FY 2018 ADUFA FINANCIAL REPORT

REQUIRED BY THE

ANIMAL DRUG USER FEE ACT OF 2003

AS AMENDED

FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

EXECUTIVE SUMMARY

The Animal Drug User Fee Act of 2003 (ADUFA), as amended, requires the Food and Drug Administration (FDA or the Agency) to report annually on the financial aspects of its implementation of ADUFA. This report covers activities for fiscal year (FY) 2018.

ADUFA, as amended, specifies that the following three legal conditions must be satisfied each fiscal year in order for FDA to collect and spend ADUFA 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 appropriations acts.

3. FDA must spend at least as much from appropriations for the review of animal drug applications as it spent in FY 2003, multiplied by the adjustment factor.

FDA met the three legal conditions in FY 2018, and this report explains how these legal conditions were satisfied.

The statements and tables in the report provide data on FY 2018 animal drug user fee collections, expenditures, and carryover balance, as well as comparative data from earlier periods. In FY 2018, FDA had net collections of $15.5 million in animal drug user fees, spent $27.0 million in user fees for the animal drug review process, and carried a cash balance of $15.8 million forward for future fiscal years.

In FY 2018, ADUFA user fees and non-user fee appropriations supported 325 full-time equivalents, including salaries and operational expenses to support the process for the review of animal drug applications. Detailed program accomplishments can be found in the FY 2018 ADUFA Performance Report.

In FY 2019, FDA will spend user fees to continue enhancing the new animal drug review process, focusing on improving the efficiency, quality, and predictability of the program. Some challenges FDA faces in FY 2019 include an all-electronic review environment; developing a US-European Union Good Manufacturing Practices Inspection Mutual Recognition Agreement; and meeting timeframes and implementing processes for four new sentinel submission types (Animal Drug Availability Act Combination Medicated Feeds Applications, Categorial Exclusions, Presubmission Conferences, and Tissue Residue Methods). Additionally, FDA must comply with new legislative requirements to issue guidance or regulations to clarify the criteria for expanded conditional approval, hold a public meeting on investigational designs, post additional information about food additive petitions on the FDA website, issue a draft guidance on the voluntary pre-petition consultation process for food additives intended for use in animal food, and meet new congressional reporting requirements on antimicrobial resistance.

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1: BACKGROUND

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Animal Drug User Fee Act (ADUFA), 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 animal drug review process. FDA spends user fee revenues and non-user fee appropriations to hire, support, and maintain personnel for the review of animal drug applications to help ensure that safe and effective animal drug products reach the American public.

ADUFA was first enacted on November 18, 2003, and it authorized the animal drug user fee program for 5 years—from FY 2004 through FY 2008. The Animal Drug User Fee Amendments of 2008 (Public Law 110-316) extended the program's authorization for an additional 5 years through FY 2013 (ADUFA II). On June 13, 2013, the program was reauthorized for an additional 5 years from FY 2014 through FY 2018 (ADUFA III).

Under ADUFA III, four types of user fees are established: (1) fees for certain types of animal drug applications and supplemental animal drug applications (for which safety or effectiveness data are required) (20 percent of estimated revenue); (2) annual fees for certain animal drug products (27 percent of estimated revenue); (3) annual fees for certain establishments where such products are made (26 percent of estimated revenue); and (4) annual fees for certain animal drug sponsors of animal drug applications and/or investigational animal drug submissions (27 percent of estimated revenue).

The total annual fee revenue amounts are set by the statute for ADUFA, with provisions for adjustment over time. ADUFA III authorizes FDA to set fees 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 for workload, if applicable, and inflation after FY 2014. 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 2017, FDA set fees for FY 2018 in accordance with the amounts specified in ADUFA III (see 82 FR 35966, August 2, 2017). Fee revenues are adjusted each year after FY 2014 to reflect changes in inflation and review workload, if applicable. In FY 2018, the fee revenues were adjusted by 1.9799 percent to account for inflation. A workload adjustment of 5.4599 percent was applied in FY 2018.

