FY 2019 AGDUFA
FINANCIAL REPORT

REQUIRED BY THE

ANIMAL GENERIC DRUG USER FEE ACT

FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Table of Contents

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 to Congress annually on the financial aspects of AGDUFA implementation. This is the first report under the third authorization of AGDUFA (AGDUFA III) and covers fiscal year (FY) 2019.

AGDUFA III specifies that the following three legal conditions must be satisfied each year 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 an adjustment factor specified in the statute.

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

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

FDA met the three legal conditions in FY 2019, and this report explains how these legal conditions were satisfied. The statements and tables in this report provide data on generic new animal drug user fee collections, expenditures, and carryover balances, as well as comparative data from prior fiscal years.

In FY 2019, FDA had net collections of $19 million in AGDUFA fees, spent $15 million in user fees for the process for the review of abbreviated applications for generic new animal drugs, and carried a cumulative balance of $15 million forward for future fiscal years.

AGDUFA user fees and non-user fee appropriations in FY 2019 supported 112 full-time equivalents, including salaries and operational expenses, to support the process for the review of generic new animal drug abbreviated applications. Detailed program accomplishments can be found in the FY 2019 AGDUFA Performance Report.

Report Overview

A. Scope

This financial report describes the collection and use of generic new animal drug user fees by the Food and Drug Administration (FDA or the Agency) during the period from October 1, 2018, through September 30, 2019. It specifies the legal conditions that FDA must satisfy each year to collect and spend Animal Generic Drug User Fee Act of 2008 (AGDUFA) fees and documents how FDA determined that it met those requirements for fiscal year (FY) 2019. In addition, this report presents summary statements of FY 2019 fee collections, carryover balances, obligations of user fees, and total costs of the process for the review of abbreviated applications for generic new animal drugs.

B. Report Requirements

In accordance with section 742(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), FDA will submit to Congress an annual financial report on the implementation of FDA's authority for user fees during the fiscal year for which the report is made and the use by the Agency of the fees collected for such fiscal year. The purpose of this report is to meet these requirements for FY 2019.

FDA is required to submit the financial report to Congress no later than 120 days after the end of each fiscal year. FDA also must make the report available to the public on its Internet website. Additional details on the reporting requirements are included in **Appendix A**.

Management Discussion

C. Organization Background

FDA is responsible for protecting the public health by helping to ensure the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation. FDA also has responsibility for regulating the manufacturing, marketing, and distribution of tobacco products and advancing the public health by helping to speed innovations that make medical products more effective, safe, and affordable and by helping the public get accurate, science-based information needed to use medical products and to consume foods to maintain and improve their health. FDA similarly plays a significant role in the nation's counterterrorism capability.

The Center for Veterinary Medicine (CVM) is responsible for regulating animal drugs, devices, and food. CVM evaluates new animal drug applications for safety and effectiveness; monitors animal drugs, foods, and devices on the market; evaluates animal food additives for safety and utility; and conducts applied research to further protect human and animal health. CVM also helps promote and provide incentives for the availability of animal drugs to meet the needs of the large number and wide diversity of minor species, such as fish, honey bees, and birds, and for minor uses (infrequent and limited) in the major species: cattle, pigs, chickens, dogs, cats, horses, and turkeys.

Program Organization

There are three major FDA components that support the AGDUFA program: CVM, the Office of Regulatory Affairs (ORA), and Headquarters (HQ).

Exhibit 1 provides an overview of the mission for each of these components.

Exhibit 1: User Fee Program Components

Component	Mission
CVM	CVM protects and promotes the health of humans and animals by helping to ensure the safety of the American food supply, the safety of animal food and devices, and the safety and effectiveness of animal drugs.
ORA	ORA protects consumers and enhances the public health by maximizing the compliance of FDA-regulated products and minimizing the risk associated with those products.
HQ	HQ provides FDA-wide program direction and administrative services to ensure FDA programs are effective and efficient.

User Fee Governance

The Agency's expanding level of user fees, the reporting of the Agency's performance commitments associated with these fees, and the need for FDA to convey how these fees are executed calls for strong financial governance. This includes an understanding of the design of these programs, clear financial plans, data-driven decisions on resource allocation, consistency and transparency about assumptions, reliable financial forecasting, and accountability for resources spent.

FDA leverages the User Fee Financial Management Committee for user fee governance. The User Fee Financial Management Committee consists of senior financial, business operations, and program experts across the Agency that evaluate user fee resource needs, develop financial allocation plans, and forecast resource requirements – both programmatic and administrative – to support user fee financial decisions. The User Fee Financial Management Committee is responsible for providing oversight and support of appropriate standards and policies to ensure FDA's compliance with sound financial management practices, as well as FDA's compliance with statutory provisions that authorize FDA to collect and spend user fees. The User Fee Financial Management Committee receives policy guidance and strategic direction directly from FDA's Executive Committee relative to how the Agency will forecast and react to industry trends, plan and manage its research agenda in support of the user fee programs, and forecast its user fee workload. The User Fee Financial Management Committee advises the Executive Committee and other Center- and Office-level bodies on a variety of financial and performance-related topics.

D. User Fee Background and Structure

The FD&C Act, as amended by AGDUFA, authorizes FDA to collect fees from industry to supplement non-user fee appropriations that the Agency spends on the process for the review of abbreviated applications for generic new animal drugs.

The Animal Drug and Animal Generic Drug User Fee Amendments of 2018 includes the reauthorization of AGDUFA, also known as AGDUFA III, which extends the AGDUFA program from October 1, 2018, through September 30, 2023. This 5-year reauthorization provides continued funding for FDA from FY 2019 through FY 2023 to support program operations, evaluation, and improvement. AGDUFA III continues to deliver tremendous public health benefits by enhancing FDA's capacity to review generic new animal drug submissions to help ensure that products coming to the market for the American public will be safe and effective.

FDA spends AGDUFA user fee collections and non-user fee appropriations to hire, support, and maintain personnel for the review of generic new animal drug abbreviated applications.

AGDUFA III establishes a fee structure comprised of the following three types of fees: application fee, product fee, and sponsor fee.

Exhibit 2 outlines the types of user fees under AGDUFA III.

