	$8,611,608	88%	$565,977	6%	$652,852	7%
2010	$11,145,109	$9,846,687	88%	$403,145	4%	$895,277	8%
2011	$11,505,084	$10,474,643	91%	$212,936	2%	$817,505	7%
2012	$12,016,253	$10,538,134	88%	$457,929	4%	$1,020,190	8%
2013	$11,300,281	$10,070,504	89%	$214,753	2%	$1,015,024	9%
2014	$13,108,430	$11,362,734	87%	$462,814	3%	$1,282,882	10%
2015	$16,393,690	$14,674,326	90%	$454,419	3%	$1,264,945	7%
2016	$15,212,327	$13,427,926	88%	$461,358	3%	$1,323,043	9%

Numbers have been rounded to the nearest dollar

Table 7 provides the total amount spent on the AGDUFA program for the last 8 years, and the dollar amount and percentage derived from user fees and non-user fee appropriations. The percentage associated with user fees has been growing over time.

Of the $15,212,327 obligated in support of the AGDUFA program in FY 2016, about 59 percent came from AGDUFA fees and about 41 percent came from non-user fee appropriations.

TABLE 7: AGDUFA 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 AGDUFA Fees	AGDUFA Fee Percent
2009	$9,830,437	$7,705,137	78%	$2,125,300	22%
2010	$11,145,109	$6,408,309	57%	$4,736,800	43%
2011	$11,505,084	$6,819,284	59%	$4,685,800	41%
2012	$12,016,253	$7,649,902	64%	$4,366,351	36%
2013	$11,300,281	$6,119,381	54%	$5,180,900	46%
2014	$13,108,430	$6,949,763	53%	$6,158,667	47%
2015	$16,393,690	$7,700,164	47%	$8,693,525	53%
2016	$15,212,327	$6,300,520	41%	$8,911,806	59%

Numbers have been rounded to the nearest dollar

References

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

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

Data

Table 8 presents total FTE levels that support the AGDUFA program by FDA organizational component for the last 8 years, paid from both user fees and non-user fee appropriations. The table displays data for CVM, ORA, and HQ. 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. In addition, beginning in FY 2015, the calculation to determine the spread of shared services FTEs was amended to more accurately estimate labor hours expended on AGDUFA 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 8: HISTORICAL TREND OF TOTAL FTES UTILIZED BY CENTER

Fiscal Year	CVM	ORA	HQ	Total
2009	35	3	3	41
2010	44	2	3	49
2011	49	1	3	53
2012	51	2	4	57
2013	48	1	4	53
2014	55	2	5	62
2015	64	2	5	71
2016	65	1	5	71

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 AGDUFA, specifies three legal conditions that must be met each fiscal year for FDA to collect and spend generic new animal 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 741(k)(2) of the FD&C Act, as amended by AGDUFA II) in the assessments of the first and third conditions.

Section 741(k)(2) of the FD&C Act states the following definition:

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

A. for purposes of subsection (f)(1), such Index for October 2002; and

B. for purposes of subsection (g)(2)(A)(ii), such index for October 2007.

The Agency refers to item (A) above as the first legal condition adjustment factor, and to item (B) above as the third legal condition adjustment factor. (The second legal condition does not have an adjustment factor associated with it.)

For the first legal condition (subsection (f)(1)), the CPI for October 2014, the October of the FY preceding FY 2016, was 237.433. The CPI for October 2002 was 181.3. Dividing the CPI of October 2014 by the CPI of October 2002 yields an adjustment factor of 1.309614 (rounded to six decimal places) for FY 2016.

For the third legal condition (subsection (g)(2)(A)(ii)) adjustment factor above, the base month is October 2007. The CPI for October 2014, the October of the FY preceding FY 2016, was 237.433. The CPI for October 2007 was 208.936. Dividing the CPI of October 2014 by the CPI of October 2007 yields an adjustment factor of 1.136391 (rounded to six decimal places) for FY 2016.