ADUFA III requires FDA to submit a financial report to Congress within 120 days after the end of each fiscal year. This financial report addresses the implementation and use of animal drug user fees by FDA during the period October 1, 2017, through September 30, 2018. The report discusses how the Agency met the legal conditions that must be satisfied for FDA to collect and spend animal drug user fees each year and shows how FDA determined that it met those requirements. This report also presents statements related to FY 2018 fee collections, carryover balances, obligations of user fees, and the total costs of the process for the review of animal drug applications paid from user fees and non-user fee appropriations.

2: LEGAL CONDITIONS

ADUFA imposes three legal conditions that FDA must satisfy each fiscal year for the Agency to collect and spend animal drug user fees. A summary of how each of these legal conditions was satisfied in FY 2018 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 2018, FDA's appropriation for salaries and expenses was $2,798,578,000 excluding user fees. FDA's FY 2003 Salaries and Expenses appropriation, excluding user fees, was $1,831,585,240 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 provided in that year's appropriation acts. The President signed the Consolidated Appropriations Act, 2018 (Public Law 115-141), on March 23, 2018. It specified that $18,093,000 shall be derived from animal drug user fees, and that animal 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 animal drug applications. This specified minimum is the amount FDA spent on the review of animal drug applications from appropriations (exclusive of user fees) in FY 2003, multiplied by the adjustment factor. The specified minimum level for FY 2018 is $43,663,203. In FY 2018, FDA obligated $49,940,024 from appropriations (exclusive of user fees) for the review of animal drug applications. Under ADUFA, this condition is considered met if the total review expense funded by appropriations in any year is no more than 3 percent below the specified minimum. Because FDA spent more than the specified minimum amount from appropriations in FY 2018, the third legal condition was satisfied.

References

Detailed explanations and calculations of how each of these legal conditions were satisfied in FY 2018 are described in Appendix A.

3: FINANCIAL INFORMATION

3.1 – USER FEE COLLECTIONS

Introduction

ADUFA specifies that user fees shall be collected for certain animal drug applications and supplements upon their submission, and annual fees shall be collected for certain products, establishments, and sponsors. The statute also specifies the amount FDA is allowed to collect for each of these 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 (see Appendix B). Under ADUFA, 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 2017, even if it is received in FY 2018, is attributed to FY 2017 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 updates prior-year numbers annually.

The receivables for FY 2017 and FY 2018 are from uncollected product, establishment, 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 DRUG USER FEE COHORT COLLECTIONS AND RECEIVABLES BY FEE SOURCE AS OF SEPTEMBER 30, 2018

Fees Collected	FY 2017	FY 2018	Notes
Application Fees	$2,148,038	$2,261,950	
Product Fees	$6,668,020	$4,668,300	
Establishment Fees	$6,154,500	$4,970,000	
Sponsor Fees	$7,035,433	$5,185,300	
Total Collections	**$22,005,991**	**$17,085,550**	A
Fees Receivable			
Product Fees	$8,605	$18,525	
Establishment Fees	$0	$88,750	
Sponsor Fees	$1,728,067	$1,277,550	
Total Receivables	**$1,736,672**	**$1,384,825**	

Numbers have been rounded to the nearest dollar

Notes

A. In FY 2018, FDA received a net total of $77,574 that was attributed to FY 2017 collections. Therefore, FDA increased its FY 2017 fee collections of $21,928,417 (reported last year) to $22,005,991 as of September 30, 2018.

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 2018 is provided in Appendix B.

3.2 – USER FEE OBLIGATIONS

Introduction

ADUFA fees may be expended only for costs necessary to support the "process for the review of animal drug applications," as defined in ADUFA. For ease of reading, the "process for the review of animal drug applications" is referred to as the "ADUFA 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 ADUFA program.