Exhibit 2: AGDUFA III Fee Types

Fee Type	Definition
Application (Section 741(a)(1) of the FD&C Act)	Each person that submits an abbreviated application for a generic new animal drug shall be subject to an abbreviated application fee. The terms "abbreviated application for a generic new animal drug" and "abbreviated application" mean an abbreviated application for approval of any generic new animal drug submitted under section 512(b)(2) of the FD&C Act, except that the terms do not include a supplemental abbreviated application for a generic new animal drug. An abbreviated application subject to the criteria in section 512(d)(4) of the FD&C Act shall be subject to 50 percent of the abbreviated application fee applicable to all other abbreviated applications for generic new animal drugs.
Product (Section 741(a)(2) of the FD&C Act)	Each person named as the applicant in an abbreviated application or supplemental abbreviated application for a generic new animal drug product submitted for listing under section 510 of the FD&C Act and who had an abbreviated application or supplemental abbreviated application pending at FDA after September 1, 2008, shall pay an annual fee for each such generic new animal drug product.
Sponsor (Section 741(a)(3) of the FD&C Act)	The sponsor fee must be paid annually by each person who: (1) is named as the applicant in an abbreviated application that has not been withdrawn by the applicant and for which approval has not been withdrawn by FDA or has submitted an investigational submission for a generic new animal drug that has not been terminated or otherwise rendered inactive by FDA; and, (2) had an abbreviated application for a generic new animal drug, a supplemental abbreviated application for a generic new animal drug, or an investigational submission for a generic new animal drug pending at FDA after September 1, 2008. A generic new animal drug sponsor is subject to only one such fee each fiscal year. Applicants with more than six approved abbreviated applications pay 100 percent of the sponsor fee; applicants with more than one and fewer than seven approved abbreviated applications pay 75 percent of the sponsor fee; and applicants with one or fewer approved abbreviated applications pay 50 percent of the sponsor fee.

Section 741(b) of the FD&C Act establishes the total revenue amounts from fees for each fiscal year of AGDUFA III. It also specifies the percentage of the total revenue amounts to be derived from each type of user fee: application fees (25 percent), product fees (37.5 percent), and sponsor fees (37.5 percent).

The statute specifies at section 741(c) of the FD&C Act how the fees are to be calculated each fiscal year, including annual adjustments that must be made for inflation, beginning with FY 2020. The statute also provides for the possibility of annual adjustments because of changes in FDA's workload related to the process for the review of abbreviated applications for generic new animal drugs, also beginning with FY 2020. FDA publishes the fee amounts, and the methodology it used to calculate these amounts, in the *Federal Register* each year.[1]

AGDUFA user fees are not a fee-for-service. Instead, the user fees that are collected are pooled together and may be used for any of the allowable activities as defined in the FD&C Act. Refer to **Appendix B** for a detailed list of allowable and excluded activities.

Appendix C provides more background information on the AGDUFA user fee program.

[1] See https://www.federalregister.gov/documents/2018/09/26/2018-20912/animal-generic-drug-user-fee-rates-and-payment-procedures-for-fiscal-year-2019.

E. Legal Conditions

The FD&C Act, as amended by AGDUFA, specifies three legal conditions that must be satisfied each year for FDA to collect and spend generic new animal drug user fees. **Exhibit 3** describes those legal conditions and provides a brief explanation as to how those legal conditions were met for FY 2019.

Exhibit 3: AGDUFA Legal Conditions

Legal Condition #	Details	
1	Description	FDA's overall Salaries and Expenses appropriation (excluding user fees) for the fiscal year at issue must meet or exceed the amount of FDA's FY 2003 Salaries and Expenses appropriation (excluding user fees), multiplied by an adjustment factor specified in the statute. [Section 741(f)(1) of the FD&C Act].
	Met	In FY 2019, FDA's Salaries and Expenses appropriation, excluding user fees, was $3,067,178,000. FDA's FY 2003 Salaries and Expenses appropriation, excluding user fees, was $1,868,970,866 after applying the adjustment factor. Therefore, the first legal condition was satisfied.
2	Description	The amount of user fees FDA may collect for each fiscal year must be specified in that year's appropriation acts. [Section 741(g)(2)(A)(i) of the FD&C Act].
	Met	Division A, Title VI of Public Law 116-6 specified that $18,335,000 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 appropriated for FDA. Therefore, the second legal condition was satisfied.
3	Description	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 process for the review of abbreviated applications for generic new animal drugs from appropriations (exclusive of user fees) in FY 2008, multiplied by an adjustment factor specified in the statute. [Section 741(g)(2)(A)(ii) of the FD&C Act]. Under AGDUFA, this condition is considered met if the total review expense funded by appropriations in any fiscal year is no more than three percent below the specified minimum. [Section 741(g)(2)(B) of the FD&C Act].
	Met	The specified minimum level for FY 2019 is $6,504,924. In FY 2019, FDA obligated $8,939,021 from appropriations (exclusive of user fees) for the process for the review of abbreviated applications for generic new animal drugs. Because FDA spent more than the specified minimum amount from appropriations in FY 2019, the third legal condition was satisfied.

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

F. Strategic Plan

FDA is focused on utilizing AGDUFA user fee and non-user fee appropriations to achieve the performance goals and program enhancements outlined in the AGDUFA III Commitment Letter.[2] FDA is also committed to improving its information technology (IT) to support the review process.

[2] See https://www.fda.gov/media/108440/download.

G. Performance Summary

FDA exceeded review performance goals for the FY 2018 cohort. FDA met the review-time goals in 337 of 339 submissions. The entire FY 2018 cohort has closed; therefore, there are no pending submissions.

As of September 30, 2019, preliminary performance data were available for 325 of 552 submissions filed in FY 2019. FDA is currently exceeding all performance goals. Overall, FDA met review-time goals for 324 of 325 submissions acted on. With 227 submissions pending within goal, FDA has the potential to meet or exceed all performance goals. Please refer to the FY 2019 AGDUFA Performance Report for more information.

Financial Information

This section provides an overview of the program financials for AGDUFA for FYs 2018 and 2019. These financials include user fee revenue, obligations, carryover, non-user fee appropriations, and full-time equivalents (FTEs).

H. User Fee Program Financials

Table 1 represents a summary of the AGDUFA user fee financial position for FY 2018 and FY 2019. The financial notes referenced in this table can be found in **Appendix E**.