Legal Condition 1

The first legal condition is found in section 741(f)(1) of the FD&C Act. It states:

> Fees may not be assessed under subsection (a) for a FY beginning after FY 2008 unless appropriations for salaries and expenses of FDA for such FY (excluding the amount of fees appropriated for such FY) are equal to or greater than the amount of appropriations for the salaries and expenses of FDA for the FY 2003 (excluding the

> amount of fees appropriated for such FY) multiplied by the adjustment factor applicable to the FY involved.

The first condition requires that FDA's Salaries and Expenses Appropriation (excluding user fees) for FY 2016 must be greater than or equal to FDA's Salaries and Expenses Appropriation (excluding user fees) for FY 2003 multiplied by the adjustment factor applicable to the FY involved. FDA's Salaries and Expenses Appropriation (excluding user fees) for FY 2003 was $1,373,714,000. Multiplying this amount by the adjustment factor of 1.309614 (rounded to the sixth decimal place) equals $1,799,035,086.

In FY 2016, Congress appropriated $2,719,308,000 to FDA for salaries and expenses, excluding user fees. Because the FY 2016 Salaries and Expenses Appropriation is greater than the adjusted FY 2003 Salaries and Expenses Appropriation, $1,799,035,086, the first legal condition was met.

Legal Condition 2

The second legal condition is described in section 741(g)(2)(A)(i) of the FD&C Act. It 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 President signed the Consolidated Appropriations Act, 2016 (Public Law 114-113) on December 18, 2015, which specified that $9,705,000 shall be derived from generic new animal drug user fees for FDA in FY 2016, and that generic new animal drug user fees collected in excess of this amount are also appropriated for FDA. Therefore, the second legal condition was met.

Legal Condition 3

The third legal condition is defined in section 741(g)(2)(A)(ii) of the FD&C Act. It states that fees:

> shall be available to defray increases in the costs of the resources allocated for the process for the review of abbreviated applications for generic new animal drugs (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 2008 multiplied by the adjustment factor.

The third condition requires a minimum spending from appropriations (excluding user fees) on the AGDUFA program. The minimum spending from appropriations is the amount that FDA spent on the AGDUFA program in FY 2008, multiplied by the adjustment factor. Further, FDA is considered to have met this spending requirement even if it underspends this amount by up to 3 percent (see section 741(g)(2)(B)).

In FY 2008, the amount spent from appropriations for the AGDUFA program was $5,510,000 (rounded to a thousand). After applying the adjustment factor of 1.136391 (rounded to the sixth

decimal place), the minimum appropriation spending level for the AGDUFA program for FY 2016, excluding user fees, is $6,261,514.

In FY 2016, FDA obligated $6,300,520 from appropriations, exclusive of user fees, for the AGDUFA program, which exceeds the specified minimum appropriation spending level. Therefore, the third legal condition was met.

4.2 – APPENDIX B: FEES, WAIVERS, AND REDUCTIONS

AGDUFA Fee History

AGDUFA established three fee categories and set fee revenues for each category. 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.[1]

The sponsor fee rate that a company qualifies for is based on the number of approved Abbreviated New Animal Drug Applications (ANADAs) that company held at the beginning of the fiscal year. Sponsors with one approved ANADA, or without any approved ANADAs, but with active generic investigational new animal drug submissions, qualify for the 50 percent sponsor fee rate. Sponsors with two to six approved ANADAs qualify for the 75 percent sponsor fee rate. Sponsors with more than six approved ANADAs qualify for the 100 percent sponsor fee rate.

Table 9 provides a history of fee rates for the past eight years.