Data

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

TABLE 2: ANIMAL DRUG USER FEE OBLIGATIONS BY OBJECT CLASS EXPENSE CATEGORY BREAKDOWN AS OF SEPTEMBER 30, 2017, AND 2018

Object Class Expense Category	FY 2017	FY 2018
Personnel Compensation Benefits		
Full-time permanent	$8,625,019	$12,454,530
Other than full-time permanent	$818,485	$1,291,668
Other personnel compensation	$169,977	$184,001
Military personnel	$107,850	$129,990
Special personal services payments	$0	$49
Civilian personnel benefits	$3,135,053	$4,574,583
Military personnel benefits	$55,469	$73,087
Benefits former personnel	$0	$0
Total Personnel Compensation and Benefits	**$12,911,853**	**$18,707,908**
Non-Pay Costs		
Travel & transportation of persons	$133,578	$105,278
Transportation of things	$7,819	$5,012
Rent payments to General Services Administration (GSA)	$0	$522,000
Rent payments to others	$0	$0

Object Class Expense Category	FY 2017	FY 2018
Communications, utilities, & miscellaneous	$7,646	$1,047,011
Printing & reproduction	$17,097	$0
Other Contractual Services:		
Consulting services	$383,020	$200,030
Other services	$2,124,172	$3,893,557
Purchases of goods & services from government accounts	$1,850,877	$1,917,718
Operations & maintenance of facilities	$970,550	$159,321
Research & development contracts	$0	$0
Operations & maintenance of equipment	$427,399	$253,303
Subsistence & support of persons	$0	$0
Supplies & materials	$141,004	$61,396
Equipment	$111,732	$98,876
Land & structure	$0	$0
Grants, subsidies, & contributions	$15,000	$0
Insurance claims & indemnities	$0	$0
Interest account	$0	$0
Receivables – collected	$101,000	$0
Total Non-Pay Costs	**$6,290,895**	**$8,263,502**
Total Obligations	**$19,202,748**	**$26,971,411**

Numbers have been rounded to the nearest dollar

References

Total program costs and full-time equivalent (FTE) usage by year are shown in Tables 6 and 8, respectively.

Allowable and excluded costs are described in Appendix C.

3.3 – CARRYOVER BALANCES

Introduction

ADUFA 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 carryover balance at the beginning of FY 2018 was $27,115,777, which includes $2,058,256 in resources deemed unavailable for obligation. The operations in FY 2018 resulted in a net decrease of $11,270,204 in the carryover balance, resulting in a year-end carryover balance of $15,845,573.

Data

Table 3 captures FDA's carryover balances at the beginning and end of the 5-year authorization period for ADUFA I, ADUFA II, and for each fiscal year in ADUFA III.

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, the amount obligated during the fiscal year, and the amount recovered and deobligated from prior years. The numbers do not include any accounts receivable. Therefore, the numbers for FY 2018 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.

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

Program	Fiscal Years	Beginning Carryover	Net Collection	Recoveries	Obligations	Year-End Carryover
ADUFA I	2004-2008	$0	$49,077,860	$0	($45,048,048)	$4,029,812
ADUFA II	2009-2013	$4,029,812	$89,279,716	$0	($81,350,206)	$11,959,322
ADUFA III	2014	$11,959,322	$25,455,281	$0	($19,699,833)	$17,714,770
	2015	$17,714,770	$24,889,466	$0	($21,539,034)	$21,065,201
	2016	$21,065,201	$25,058,121	$13,563	($23,018,820)	$23,118,065
	2017	$23,118,065	$22,917,184	$283,275	($19,202,748)	$27,115,777
	2018	$27,115,777	$15,540,965	$160,242	($26,971,411)	$15,845,573

Numbers have been rounded to the nearest dollar

3.4 – COLLECTIONS REALIZED

Introduction

The following information describes collections realized by cohort year (the same as "Total Collections" in Table 1), collection amounts specified in the appropriation acts, and an offset amount that was taken in FY 2018.

Under ADUFA III, 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 amounts specified in appropriation acts during that period. The offset taken in FY 2018 was $6,548,646.

Data

Previous cohort-year collections realized in FY 2018 have been updated from last year's report. The update reflects net collections for each cohort year through September 30, 2018. Cohort year fees collected after September 30, 2018, will be reported in the FY 2019 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 2019.