Table 1: Animal Generic Drug Collections, Obligations, and Carryover for FYs 2018 and 2019

Budgetary Resources	Notes	FY 2018	FY 2019
Target Revenue		**$9,419,000**	**$18,336,000**
Total Carryover, Beginning of Year		$12,675,755	$10,800,810
Net Collections		$10,030,801	$18,775,214
Recoveries	Note 1	$110,403	$237,044
Total Budgetary Resources		**$22,816,959**	**$29,813,068**

Obligations	Notes	FY 2018	FY 2019
Total Payroll and Operating	Note 2	$10,018,792	$12,420,877
Total Rent	Note 3	$565,359	$439,683
Total Shared Services	Note 4	$1,431,999	$2,028,178
Total Obligations		**$12,016,150**	**$14,888,738**

Carryover	Notes	FY 2018	FY 2019
Total Carryover, End of Year		**$10,800,810**	**$14,924,330**

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

Budgetary Resources: The "Total Budgetary Resources" component of **Table 1** illustrates the total user fee funding (i.e., the existing total carryover balance and additional user fee collections) that is used to fund obligations for FY 2018 and FY 2019. The "Target Revenue" is the total revenue amount set out in section 741(b)(1) of the FD&C Act (statutory fee revenue amount), after adjustment for inflation and/or workload when applicable. The target revenue amount is determined as part of the process of setting fee rates for the fiscal year. "Net Collections" are the actual amounts collected during the fiscal year.

AGDUFA III specifies how the fees must be calculated each fiscal year, including annual adjustments to revenue amounts that must be made for inflation for FY 2020 through FY 2023. After the applicable inflation adjustment to fees is done, FDA may further increase the fee revenue amounts to reflect changes in workload for FY 2020 through FY 2023. For FY 2021 through 2023, if fee revenue is increased to reflect changes in workload, the increase may be reduced by the amount of any excess collections for the second preceding fiscal year, up to the full amount of the workload-based fee revenue increase. However, the reduction for excess collections cannot result in fee revenues for a fiscal year that are less than the inflation-adjusted amount originally calculated.

Obligations: The "Obligations" component of **Table 1** shows the annual expenditure of AGDUFA fee funds broken out into major expense categories. AGDUFA fees may be expended only for costs to support the "process for the review of abbreviated applications for generic new animal drugs," as defined in AGDUFA III.

Carryover: AGDUFA fees are available until expended, with certain exceptions. This means that the fees that are collected, appropriated, and not obligated at the end of the fiscal year remain available to FDA for use in future fiscal years. The unobligated fee funds at the end of each fiscal year are referred to for purposes of this report as the "carryover balance." Maintaining an appropriate level of carryover balance enables FDA to mitigate financial risks to the program, including for example, the risk of under-collecting fees and the financial challenges associated with a lapse in appropriations, so that FDA can continue performing reviews of abbreviated applications for generic new animal drugs under these financial constraints. When setting fees for the final FY of AGDUFA III, FDA is authorized to increase fees, if necessary, to provide for up to 3 months of available carryover balance at the end of FY 2023 (final year adjustment reserve) to sustain operations for the first 3 months of FY 2024. See **Section K** for more information on carryover balances and the final year adjustment reserve.

I. User Fee Revenue

Table 2 outlines the annual target revenue amounts for each fiscal year. These amounts are used to establish the AGDUFA fee rates for each fiscal year. The financial notes referenced in this table can be found in **Appendix E.**

Table 2: Generic New Animal Drug Target Revenue for FY 2019

Target Revenue	Notes	FY 2019
Statutory Fee Revenue Amount		$18,336,340
Inflation Adjustment	Note 5	N/A
Workload Adjustment	Note 6	N/A
Target Revenue Total		**$18,336,000**

Target Revenue Total has been rounded to the nearest thousand dollars.

The process for adjusting the statutory fee revenue amount for inflation and/or workload, when applicable, to calculate the annual target revenue amount that will be used to set the fee rates for each FY is described in the statute. For FY 2019, the adjustments for inflation and workload do not apply. Therefore, the total target revenue amount is the same as the fee revenue amount specified in the AGDUFA statute for FY 2019. Using the target revenue amount, FDA calculates the fee rates for the fiscal year and publishes the rates in the *Federal Register*.

AGDUFA authorizes FDA to collect application fees, product fees, and sponsor fees. User fee collections are recognized and reported in the year the fee was originally due (referred to as the "cohort year"). Totals reported for each fiscal year are net of any refunds for the cohort year. To ensure the quality of the information provided in this financial report, FDA annually updates the prior years' numbers.

Cohort Year

The year in which user fee collections are originally due and reported. For example, a fee originally due in FY 2019, but received in FY 2020, is attributed to FY 2019 collections.

Increase in Collections

The primary factor in the increase in collections was the increase in target revenue in AGDUFA III.

Table 3 outlines AGDUFA collections by fee source and cohort year.

Table 3: Generic New Animal Drug User Fee Collections by Fee Type for Cohort Years 2018 and 2019

Fees Collected	Cohort Year 2018			Cohort Year 2019		
	Estimated†	Actual	% Dif.	Estimated††	Actual	% Dif.
Application Fees	$2,355,000	$2,219,500	-6%	$4,584,000	$5,942,216	30%
Product Fees	$3,532,000	$3,695,945	5%	$6,876,000	$6,720,924	-2%
Sponsor Fees	$3,532,000	$3,393,079	-4%	$6,876,000	$6,003,856	-13%
Total Collections	**$9,419,000**	**$9,308,524**	**-1%**	**$18,336,000**	**$18,666,996**	**2%**

Fees Receivable	FY 2018	FY 2019
Product Fees	$0	$15,486
Sponsor Fees	$38,125	$262,672
Total Receivables	**$38,125**	**$278,158**

Numbers have been rounded to the nearest dollar.
†Estimated values were taken from the generic new animal drug user fee rates for FY 2018.[3]
†† Estimated values were taken from the generic new animal drug user fee rates for FY 2019.[4]

J. User Fee Obligations

AGDUFA fees may be expended only for costs to support the "process for the review of abbreviated applications for generic new animal drugs," as defined in AGDUFA III. For more information on the allowable and excluded costs, see **Appendix B.**

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

[3] https://www.gpo.gov/fdsys/pkg/FR-2017-08-02/pdf/2017-16181.pdf.
[4] https://www.govinfo.gov/content/pkg/FR-2018-09-26/pdf/2018-20912.pdf

Table 4: Generic New Animal Drug User Fee Obligations by Expense Category for FYs 2018 and 2019

User Fee Obligations	Notes	FY 2018	FY 2019
Payroll & Operating	Note 2		
CVM		$9,830,749	$11,763,742
ORA		$0	$0
HQ		$188,043	$657,135
Total Rent	Note 3	$565,359	$439,683
Total Shared Services	Note 4	$1,431,999	$2,028,178
Total Obligations		**$12,016,150**	**$14,888,738**

Numbers have been rounded to the nearest dollar.