TABLE 9: TRENDS IN SPONSOR FEES, PRODUCT FEES, AND APPLICATION FEE RATES

Fiscal Year	100% Sponsor Fee	75% Sponsor Fee	50% Sponsor Fee	Product Fee	Abbreviated Application Fee - Not Subject to Section 512(d)(4)	Abbreviated Application Fee - Subject to Section 512(d)(4)
2009	$56,350	$42,265	$28,175	$3,005	$41,400	N/A
2010	$54,050	$40,537	$27,025	$3,255	$75,000	N/A
2011	$55,950	$41,963	$27,975	$5,440	$92,600	N/A
2012	$54,350	$40,763	$27,175	$6,200	$124,900	N/A
2013	$63,000	$47,250	$31,500	$6,515	$148,300	N/A
2014	$72,800	$54,600	$36,400	$8,035	$177,900	$88,950
2015	$80,900	$60,675	$40,450	$8,500	$189,200	$94,600
2016	$83,800	$62,850	$41,900	$8,705	$233,300	$116,650

[1] FDA published FY 2016 generic new animal drug user fee rates in the *Federal Register* on August 3, 2015 (80 FR 46012). https://www.gpo.gov/fdsys/pkg/FR-2015-08-03/pdf/2015-18909.pdf

AGDUFA Fees Forecasted Versus Actual Fee Paying Submissions

Table 10 summarizes the number and type of fees received by cohort year in comparison to what FDA estimated it would receive when the Agency established AGDUFA fees in the *Federal Register* (FR) notice for that cohort year. The actual numbers may change over time because of refunds or collection of open receivables. An additional billing will be sent for FY 2016 sponsor and product fees that were not included in the original billing. For that reason, the FY 2016 cohort is considered incomplete at this time.

TABLE 10: TRENDS IN FORECASTED VS. ACTUAL FEE PAYING SPONSORS, PRODUCTS, AND APPLICATIONS

Fiscal Year	Forecasted vs. Actual	Number of Sponsors	Number of Products	Number of Applications
2009	FR	30	563	35
	Actual	37	657	25
2010	FR	33	549	20
	Actual	38	402	14
2011	FR	34	347	18
	Actual	38	367	9
2012	FR	37	322	14
	Actual	44	369	25
2013	FR	34	324	12
	Actual	45	395	16
2014	FR	38	342	10
	Actual	45	426	10
2015	FR	38	364	11
	Actual	44	417	15
2016	FR	43	418	10
	Actual	43	397	6

Numbers are rounded to the nearest whole number

AGDUFA Waiver and Reductions History

AGDUFA directs FDA to waive or reduce one or more fees under AGDUFA upon request when FDA finds that the generic new animal drug is intended solely to provide for a minor use or minor species indication.

Table 11 summarizes the numbers and values of waivers and reductions granted by FDA under AGDUFA for fees payable in each FY since 2009; it also reflects the revenue that would otherwise have been collected by FDA.

TABLE 11: WAIVERS AND REDUCTIONS GRANTED AND USED BY FEE CATEGORY AS OF SEPTEMBER 30 FOR EACH FISCAL YEAR

Minor Use / Species Waivers	Applications		Products		Sponsors				Total Value of Waivers Approved
	Waivers Approved	Value of Waivers Approved	Waivers Approved	Value of Waivers Approved	Sponsors (100%) Waivers Approved	Sponsors (75%) Waivers Approved	Sponsors (50%) Waivers Approved	Value of Waivers Approved	
FY 2009	0	$0	1	$3,005	0	0	1	$28,175	$31,180
FY 2010	0	$0	1	$3,255	0	0	2	$54,050	$57,305
FY 2011	0	$0	2	$10,880	0	0	2	$55,950	$66,830
FY 2012	0	$0	2	$12,400	0	0	2	$54,350	$66,750
FY 2013	0	$0	1	$6,515	0	0	1	$31,500	$38,015
FY 2014	0	$0	1	$8,035	0	0	1	$36,400	$44,435
FY 2015	0	$0	3	$25,500	0	0	1	$40,450	$65,950
FY 2016	0	$0	3	$26,115	0	0	1	$41,900	$68,015

Numbers have been rounded to the nearest dollar

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

Introduction

The FD&C Act, as amended by AGDUFA II, defines the "process for the review of abbreviated applications for generic new animal drugs" and the costs that may be included in that process, collectively referred to as the AGDUFA 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. Using the statutory definition and the methodologies described in Appendix D, the Agency identified those activities that were applicable to the AGDUFA program.