TABLE 4: ANIMAL DRUG USER FEES COLLECTED, COLLECTION AMOUNTS SPECIFIED IN APPROPRIATIONS ACT, AND EXCESS AMOUNTS AS OF SEPTEMBER 30, 2018

Fiscal Year	Collections Realized	Collection Amount Specified in Appropriations Act	Amount in Excess of Collection Amount Specified in Appropriations Act
2004	$5,154,700	$5,000,000	$154,700
2005	$8,519,101	$8,354,000	$165,101
2006	$10,901,466	$11,318,000	$0
2007	$13,342,455	$11,604,000	$1,738,455
2008	$11,577,312	$13,696,000	$0
Total ADUFA I			**$2,058,256**
2009	$12,893,861	$15,260,000	($2,366,139)
2010	$16,541,776	$17,280,000	($738,224)
2011	$17,679,812	$19,448,000	($1,768,188)
2012	$20,276,405	$21,768,000	($1,491,595)
2013	$20,320,283	$23,848,000	($3,527,717)
Total ADUFA II			**$0**

2014	$26,193,331	$23,600,000	$2,593,331
2015	$24,535,338	$22,464,000	$2,071,338
2016	$24,924,872	$22,818,000	$2,106,872
2017	$22,005,991	$23,673,000	($1,667,009)
2018	$17,085,550	$18,093,000	($1,007,450)
Total ADUFA III			**$4,097,081**
Offset When Fees Were Set for FY 2018[1]			**$6,548,646**

Numbers have been rounded to the nearest dollar

[1] Full details about the calculation can be found in the *Federal Register* notice, which set FY 2018 fee rates (https://www.gpo.gov/fdsys/pkg/FR-2017-08-02/pdf/2017-16180.pdf).

3.5 – RESERVES AND BALANCE AVAILABLE FOR ALLOCATION

Introduction

For ADUFA, the year-end carryover balance for FY 2018 is $15,845,573. Anticipated claims on this balance are described below. After subtracting these claims, FDA's remaining carryover balance is $5,204,567.

Data

Table 5 provides a summary of carryover balances as of September 30, 2018, and anticipated claims on those balances.

TABLE 5: SUMMARY STATEMENT OF ANIMAL DRUG USER FEE CARRYOVER BALANCE AS OF SEPTEMBER 30, 2018

Status of Carryover Funds	Amount	Notes
Total Carryover Balance	$15,845,573	
Reserve for Refunds	($1,000,000)	A
Reserve for Collections Deemed Unavailable Due to Lack of Appropriations	($2,058,256)	B
3-Month Operating Reserve	($7,582,750)	C
Remaining Carryover Balance	**$5,204,567**	

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 $1,000,000 is being set aside.

B. $2,058,256 collected in excess of appropriations during ADUFA I are deemed unavailable for obligation.

C. ADUFA III authorized 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. If carryover balances had been less than the amount FDA needed to fund the first 3 months of operations in FY 2019, FDA was authorized to add up to the full shortfall amount to the fee revenues when setting fees for FY 2018. At the end of FY 2018, the amount of carryover needed to sustain operations for 3 months was $7,582,750. This amount is currently covered by the carryover balance available to FDA.

3.6 – TOTAL ADUFA PROGRAM COSTS

Introduction

There are three organizations that contribute to the ADUFA program: the Center for Veterinary Medicine (CVM), the Office of Regulatory Affairs (ORA), and FDA Headquarters (HQ). The ADUFA program is supported by both user fees and non-user fee appropriations. As in prior years, resources expended in FY 2018 by the Office of Shared Services in supporting the ADUFA program are reported as if they were incurred in CVM, ORA, or HQ.