Total obligations include payroll and operating, rent, and shared services costs. The details of each component of total obligations are as follows:

- **Payroll and Operating:** These obligations provide for all payroll and operating costs that support the allowable activities for which AGDUFA fees may be expended, as set forth in the statute. Payroll and operating includes, for example, core regulatory review functions, pre-approval inspections, guidance and policy development activities, scientific activities, and management and administrative functions that support the AGDUFA program.
- **Rent:** This is paid to the General Services Administration (GSA) for the federal buildings that FDA occupies, as well as to non-federal sources for direct leases and services. Rent is charged at different rates depending on the type and location of the space provided.
- **Shared Services:** FDA has several shared service organizations that provide support across the user fee programs, such as human resources and IT.

In preparation for the start of AGDUFA III in FY 2019 with significantly reduced review timeframe performance goals, CVM hired additional FTEs. CVM began hiring the FTEs in FY 2018, with the full payroll for the additional hires realized in FY 2019. There were two additional HQ FTEs negotiated ahead of the reauthorization, which caused the increase in HQ from FY 2018 to FY 2019.

For historical context, **Table 5** provides the total amount spent by FDA and by each FDA organization on the AGDUFA program for the past 5 years, including both user fee and non-user fee appropriation obligations. As illustrated by the table, costs have increased over time and the percentage spent by each FDA organizational component has remained steady.

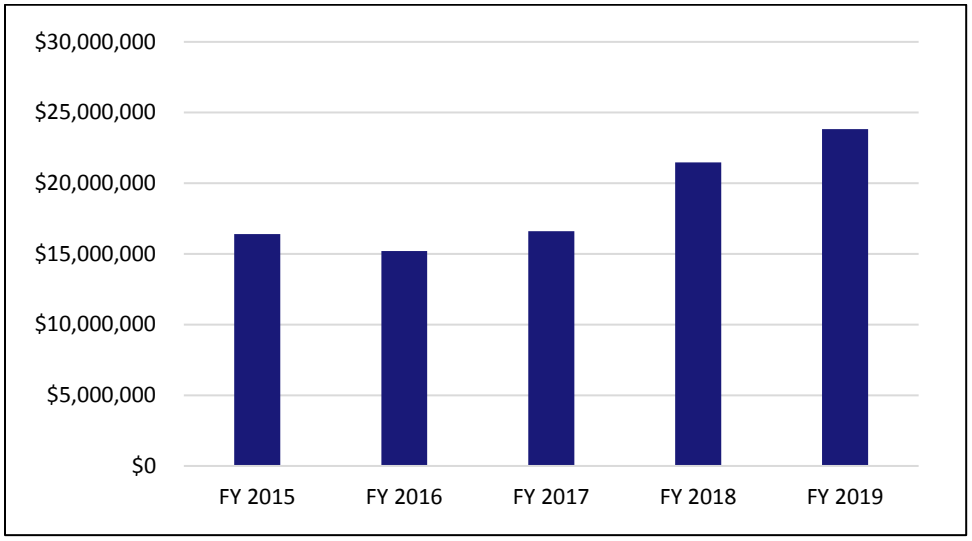
Table 5: AGDUFA Program – Historical Trend of Total Costs by Organization as of September 30 of Each Fiscal Year

Costs		FY 2015	FY 2016	FY 2017	FY 2018	FY 2019
Total Spent		$16,393,690	$15,212,327	$16,605,270	$21,474,259	$23,827,759
CVM	Spent	$14,674,326	$13,427,926	$14,819,138	$19,293,437	$21,239,206
	Percent	90%	88%	89%	90%	89%
ORA	Spent	$454,419	$461,358	$198,813	$481,508	$293,381
	Percent	3%	3%	1%	2%	1%
HQ	Spent	$1,264,945	$1,323,043	$1,587,319	$1,699,314	$2,295,172
	Percent	8%	9%	10%	8%	10%

Numbers have been rounded to the nearest dollar.

Exhibit 4 below provides an illustration of the combined historical AGDUFA costs for CVM, ORA, and HQ for the past 5 fiscal years.

Exhibit 4: Historical Total Costs by Fiscal Year



As demonstrated by this graph, there was a significant increase in AGDUFA program expenditures over the last 5 years. This increase was largely driven by adjustment for significant increase in workload and the increase of non-user fee appropriations received from Congress.

K. User Fee Carryover

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

Maintaining an appropriate level of carryover balance enables FDA to mitigate financial risks to the program, including for example, the risk of under-collecting fee amounts and the risk of a lapse in appropriations. FDA requires approximately 8 to 10 weeks of operating expenses to mitigate financial risks to the program.

The carryover balance includes two categories:

- **Carryover Unavailable for Use** – This value represents carryover funds subject to claims or restrictions that preclude FDA from obligating the carryover funds.
- **Carryover Available for Use** – This value represents carryover funds that are not subject to any claims or restrictions and are therefore available for obligation.

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

Table 6 provides the AGDUFA carryover balance at the end of FY 2019. The financial notes can be found in **Appendix E.**

Table 6: AGDUFA Carryover Balance for FY 2019

Carryover Balance	Notes	FY 2019
Total Carryover, End of Year		**$14,924,330**
Refunds	Note 7	$100,000
Unappropriated Amounts		$2,363,711
Final Year Adjustment Reserve		$5,037,750
Carryover Unavailable for Use, End of Year		**$7,501,461**
Carryover Available for Use, End of Year		**$7,422,869**

Numbers have been rounded to the nearest dollar.

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

- **Total Carryover, End of Year** – This is the total amount of unobligated fee funds at the end of the fiscal year.
- **Carryover Unavailable for Use, End of Year** – As noted above, this value includes unobligated fee funds subject to claims or restrictions. This includes:
    - **Refunds** – FDA maintains a small amount to provide for any refunds, as a matter of prudent operations. For that purpose, a total of $100,000 is set aside. See **Note 7** for additional details.
    - **Unappropriated amounts** - $2,363,711 was collected in excess of appropriations during AGDUFA I (FY 2009 to FY 2013) and is deemed unavailable for obligation.
    - **Final Year Adjustment Reserve** – FDA requires approximately 8 to 10 weeks of operating expenses to mitigate financial risks to the program but for FY 2023 has the authority to collect up to 12 weeks (3 months) of operating expenses for this purpose.
- **Carryover Available for Use, End of Year** – As noted above, this is the total carryover balance less any carryover balance unavailable for use. These funds become the carryover balance available for use at the beginning of the next fiscal year.

The operations in FY 2019 resulted in a net increase of the total carryover balance of $4,123,520 from $10,800,810 at the end of FY 2018 to $14,924,330 at the end of FY 2019. CVM obligated less than the FY 2019 net collections, resulting in an increase to the carryover balance. Early in reauthorization cycles, collections outpace obligations because of the timing of obligating funds within the fiscal year, resulting in new carryover. For the AGDUFA program, user fee expenditures increased from FY 2018 to FY 2019, and CVM anticipates that these expenditures will also increase in FY 2020 as the program spends additional resources to continue meeting performance goals.