AGDUFA Program Costs

Included Activities

Section 741(k)(3) *The term 'costs of resources allocated for the process for the review of abbreviated applications for generic new animal drugs' means the expenses incurred in connection with the process for the review of abbreviated applications for generic new animal drugs for—*

Section 741(k)(3)(A) *officers and employees of the Food and Drug Administration, contractors of the Food and Drug Administration, advisory committees consulted with respect to the review of specific abbreviated applications, supplemental abbreviated applications, or investigational submissions, and costs related to such officers, employees, committees, and contractors, including costs for travel, education, and recruitment and other personnel activities;*

This includes costs for management and administrative services related to the AGDUFA program, as well as costs for personnel development and training such as:

- scientific, clinical, and statistical training;
- managerial and other administrative training;
- policy/regulatory training;
- professional development (coursework, attendance at professional meetings, library resources); and
- site visit program for premarket reviewers.

Section 741(k)(3)(B) *management of information, and the acquisition, maintenance, and repair of computer resources;*

Section 741(k)(3)(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*

Section 741(k)(3)(D) *collecting fees under this section and accounting for resources allocated for the review of abbreviated applications, supplemental abbreviated applications, and investigational submissions.*

Sections 741(k)(3)(B) through (D) include, but are not limited to, all forms of information management, facility rental, maintenance and repair, and infrastructure acquisitions in support of the AGDUFA program and in support of user fee collections and accounting.

Section 741(k)(10) *The term 'process for the review of abbreviated applications for generic new animal drugs' means the following activities of the Secretary with respect to the review of abbreviated applications, supplemental abbreviated applications, and investigational submissions:*

Section 741(k)(10)(A) *The activities necessary for the review of abbreviated applications, supplemental abbreviated applications, and investigational submissions.*

This encompasses, among other things, the review of the following types of information:

- with respect to ANADAs—original applications, pre- and post-market supplements, chemistry reports, reactivations, Veterinary Master Files, Public Master Files, and application-related correspondence; and

- with respect to Generic Investigational New Animal Drug Submissions (JINADs)—initial submissions, reauthorization requests, protocols with or without data, and studies with or without data.

Furthermore, the activities necessary for the review of ANADAs, supplemental ANADAs, and JINADs include:

- Agency-initiated action related to these applications and submissions;

- general ANADA and JINAD activities that do not directly relate to a pending submission, such as staff training and administrative support;

- administrative processing of these applications and submissions;

- maintenance and support of automated systems that track these applications and submissions; and

- quality assurance and quality control standards and policy development activities related to the review of these applications and submissions.

Section 741(k)(10)(B) *The issuance of action letters which approve abbreviated applications or supplemental abbreviated applications or which set forth in detail the specific deficiencies in abbreviated applications, supplemental abbreviated applications, or investigational submissions and, where appropriate, the actions necessary to place such applications, supplemental applications, or submissions in condition for approval.*

This includes activities such as the issuance of deficiency letters, meetings with applicants to discuss such letters, and review of the responses.

Section 741(k)(10)(C) *The inspection of generic new animal drug establishments and other facilities undertaken as part of the Secretary's review of pending abbreviated applications, supplemental abbreviated applications, and investigational submissions.*

Section 741(k)(10)(D) *Monitoring of research conducted in connection with the review of abbreviated applications, supplemental abbreviated applications, and investigational submissions.*

This includes monitoring of clinical and other research conducted in connection with the review of these applications and submissions.

Section 741(k)(10)(E) *The development of regulations and policy related to the review of abbreviated applications, supplemental abbreviated applications, and investigational submissions.*

This includes activities such as development of drug-specific, cross-cutting, and program-related guidance, and Standard Operating Procedures.

Section 741(k)(10)(F) *Development of standards for products subject to review.*

This includes FDA activities on national and international standards development for products subject to review.