Data

Table 6 shows, by FDA organizational component, the costs for the ADUFA program (non-user fee appropriations and user fees) during the past 10 fiscal years. 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: ADUFA PROGRAM – HISTORICAL TREND OF TOTAL COSTS BY ORGANIZATION 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	$63,242,475	$56,692,025	90%	$1,886,441	3%	$4,664,009	7%
2010	$64,683,379	$57,086,985	88%	$2,015,514	3%	$5,580,880	9%
2011	$62,513,581	$55,540,087	89%	$2,342,053	4%	$4,631,441	7%
2012	$65,157,030	$56,794,781	87%	$2,747,298	4%	$5,614,951	9%
2013	$60,518,099	$52,458,322	87%	$2,147,856	4%	$5,911,921	10%
2014	$65,201,329	$57,557,355	88%	$1,619,848	2%	$6,024,126	9%
2015	$68,360,353	$61,285,840	90%	$1,590,465	2%	$5,484,048	8%
2016	$68,588,677	$60,851,351	89%	$1,735,789	2%	$6,001,538	9%
2017	$67,887,740	$60,212,621	89%	$1,476,326	2%	$6,198,793	9%
2018	$76,911,434	$68,342,900	89%	$1,627,530	2%	$6,941,005	9%

Numbers have been rounded to the nearest dollar

Table 7 provides the total amount spent on the ADUFA program for the last 10 years, and the dollar amount and percentage derived from fees and non-user fee appropriations.

Of the $76,911,434 obligated in support of the ADUFA program in FY 2018, as defined in ADUFA, about 35 percent came from ADUFA fees and about 65 percent came from non-user fee appropriations.

TABLE 7: ADUFA 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 ADUFA Fees	ADUFA Fee Percent
2009	$63,242,475	$49,863,275	79%	$13,379,200	21%
2010	$64,683,379	$48,082,679	74%	$16,600,700	26%
2011	$62,513,581	$45,880,781	73%	$16,632,800	27%
2012	$65,157,030	$49,019,929	75%	$16,137,101	25%
2013	$60,518,099	$41,917,694	69%	$18,600,405	31%
2014	$65,201,329	$45,501,496	70%	$19,699,833	30%
2015	$68,360,353	$46,821,318	68%	$21,539,035	32%
2016	$68,588,677	$45,569,857	66%	$23,018,820	34%
2017	$67,887,740	$48,684,992	72%	$19,202,748	28%
2018	$76,911,434	$49,940,024	65%	$26,971,411	35%

Numbers have been rounded to the nearest dollar

References

An expense category breakout of the FY 2017 and FY 2018 dollar amount spent from ADUFA fees is provided in Table 2 in section 3.2.

The development of the costs associated with the ADUFA program is described in more detail in Appendix D.

3.7 – FULL-TIME EQUIVALENT

Introduction

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

Data

Table 8 presents total FTE levels that support the ADUFA program by FDA organizational component for the last 10 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 services, etc.) is included in the FTE levels for the various components.

TABLE 8: HISTORICAL TREND OF TOTAL FTES UTILIZED BY ORGANIZATION

Fiscal Year	CVM	ORA	HQ	Total
2009	250	10	21	281
2010	255	10	20	285
2011	260	11	18	289
2012	272	12	19	303
2013	261	10	20	291
2014	264	7	22	293
2015	278	7	21	306
2016	291	6	22	319
2017	292	6	22	320
2018	298	7	20	325

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 ADUFA, specifies three legal conditions that must be met each fiscal year for FDA to collect and spend animal drug user fees. This appendix provides detailed descriptions of these conditions and explanations of how FDA met these conditions in FY 2018. 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 739(10) of the FD&C Act, as amended by ADUFA III) in the assessments of the first and the third conditions. The FD&C Act states:

> *The term 'adjustment factor' applicable to a fiscal year refers to the formula set forth in section 735(8) with the base or comparator month being October 2002.*

Section 735(8) of the FD&C Act, which is the adjustment factor for the Prescription Drug User Fee Act (PDUFA), provides the following definition:

> *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.*

For ADUFA III, the base month is October 2002 rather than October 1996, as reflected in the first statutory citation above. The consumer price index (CPI) for October 2016—the October of the fiscal year preceding FY 2018—was 241.729. The CPI for October 2002 was 181.3. Dividing the CPI of October 2016 by the CPI of October 2002 yields an adjustment factor of 1.333309 (rounded to six decimal places) for FY 2018.