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

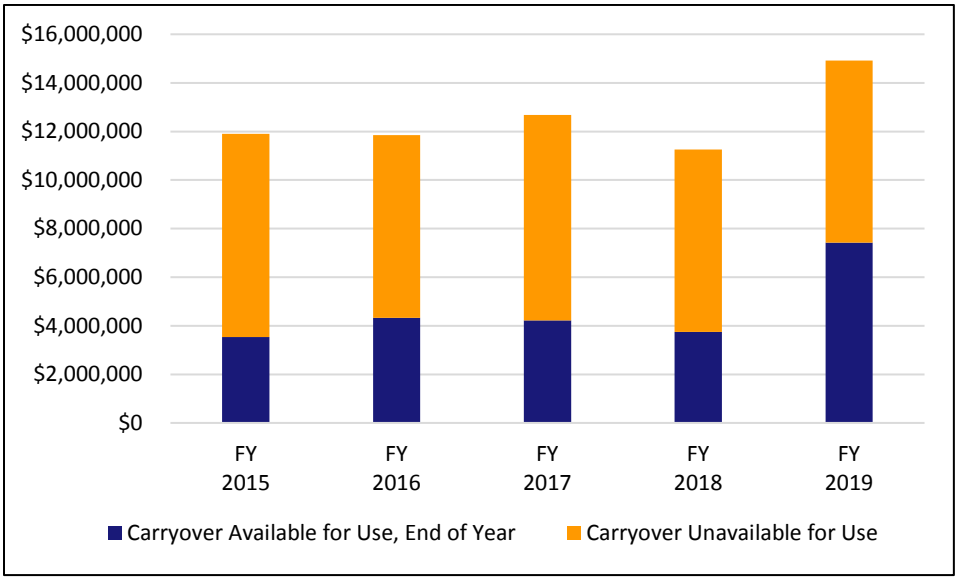
Table 7: Historical Generic New Animal Drug User Fee Collections, Obligations, and Carryover Balances by Reauthorization Period

Carryover Balance	Notes	AGDUFA I	AGDUFA II	AGDUFA III
		FY 2009 – 2013	FY 2014 – 2018	FY 2019
Total Carryover, Beginning of Year		**$0**	**$8,546,799**	**$10,800,810**
Net Collections		$29,641,950	$48,190,167	$18,775,214
Recoveries	Note 1	$0	$203,538	$237,044
Total Obligations		($21,095,151)	($46,139,693)	($14,888,738)
Total Carryover, End of Year		**$8,546,799**	**$10,800,810**	**$14,924,330**

Numbers have been rounded to the nearest dollar.

Exhibit 5 provides a historical perspective of carryover balances for the last 5 fiscal years. FY 2018 shows a decrease in the carryover balance as the funds that had been held for the AGDUFA II final year offset were used to reduce the FY 2018 AGDUFA fee amounts, as authorized by AGDUFA II. The offset provision has been removed for AGDUFA III in favor of a provision allowing the reduction of any workload-based increase by the amount of certain excess collections in FY 2021 through FY 2023.

Exhibit 5: Historical Carryover Balances by Fiscal Year



L. Non-User Fee Appropriations

For FDA to obligate user fees collected under AGDUFA, a certain minimum amount of non-user fee appropriations must be spent on the process for the review of generic new animal drug applications during that fiscal year. This is often referred to as a "non-user fee spending trigger." (See Legal Condition 3 in Exhibit 3). The non-user fee spending trigger was $6,504,924 for FY 2019.

The "non-user fee spending trigger amount" is the amount of non-user fee appropriations spent on the generic new animal drug review process in FY 2008 ($5,510,000), multiplied by the adjustment factor. See **Note 8** for more details on the adjustment factor.

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

Table 8: Historical Animal Generic Drug User Fee Obligations by Funding Source as of September 30 of Each Fiscal Year

Obligations		FY 2015	FY 2016	FY 2017	FY 2018	FY 2019
Total Obligated		$16,393,689	$15,212,327	$16,605,270	$21,474,259	$23,827,759
Non-User Fee Appropriations	Total	$7,700,164	$6,300,520	$6,245,725	$9,458,110	$8,939,021
	Percent	47%	41%	38%	44%	38%
User Fee Funds	Total	$8,693,525	$8,911,806	$10,359,544	$12,016,150	$14,888,738
	Percent	53%	59%	62%	56%	62%

Numbers have been rounded to the nearest dollar.

M. Full-Time Equivalents

"FTE employment" (often referred to as "staff year") as defined by Office of Management and Budget (OMB) Circular No. A-11, section 85, means the total number of regular straight-time hours—not including overtime or holiday hours—worked by employees, divided by the number of compensable hours applicable to each fiscal year. Annual leave, sick leave, compensatory time off, and other approved leave categories are considered "hours worked" for purposes of defining FTE employment.

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

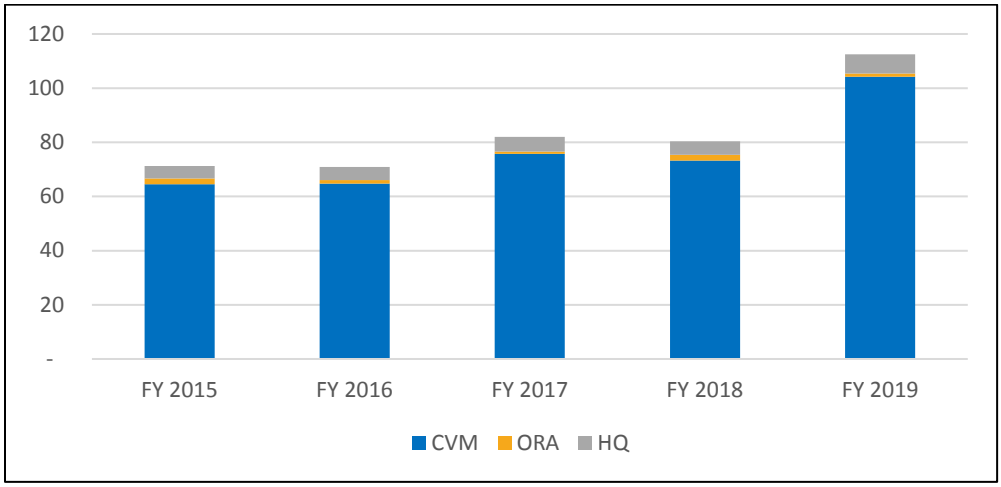
Table 9 presents total Process FTE levels, paid from user fee collections and non-user fee appropriations, that support the AGDUFA program. The data cover the past 5 years and are arranged by FDA organizational components (CVM, ORA, and HQ). Staff in the consolidated shared services organizations (facilities,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

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

Fiscal Year	FY 2015	FY 2016	FY 2017	FY 2018	FY 2019
CVM	64	65	76	73	104
ORA	2	1	1	2	1
HQ	5	5	5	5	7
Total	**71**	**71**	**82**	**80**	**112**

Exhibit 6 provides the historical trend of total Process FTE levels for AGDUFA across CVM, ORA, and HQ for the past 5 years. AGDUFA III allowed for a significant increase in FTEs in FY 2019 to support reduced review time performance goals.