Section 741(k)(10)(G) *Meetings between the Agency and the generic new animal drug sponsor.*

This includes activities such as:

- informal consultation in person and via phone, mail, e-mail, and facsimile;
- meetings between FDA and sponsors, such as pre-submission conferences;
- use of advisory committees and outside experts in the review of ANADAs; and
- FDA-sponsored conferences/workshops related to ANADAs.

Section 741(k)(10)(H) *Review of advertising and labeling prior to approval of an abbreviated application or supplemental abbreviated application, but not after such application has been approved.*

Excluded Activities

- Review of new animal drug applications and other pioneer submissions;
- Enforcement policy development;
- Post-approval surveillance and compliance activities;
- Post-approval activities relating to the review of advertising;
- Inspections unrelated to the AGDUFA program; and
- Research unrelated to the AGDUFA program.

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

General Methodology

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

Cost Category	FDA Organization
Costs for the Review of ANADAs, Supplemental Abbreviated applications and Investigational Submissions for Generic New Animal Drugs	CVM
Costs for Field Pre-approval Inspection and Investigation	ORA
Costs for Agency General and Administrative Activities	HQ

The costs for each component are shown in Table 6. They were derived using time-reporting systems in CVM 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 AGDUFA program, as explained in the discussion in Appendix C, the cost categories within each organization listed above were identified as parts of the generic new animal drug application review process.

Center Costs

Costs of the AGDUFA program are tracked for each organizational component in CVM, usually at the division level. Most CVM divisions involved in the generic new animal drug review process perform a mixture of activities – some within the scope of AGDUFA program, and some not. CVM groups its organizational components into three categories:

- Direct process activities, such as submission-specific work;
- Indirect process and support activities, such as standard operating procedures and application review support; and
- Center-wide support activities.

CVM's Activity Time Reporting (ATR) System supports the allocations for all three areas.

CVM's ATR

Using the Activity Dictionary in conjunction with the definition of the "process for the review of abbreviated applications for generic new animal drugs" in AGDUFA, CVM was able to attribute activity time reported by its employees to direct and indirect process and support activities as distinguished from non-process activities. These activity definitions are consistent with the allowable costs for the AGDUFA program as detailed in Appendix C.

Center-Wide Costs and Agency-Wide Expenses

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-wide and FDA-wide costs are chargeable to the AGDUFA 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 AGDUFA program are reported as if they were incurred in CVM, 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 which 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 AGDUFA program.

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 the ORA administrative and management personnel. The Agency then multiplies the total number of FTEs used in the AGDUFA program by the average salary cost in ORA to arrive at the ORA salary costs for work that is within the scope of the AGDUFA program. The final step is to allocate ORA obligations for operations and rent to the AGDUFA program based upon the ratio of user fee-related FTEs to total ORA FTEs.

Table 12 summarizes the calculation of ORA costs for the AGDUFA program for FY 2015 and FY 2016.

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

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.

FDA multiplies the total number of FTEs used in the AGDUFA 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 AGDUFA program. FDA then allocates ORA obligations for operations and other costs to the generic new animal drug review activities based upon the ratio of user fee-related FTEs to total ORA FTEs.

TABLE 12: OFFICE OF REGULATORY AFFAIRS COSTS OF THE AGDUFA PROGRAM AS OF SEPTEMBER 30, 2015 AND 2016

Cost Component	FY 2015	FY 2016
FTE Utilized	2.0	1.2
ORA Average Salary and Benefits	$124,714	$124,404
Total Salary and Benefits	$249,428	$149,285
Operating and Other Costs[2]	$204,991	$312,073
Total	**$454,419**	**$461,358**

Numbers have been rounded to the nearest dollar

[2] Other costs are central, GSA, rent, rent-related, and Shared Services costs that are applicable to the AGDUFA 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 the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, 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 AGDUFA 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 AGDUFA program in CVM and ORA to derive the applicable Agency general and administrative costs. Using this methodology, FDA dedicated $1,323,043 in general and administrative costs to the AGDUFA 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 AGDUFA program. General and administrative costs are approximately 9 percent of the FY 2016 AGDUFA program costs.