Legal Condition 1

The first legal condition is found in section 740(f)(1) of the FD&C Act. It states:

> *Fees may not be assessed under subsection (a) for a fiscal year beginning after fiscal year 2003 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 2003 (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 Salaries and Expenses appropriation (excluding user fees) for FY 2018 must be greater than or equal to FDA's Salaries and Expenses appropriation (excluding user fees) for FY 2003 multiplied by the adjustment factor. 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 1.333309 (rounded to the sixth decimal place) equals$1,831,585,240.

In FY 2018, Congress appropriated $2,798,578,000 to FDA for salaries and expenses, excluding user fees. Because the FY 2018 Salaries and Expenses appropriation is greater than the adjusted FY 2003 Salaries and Expenses appropriation, $1,831,585,240, the first legal condition was met.

Legal Condition 2

The second legal condition is described in section 740(g)(2)(A)(i) of the FD&C Act. It 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.*

The President signed the Consolidated Appropriations Act, 2018 (Public Law 115-141), on March 23, 2018. It specified that $18,093,000 shall be derived from animal drug user fees for FDA in FY 2018, and that 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 740(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 animal 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 2003 multiplied by the adjustment factor.*

The third condition requires a minimum spending from appropriations, excluding user fees, on the ADUFA program. The minimum spending from appropriations is the amount that FDA spent on the process for the review of animal drug applications in FY 2003, multiplied by the adjustment factor. Further, FDA is considered to have met this requirement if it underspends this amount by up to 3 percent (see section 740(g)(2)(B)).

In FY 2003, the amount spent from appropriations for the ADUFA program was $32,748,000 (rounded to the nearest thousand). After applying the adjustment factor of 1.333309 (rounded to the sixth decimal place), the minimum appropriation spending level for the ADUFA program for FY 2018, excluding user fees, is $43,663,203.

In FY 2018, FDA obligated $49,940,024 from appropriations, exclusive of user fees, for the ADUFA program, which exceeds the specified minimum appropriation spending level. Therefore, the third legal condition was met.

4.2 – APPENDIX B: FEES, WAIVERS, AND REDUCTIONS

ADUFA Fee History

ADUFA III includes four fee categories (establishment, sponsor, product, and application fees) and sets out the percentage of the total fee revenue amount to be used in determining the fee revenue amounts for each category. Based on the statutory revenues and estimated numbers of fees that would be paid in each category, FDA published the FY 2018 fee rates for all categories in August 2017.[2] Table 9 provides a history of fee rates for the past 10 years.

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

Fiscal Year	Establishment Fee	Sponsor Fee	Product Fee	Application Fee	Supplemental Application Fee
2009	$59,450	$52,700	$4,925	$246,300	$123,150
2010	$73,850	$57,100	$6,185	$290,400	$145,200
2011	$83,100	$64,000	$7,235	$316,200	$158,100
2012	$93,050	$67,200	$7,935	$372,100	$186,050
2013	$104,600	$87,700	$8,640	$435,200	$217,600
2014	$105,800	$101,150	$9,075	$396,600	$198,300
2015	$104,150	$94,450	$8,075	$400,600	$200,300
2016	$105,950	$101,000	$7,790	$351,100	$175,550
2017	$111,900	$103,100	$8,195	$350,700	$175,350
2018	$88,750	$75,150	$6,175	$238,100	$119,050

[2] FDA published FY 2018 animal drug user fee rates in the *Federal Register* on August 2, 2017 (82 FR 35966) https://www.gpo.gov/fdsys/pkg/FR-2017-08-02/pdf/2017-16180.pdf

ADUFA 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 ADUFA fees in the *Federal Register* (FR) over the past 10 years. The actual numbers may change over time because of refunds or collection of open receivables. An additional billing will be sent for FY 2018 establishment, sponsor, and product fees that were not included in the original billing. For that reason, the FY 2018 cohort is considered incomplete at this time.