Exhibit 6: Historical Total Process FTE Levels by FDA Organization



Management Assurance

N. Internal Controls

The Federal Managers' Financial Integrity Act of 1982 (FMFIA) is intended to strengthen internal controls and accounting systems. OMB Circular No. A-123, *Management's Responsibility for Internal Control and Enterprise Risk Management* (OMB A-123), implements the requirements of the FMFIA. The FMFIA requires that management establish and maintain effective internal control to achieve the following objectives:

1. Effective and efficient operations,
2. Reliable financial reporting, and
3. Compliance with applicable laws and regulations.

The Department of Health and Human Services (HHS) provides guidance to its operating divisions (OpDivs) to implement FMFIA through its FMFIA Guidelines. OpDivs, including FDA, are responsible for developing and maintaining a cost-effective internal control and compliance program that includes programmatic and operational controls, as well as controls over financial reporting, and supports sound financial management. The Government Accountability Office *Standards for Internal Control in the Federal Government* (Green Book) states, "Management is responsible for an effective internal control system. As part of this responsibility, management sets the entity's objectives, implements controls,

and evaluates the internal control system." OMB A-123 requires an annual internal control assessment, and FMFIA requires the head of each executive agency to report annually to the President and Congress on the effectiveness of the internal controls and any identified material weaknesses in those controls. FDA's FY 2019 Assurance Statement, already submitted to HHS, found no material weaknesses or financial system nonconformances.

Additionally, FDA has established a Senior Assessment Team (SAT) as the governance body responsible for providing oversight and accountability for FDA's internal control over financial reporting, including overseeing the FMFIA and OMB A-123 assessments, and for fostering an environment that promotes strong internal control. The SAT is chaired by the FDA Chief Financial Officer (CFO) and co-chaired by the Deputy CFO and Director of the Office of Financial Management, as well as a Program Co-Chair who is a Center Deputy Executive appointed by the CFO. The SAT members are representatives from each FDA Center and Office.

In accordance with FMFIA, OMB A-123, the Green Book, and HHS guidelines, FDA has a robust internal control program, including integrated controls throughout processes. The Agency also conducts an annual assessment of its internal control activities as well as operational risk reviews. In addition, FDA has an Enterprise Risk Management (ERM) Program, which began in earnest in FY 2016 and is integrated with FDA's FMFIA efforts. Under the ERM Program, FDA has refreshed the enterprise risk profile and facilitated risk response planning for five priority enterprise risks. To accomplish this, Centers and Offices have engaged through senior leadership interviews, as well as working groups and problem-solving sessions. Further, FDA has established an ERM Community of Practice and continues to align and integrate core ERM methodologies with those of internal controls. FDA's ERM Program has facilitated cross-Center and Office collaboration to identify and manage risks. This program is governed by the ERM Council, which is chaired by the Chief Operating Officer and the Center for Drug Evaluation and Research Deputy Director for Operations.

FDA's internal control program includes an evaluation of controls over reporting, charge card compliance, improper payments, and financial systems compliance. One of the cycle memos included in the assessment scope includes internal controls over reporting for the reimbursable activity process, specifically focused on the Accounts Receivable and Payment process associated with the user fee programs. This includes controls over reconciliation performance, aging, write-offs, and the interface between the User Fee System and the Unified Financial Management System. As an FDA-owned system, FDA's User Fee System is compliant with HHS requirements and requirements of the Federal Financial Management Improvement Act of 1996 (FFMIA). In addition, FDA's Integrated Budget and Acquisition Planning System (IBAPS) meets FDA and HHS system requirements.

FDA is also a participant in the annual audit of the consolidated financial statements of HHS, including the consolidated balance sheet, the related consolidated statement of net costs and changes in net position, the combined statement of budgetary resources, and the related notes to the financial statements. The FY 2019 audit found that the financial statements fairly present, in all material respects, the consolidated financial position of HHS as of September 30, 2019, and 2018, and its consolidated net cost, changes in net position, budgetary resources, and related notes are in accordance with generally accepted accounting principles in the United States.

FDA has also implemented other internal control procedures, including a continuous monitoring program to oversee the timely implementation of corrective action plans for deficiencies identified through any of its control assessments. This continuous monitoring program allows for management oversight of targeted remediation efforts and strengthening of internal controls. In addition, FDA offers annual internal control training sessions, which cover the importance of internal controls, timely deficiency remediation, and roles and responsibilities.

O. Risks and Challenges

Financial Risks and Mitigation

As is the case with all financial programs, there are certain financial risks and challenges that exist with FDA's user fee programs. These risks and challenges can vary from program to program, with some being in FDA's control and some out of FDA's control. An example of a shared financial risk across all user fee programs is that FDA cannot obligate funds in advance of receiving the funds, either through appropriated user fee collections or non-user fee appropriations. FDA can assume only what the Agency's total appropriation will be in any given year. As a result, FDA has some risk of missing important performance goals, or failing to meet the non-user fee spending trigger for the fiscal year if that total appropriation comes in considerably lower than anticipated. Below is a list of foreseeable risks associated with the collections and obligations of funds for which FDA has identified contingency plans in order to move forward in the best interest of the program.

- **Uncertainty of User Fee Collections and Non-User Fee Appropriations Levels:** It is difficult to predict the amount of non-user fee appropriations that will be approved by Congress, which creates planning challenges as non-user fee fund levels are often uncertain for a good portion of the fiscal year. This is because of prolonged Continuing Resolutions (CRs), versus enactment of annual appropriations bills early in the fiscal year. Fluctuations in industry submissions from year to year can change the total program cost. This creates a situation where, because of extended CR periods, FDA is uncertain of its non-user fee appropriations for a significant portion of the fiscal year, yet it must still meet the non-user fee spending trigger.

- **Lapse in Non-User Fee Appropriations:** FDA is mitigating this risk to the program by maintaining a certain level of AGDUFA fees collected as a carryover balance. FDA requires approximately 8 to 10 weeks of operating expenses to mitigate financial risks to the program. This reserve can be used to help support program operations in the event of a shutdown.

- **Under-Executing Planned Spending:** Historically, AGDUFA budgetary resources have been under-spent because of the uncertainty of revenue (user fee and non-user fee) and non-user fee spending trigger requirements. To minimize this risk, FDA worked with Congress on a non-user fee appropriation increase in FY 2017 and FY 2018 to alleviate some of the challenges meeting the spending trigger requirement.

- **Under Collecting and Over Collecting Fees:** If FDA does not receive the estimated number of industry submissions, there may be an excess or deficit in net collections as compared to the target revenue. When FDA under-collects user fees, it leverages its carryover balance to maintain continuity in operations. If FDA over-collects in FY 2021 through FY 2023, the excess collections will be used to reduce any increases in fee revenue resulting from workload-based adjustments, up to the amount of the fee revenue increase. FDA monitors collections throughout the fiscal year, and the User Fee Financial Management Committee and other FDA senior leaders determine how to mitigate any instances when user fee collection is off forecasted estimates.

In addition to these mitigation strategies, FDA implemented IBAPS to enable greater and more timely insight into budget activity across the Agency. IBAPS improves the accuracy and availability of budget and acquisition information that enables FDA to better plan, forecast, track, and analyze the data to make better decisions about the best use of its resources.

Strategic Challenges

In FY 2020, 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 FY 2020 include continued support of an all-electronic review environment and responding to increases in the volume of submissions.

Appendices

A. Reporting Requirements

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

Requirement	Details
Section 742(b) of the FD&C Act	"Beginning with fiscal year 2019, not later than 120 days after the end of each fiscal year during which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Health, Education, Labor and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected during such fiscal year for which the report is made."

B. Allowable and Excluded Costs for the AGDUFA Program

Section 741(k)(10) of the FD&C Act defines the phrase "process for the review of abbreviated applications for generic new animal drugs" to mean the following activities of FDA with respect to the review of abbreviated applications, supplemental abbreviated applications, and investigational submissions:

Included Activities	
1. The activities necessary for the review of abbreviated applications, supplemental abbreviated applications, and investigational submissions. 2. 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. 3. 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. 4. Monitoring of research conducted in connection with the review of abbreviated applications, supplemental abbreviated applications, and investigational submissions.	5. The development of regulations and policy related to the review of abbreviated applications, supplemental abbreviated applications, and investigational submissions. 6. Development of standards for products subject to review. 7. Meetings between the Agency and generic new animal drug sponsor. 8. Review of advertising and labeling prior to approval of an abbreviated application or supplemental abbreviated application, but not after such application has been approved.

Section 741(k)(3) of the FD&C Act defines the phrase "costs of resources allocated for the process for the review of abbreviated applications for generic new animal drugs" as the expenses in connection with the process for the review of abbreviated applications for generic new animal drugs for:

Included Expenses
1. Officers and employees of FDA; contractors of FDA; 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, recruitment, and other personnel activities; 2. Management of information and the acquisition, maintenance, and repair of computer resources; 3. Leasing, maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, scientific equipment, and other necessary materials and supplies; and 4. Collecting fees under this section and accounting for resources allocated for the review of abbreviated applications, supplemental abbreviated applications, and investigational submissions.

The AGDUFA program does not include costs related to the following activities:

Excluded Activities
1. Review of new animal drug applications and other pioneer submissions 2. Enforcement policy development 3. Post-approval surveillance and compliance activities 4. Post-approval activities relating to the review of advertising 5. Inspections unrelated to the AGDUFA program 6. Research unrelated to the AGDUFA program

C. User Fee Program History

AGDUFA was enacted in 2008 and reauthorized in 2013 (AGDUFA II) and 2018 (AGDUFA III) with the support of industry, other stakeholders, Congress, and the Administration. The FD&C Act, as amended by AGDUFA III, authorizes FDA to collect user fees from the animal drug industry to supplement the non-user fee appropriations that the Agency spends on the process for the review of abbreviated applications for generic new animal drugs. FDA spends fee revenues and non-user fee appropriations to hire, support, and maintain personnel for this review to help ensure that safe and effective generic new animal drugs reach the American public in a timely manner.

D. Conditions for Assessment and Use of Fees

Introduction

The FD&C Act, as amended by AGDUFA III, 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 describes these legal conditions and the applicable adjustment factors, as described in the FD&C Act.

Adjustment Factor

To determine whether the legal conditions are satisfied, FDA must calculate and incorporate "adjustment factors" (as defined in section 741(k)(2)) in the assessment of the first and third legal conditions.

Section 741(k)(2) of the FD&C Act 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

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.

For the first legal condition (section 741(f)(1) of the FD&C Act) adjustment factor, the Consumer Price Index (CPI) for October 2017, the October of the fiscal year preceding FY 2019, was 246.663. The CPI for October 2002 was 181.3. Dividing the CPI of October 2017 by the CPI of October 2002 yields an adjustment factor of 1.360524 (rounded to six decimal places) for FY 2019.

For the third legal condition (section 741(g)(2)(A)(ii) of the FD&C Act) adjustment factor, the base month is October 2007. The CPI for October 2017, the October of the FY preceding FY 2019, was 246.663. The CPI for October 2007 was 208.936. Dividing the CPI of October 2017 by the CPI of October 2007 yields an adjustment factor of 1.180567 (rounded to six decimal places) for FY 2019.

Legal Conditions

First legal condition: 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 1.360524 (rounded to the sixth decimal place) equals $1,868,970,866.

Second legal condition: Division A, Title VI of Public Law 116-6 specified that $18,335,000 shall be derived from generic new animal drug user fees, and that generic new animal drug user fees collected in excess of this amount, if any, are appropriated for FDA.

Third legal condition: In FY 2008, the amount spent from appropriations for the AGDUFA program was $5,510,000 (rounded to the nearest thousand). After applying the adjustment factor of 1.180567 (rounded to the sixth decimal place), the minimum appropriation spending level for the AGDUFA program for FY 2019, excluding user fees, is $6,504,924.

Exhibit 7 below provides the details regarding each of the three legal condition that must be met each fiscal year, as quoted from the FD&C Act.