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

Fiscal Year	Forecasted vs. Actual	Number of Establishments	Number of Sponsors	Number of Products	Number of Applications
2009	FR	59	66	707	14
	Actual	59	67	785	8
2010	FR	59	76	698	15
	Actual	60	63	773	13
2011	FR	59	76	672	15
	Actual	57	63	754	11
2012	FR	59	81	686	15
	Actual	56	61	749	14
2013	FR	57	68	690	14
	Actual	54	63	728	7
2014	FR	58	63	702	12
	Actual	56	50	849	19
2015	FR	55	63	737	11
	Actual	56	59	885	15
2016	FR	56	61	791	13
	Actual	54	64	847	18
2017	FR	55	62	780	14
	Actual	55	68	814	6
2018	FR	53	65	791	15
	Actual	56	69	756	10

Numbers are rounded to the nearest whole number

ADUFA Waiver and Exemption History

ADUFA III directs FDA to waive or reduce fees in five different circumstances, upon request, when the Agency finds that:

- the assessment of the fee would present a significant barrier to innovation because of limited resources available to such person or other circumstances;
- the fees to be paid by such person will exceed the anticipated present and future costs incurred by FDA in conducting the process for the review of animal drug applications for such person;
- the animal drug application or the supplemental animal drug application is intended solely to provide for use of the animal drug in a free-choice medicated feed;
- the animal drug application or the supplemental animal drug application is intended solely to provide for a minor use or minor species indication; or
- the sponsor involved is a small business submitting its first animal drug application to FDA for review.

Table 11 summarizes the waivers and the reductions granted by FDA for fees payable, as well as the value of each waiver or reduction granted by cohort year over the past 10 years. Information for the FY 2018 Fees Exceed Costs waivers was not complete at the end of FY 2018. It will be reported in the FY 2019 ADUFA Financial Report.

TABLE 11: WAIVERS AND REDUCTIONS GRANTED AND USED BY FEE CATEGORY AS OF SEPTEMBER 30, 2018

Waivers	Types of Waivers					Total Waivers	Value of Waivers Approved by Fee Category				Total Value of Waivers Approved
	Significant Barrier to Innovation Waivers Approved	Fees Exceed Costs Waivers Approved	Free Choice Feeds Waivers Approved	Minor Use or Minor Species Waivers Approved	Small Business Waivers Approved		Applications	Products	Establishments	Sponsors	
FY 2009	36	11	2	66	1	116	$985,200	$78,800	$356,700	$4,743,000	$6,163,700
FY 2010	43	10	3	72	3	131	$871,200	$105,145	$516,950	$5,938,400	$7,431,695
FY 2011	43	33	6	72	1	155	$1,264,800	$209,815	$747,900	$7,552,000	$9,774,515
FY 2012	40	31	5	77	6	159	$3,348,900	$206,310	$651,350	$7,862,400	$12,068,960
FY 2013	40	33	5	74	1	153	$1,305,600	$259,200	$836,800	$9,822,400	$12,224,000
FY 2014	52	29	5	72.5	-	158.5	$594,900	$190,575	$740,600	$13,048,350	$14,574,425
FY 2015	49	24	6	71.5	-	150.5	$1,001,500	$177,650	$520,750	$11,428,450	$13,128,350
FY 2016	64	24	5	71	1	165	$2,808,800	$171,380	$635,700	$13,029,000	$16,644,880
FY 2017	72	23	5	79	1	180	$2,104,200	$172,095	$559,500	$14,846,400	$17,682,195
FY 2018	56	-	4	73	-	133	$238,100	$49,400	$177,500	$9,168,300	$9,633,300

Numbers have been rounded to the nearest dollar

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

Introduction

The FD&C Act, as amended, defines the "process for the review of animal drug applications" and the costs that may be included in that process; this is collectively referred to as the "ADUFA 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 ADUFA program.

ADUFA Program Costs

Included Activities

Section 739(8) *The term 'process for the review of animal drug applications' means the following activities of the Secretary with respect to the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions:*

Section 739(8)(A) *The activities necessary for the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions.*

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

- with respect to New Animal Drug Applications (NADAs)—original applications, pre- and post-market supplements, chemistry reports, reactivations, Veterinary Master Files, Public Master Files, and application-related correspondence; and

- with respect to Investigational New Animal Drugs (INADs)—initial submissions, reauthorization requests, protocols with or without data, and studies with or without data.