Exhibit 7: Legal Conditions

Legal Condition #	FD&C Act Section	Details
1	741(f)(1)	Fees may not be assessed under [section 741(a) of the FD&C Act] for a fiscal year beginning after fiscal year 2008 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.
2	741(g)(2)(A)(i)	The fees authorized by [section 741 of the FD&C Act]--subject to [section 741(g)(2)(C)], shall be collected and available in each fiscal year in an amount not to exceed the amount specified in appropriation Acts, or otherwise made available for obligation for such fiscal year.
3	741(g)(2)(A)(ii)	The fees authorized by [section 741 of the FD&C Act] 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.

E. Financial Notes

Note 1. Recoveries

Recoveries account for funds returned to the Agency in the form of deobligations of prior year obligations. For example, recoveries could include funding from a contract that ended in a prior year and was not expended.

Note 2. Payroll and Operating Costs

Payroll and operating costs associated with the AGDUFA program are based on obligations attributed to CVM, ORA, and HQ. These costs relate to how much of the AGDUFA revenue is going toward payroll and operating expenses.

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

Note 3. Rent Costs

GSA charges rent to FDA for the federal buildings that FDA occupies. Rental rates vary based on the type and location of the space provided. Because rent is an essential support cost for the process for the review of abbreviated applications for generic new animal drugs, a portion of those charges is paid from non-user fee appropriations and a portion is paid from AGDUFA fees. Also included in this account are recurring costs that FDA pays to non-federal sources under the delegation of direct lease and service authority. These services include rental of space and all recurring services for building operations such as overtime utilities, janitorial services, guards, and ground maintenance. The amount of rent and rent-related costs each Center pays is directly related to the number of employees that must be housed for that Center.

Note 4. Shared Service Costs

FDA contains several shared service organizations that provide support across the user fee programs. The shared service organizations include:

- **FDA Central**: Provides for Center-wide and Agency-wide services such as telecommunications, training, printing, mail and document management, IT systems, employee health units, and other support and miscellaneous services.
- **Employee Resource & Information Center (ERIC)**: Provides support to all FDA employees requesting administrative, IT, facilities, human resources, and other employee services.
- **Employee Safety & Environmental Management (ESEM)**: Provides safety, health, and environmental compliance for all FDA employees.
- **Office of Acquisitions and Grants Services (OAGS)**: Manages contracts, grants, and other agreements.
- **Office of Equal Employment Opportunity (OEEO)**: Promotes an inclusive work environment that ensures equal employment opportunity and fosters a culture that values diversity and empowers individuals.

- **Office of Facilities, Engineering, and Mission Support Services (OFEMS)**: Provides FDA employees with office and laboratory facilities.
- **Office of Financial Management (OFM):** Provides financial managerial services and policy guidance.
- **Office of Human Resources (OHR)**: Supports workforce relations, client services, executive resources, accountability programs, policy and program development, and systems data and management.
- **Office of Information Management and Technology (OIMT)**: Provides the information, communication, and knowledge infrastructure and services that enhance, transform, and sustain the ability of FDA to protect and promote the public health.
- **Alternative Dispute Resolution (ADR):** Provides an alternative resource to existing administrative processes and assists in addressing work-related issues.
- **Division of Budget Execution and Control (DBEC):** Initiates, monitors, and analyzes FDA budget resources. The Agency budget is comprised of several appropriation accounts, including: Salaries and Expenses, Revolving Fund for Color Certification and other Services, Cooperative Research and Development Agreement, Contingency Fund, Building and Facilities, and Royalties.
- **Division of Ethics and Integrity (DEI):** Protects the integrity of FDA's programs and operations by promoting an ethical culture and ensuring compliance with applicable federal ethics laws.
- **Management Analysis Services Staff (MASS):** Provides organizational expertise and policy advice, as well as consultation and support to ensure an efficient Agency structure that delivers on the FDA mission.
- **Office of External Affairs – History:** Provides research, documentation, and preservation of significant FDA historical resources, as well as serving as historian for the Agency.
- **Office of Security Operations (OSO):** Develops and implements the Agency-wide security policies and programs by providing leadership and guidance to managers and staff on all aspects of security. Administers vital security functions that contribute to the Agency's mission of protecting the public health by enhancing the safety and security of all personnel, facilities, and information.
- **Paperwork Reduction Act (PRA):** Acts as the liaison between FDA Centers, HHS, and OMB on all information collection matters.

Note 5. Inflation Adjustment

The fee revenue amount established in AGDUFA III for FY 2020 and subsequent fiscal years is subject to adjustment to account for inflation. The inflation adjustment adjusts the annual fee revenue amounts specified in the AGDUFA statute (see section 741(b)(1) of the FD&C Act) to maintain the purchasing power of fee funds despite inflation. The adjustment adjusts the non-payroll-related portion by changes in the Consumer Price Index (CPI) and adjusts the payroll-related portion by changes in FDA's average personnel compensation and benefits.

AGDUFA III did not provide for an inflation adjustment in FY 2019 (see section 741(c)(2) of the FD&C Act).

Note 6. Workload Adjustment

The fee revenue amounts established in AGDUFA III for FY 2020 and subsequent fiscal years are also subject to adjustment to reflect changes in FDA's workload for the process for the review of abbreviated applications. A workload adjustment will be applied to the inflation-adjusted fee revenue amount (section 741(c)(3) of the FD&C Act).

AGDUFA III specifies that FDA shall calculate the weighted average of the change in the total number of each of the four types of applications and submissions specified in the workload adjustment provision: 1) abbreviated applications for generic new animal drugs, 2) manufacturing supplemental abbreviated applications for generic new animal drugs, 3) investigational generic new animal drug study submissions, and 4) investigational generic new animal drug protocol submissions. Because the adjustment for workload does not take effect until FY 2020, FDA did not adjust the FY 2019 fee revenue amount for workload changes.

Note 7. Refunds

If a sponsor pays the fee for an abbreviated application which is subsequently refused for filing, the sponsor receives a refund for 75 percent of the fee paid (section 741(a)(1)(D) of the FD&C Act). If an abbreviated application is withdrawn after the application has been filed, the sponsor may receive a refund of the fee or portion of the fee paid if no substantial work was performed by the Agency on the application after it was filed (section 741(a)(1)(E) of the FD&C Act).

To qualify for consideration for a waiver or reduction in fees, or for a refund, a written request must be submitted to FDA no later than 180 days after such fee is due (section 741(i) of the FD&C Act).

Note 8. Minimum Non-User Fee Appropriations Adjustment Factor

FDA must calculate and incorporate an adjustment factor for the third legal condition. For purposes of AGDUFA III, the following definition is applied:

> 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[,] … for purposes of [section 741(g)(2)(A)(ii) of the Act (the third legal condition)], such Index for October 2007 (section 741(k)(2)(B) of the FD&C Act).