Furthermore, the activities necessary for the review of NADAs, supplemental animal drug applications, and INADs include among other activities:

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

- general NADA and INAD 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 739(8)(B) *The issuance of action letters which approve animal drug applications or supplemental animal drug applications or which set forth in detail the specific deficiencies in animal drug applications, supplemental animal drug applications, or investigational animal drug*

submissions and, where appropriate, the actions necessary to place such applications, supplements 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 739(8)(C) *The inspection of animal drug establishments and other facilities undertaken as part of the Secretary's review of pending animal drug applications, supplemental animal drug applications, and investigational animal drug submissions.*

Section 739(8)(D) *Monitoring of research conducted in connection with the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions.*

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

Section 739(8)(E) *The development of regulations and policy related to the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions.*

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

Section 739(8)(F) *Development of standards for products subject to review.*

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

Section 739(8)(G) *Meetings between the Agency and the 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 pre-market applications; and
- FDA-sponsored conferences/workshops related to pre-market submissions.

Section 739(8)(H) *Review of advertising and labeling prior to approval of an animal drug application or supplemental animal drug application, but not after such application has been approved.*

Section 739(9) *The term 'costs of resources allocated for the process for the review of animal drug applications' means the expenses incurred in connection with the process for the review of animal drug applications for—*

Section 739(9)(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 animal drug applications, supplemental animal drug applications, or investigational animal drug 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 ADUFA 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
- a site visit program for premarket reviewers.

Section 739(9)(B) *management of information, and the acquisition, maintenance, and repair of computer resources,*

Section 739(9)(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 739(9)(D) *collecting fees under section 740 and accounting for resources allocated for the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions.*

Sections 739(9)(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 ADUFA program and in support of user fee collections and accounting.

Excluded Activities

- Review of Abbreviated New Animal Drug Applications
- Enforcement policy development
- Post-approval surveillance and compliance activities
- Post-approval activities relating to the review of advertising
- Inspections unrelated to the ADUFA program
- Research unrelated to the ADUFA program

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

General Methodology

The costs associated with the ADUFA 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 NADAs, Supplemental Animal Drug Applications, and INADs	CVM
Costs for Field Pre-approval Inspection and Investigation	ORA
Costs for Agency General and Administrative	HQ

The costs for each component were 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 ADUFA program, as explained in the discussion in Appendix C, the cost categories within each organization listed above were identified as parts of the animal drug application review process.

Center Costs

Costs of the ADUFA program are tracked for each organizational component in CVM, usually at the division level. Most CVM divisions involved in the ADUFA program perform a mixture of activities – some within the scope of the ADUFA program, and some not. CVM groups its organization 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 animal drug applications under ADUFA, 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 ADUFA 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 and FDA-wide costs are chargeable to the ADUFA 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 2018 by the Office of Shared Services in supporting the ADUFA 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 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 ADUFA program.

Table 12 summarizes the calculation of ORA costs for the ADUFA program for FY 2017 and FY 2018.

ORA costs for the ADUFA 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 ADUFA 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 ADUFA program.

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

TABLE 12: ORA COSTS OF THE ADUFA PROGRAM
AS OF SEPTEMBER 30, 2017 AND 2018

Cost Component	FY 2017	FY 2018
FTE Utilized	6	6
ORA Average Salary and Benefits	$128,889	$134,882
Total Salary and Benefits	$786,223	$849,757
Operating and Other Costs[3]	$690,103	$777,773
Total	**$1,476,326**	**$1,627,530**

Numbers have been rounded to the nearest dollar

[3] Other costs are central, GSA, rent, rent-related, and Shared Services costs that are applicable to the ADUFA 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)
- Office of Laboratory Science and Safety

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 ADUFA 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 ADUFA program in CVM and ORA to derive the applicable Agency general and administrative costs.

Using this methodology, FDA dedicated $6,941,005 in general and administrative costs to the ADUFA program in FY 2018. The costs are total costs obligated from appropriations and user

fees. FDA strives to maintain a low overhead cost for the ADUFA program. General and administrative costs are approximately 9 percent of the FY 2018 ADUFA program costs.