Financial Report to Congress

Animal Generic Drug User Fee Act

FY 2025

U.S. FOOD & DRUG ADMINISTRATION

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Executive Summary

The Animal Generic Drug User Fee Act of 2008 (AGDUFA), as amended, requires the Food and Drug Administration (FDA) to report to Congress annually on the financial aspects of AGDUFA implementation. This is the second report under the fourth authorization of AGDUFA (AGDUFA IV) and covers fiscal year (FY) 2025.

AGDUFA 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 2025 and this report explains how these legal conditions were satisfied. The statements and tables in this report provide data on animal generic drug user fee collections, expenditures, and carryover, as well as comparative data from prior fiscal years.

In FY 2025, FDA had net collections of $29 million in animal generic drug user fees, spent $22 million in user fees for the animal generic drug review process, and carried $68 million forward for future fiscal years.

AGDUFA user fees and non-user fee appropriations in FY 2025 supported 142 full-time equivalents, including salaries and operational expenses, to support the process for the review of generic new animal drug applications. Detailed program accomplishments can be found in the AGDUFA Performance Report.[1]

[1] The AGDUFA Performance Report is available at https://www.fda.gov/about-fda/fda-track-agency-wide-program-performance/fda-track-animal-generic-drug-user-fee-act-agdufa-performance-reports.

Report Overview

A. Scope

This financial report addresses the implementation and use of animal generic drug user fees by the Food and Drug Administration (FDA or Agency) during the period from October 1, 2024, through September 30, 2025. It presents the legal conditions that FDA must satisfy to collect and spend animal generic drug user fees each year and documents how FDA determined that it had met those requirements. In addition, this report presents summary statements of fiscal year (FY) 2025 fee collections, carryover, obligations of user fees, and total costs of the process for the review of generic new animal drug applications from both Animal Generic Drug User Fee Act of 2008 (AGDUFA) fees and non-user fee appropriations.

B. Report Requirements

In accordance with section 742(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), FDA will publish an annual financial report on the implementation of the authority for user fees during such fiscal year and the use by FDA of the fees collected for such fiscal year.

FDA is required to submit the financial report to Congress no later than 120 days after the end of each fiscal year (September 30). The purpose of this report is to meet these requirements.

The Animal Drug and Animal Generic Drug User Fee Amendments of 2023 extends FDA's requirements for financial reports through FY 2028.

C. User Fee Background and Structure

Under AGDUFA, FDA assesses and collects fees from animal generic drug sponsors to help fund the generic new animal drug review process. The FD&C Act, as amended by AGDUFA, authorizes FDA to collect fees from industry to supplement the non-user fee appropriations that the Agency spends on the process for the review of generic new animal drug applications.

AGDUFA was enacted in 2008, reauthorized in 2013 (AGDUFA II), 2018 (AGDUFA III), and most recently in 2023 (AGDUFA IV) via the Animal Drug and Animal Generic Drug User Fee Amendments of 2023. AGDUFA IV authorizes continued user fee funding for FDA from FY 2024 through FY 2028 to support program operations, evaluation, and improvement. 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 applications. AGDUFA has delivered public health benefits by enhancing FDA's capacity to review generic new animal drug submissions so that safe and effective products can be brought to the market.

AGDUFA IV establishes four different types of user fees: (1) fees for certain types of abbreviated applications for generic new animal drugs; (2) annual fees for certain generic new animal drug products; (3) annual fees for certain sponsors of abbreviated applications for generic new animal drugs and/or investigational submissions for generic new animal drugs; and, (4) generic investigational new animal drug (JINAD) file fees.

The proportion of target revenue derived from each type of user fee are 20 percent from fees for abbreviated applications for a generic new animal drug and JINAD file fees, 40 percent from fees for generic new animal drug products, and 40 percent from fees for generic new animal drug sponsors.

Exhibit 1 outlines the AGDUFA IV fee structure.

Exhibit 1: AGDUFA IV Fee Structure

Fee Type	Definition
Application: (FD&C Act Section 741(a)(1))	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: (FD&C Act Section 741(a)(2))	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 for a generic new animal drug product pending at FDA after September 1, 2008, shall pay an annual fee for each such animal drug product.
Sponsor: (FD&C Act Section 741(a)(3))	The sponsor fee must be paid annually by each person who: (1) is named as the applicant in an abbreviated application for a generic new animal drug 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 and, (2) had an abbreviated application for a generic new animal drug, supplemental abbreviated application for a generic new animal drug, or investigational submission for a generic new animal drug pending at FDA after September 1, 2008. An animal drug sponsor is subject to only one fee each fiscal year.
JINAD: (FD&C Act Section 741(a)(4))	Each person that (1) submits a request to establish a new JINAD file on or after October 1, 2023, or, (2) makes a submission to a JINAD on or after October 1, 2023, where such file was established prior to that date shall be subject to a JINAD fee, under section 741(a)(4) of the FD&C Act. Regarding the fee for a person's first submission to an existing (prior to October 1, 2023) JINAD file on or after October 1, 2023, FDA intends to assess a fee only for the first data (or “P”) submission to the Bioequivalence (BE) or Chemistry, Manufacturing, and Controls (CMC) technical sections of the JINAD file. The Agency has selected P submissions to the BE or CMC technical sections as the basis for assessing this fee because P submissions to these sections consistently entail the substantial use of FDA review hours during the phased review process.

Section 741(c) of the FD&C Act specifies how the fees must be calculated each fiscal year, including annual adjustments that must be made for inflation, workload, and final year adjustment. The fee amounts are published in the *Federal Register* each year, typically at the beginning of August.[2]

AGDUFA user fees are not a fee-for-service. User fees are pooled and may be used for the allowable activities as defined in the FD&C Act. Refer to **Appendix A** for a detailed list of allowable and excluded activities.

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 animal generic drug user fees. **Exhibit 2** describes those legal conditions and provides a brief explanation as to how those legal conditions were met for FY 2025.

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

[2] See https://www.federalregister.gov/documents/2024/07/31/2024-16885/animal-generic-drug-user-fee-program-rates-and-payment-procedures-for-fiscal-year-2025.

Exhibit 2: AGDUFA Legal Conditions

Legal Condition #	Details	
1	Description	The first condition requires that FDA's FY 2025 Salaries and Expenses Appropriation (excluding user fees) be greater than or equal to FDA's Salaries and Expenses Appropriation (excluding user fees) for FY 2003, multiplied by an adjustment factor for inflation.
	Met	In FY 2025, FDA's appropriation for salaries and expenses was $3,522,150,000 (excluding user fees). FDA's FY 2003 Salaries and Expenses Appropriation (excluding user fees) was $1,890,052,584 after applying the FY 2025 adjustment factor. Therefore, the first legal condition was satisfied.
2	Description	The second condition requires that the user fee amounts FDA may collect for each fiscal year must be specified in that year's appropriation acts.
	Met	The Full-Year Continuing Appropriations Act, 2025 (Division A of the Full-Year Continuing Appropriations and Extensions Act, 2025, Public Law 119-4), which the President signed on March 15, 2025, specified an approval of funding at the level provided for in the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act (Division B of the Consolidated Appropriations Act, 2024, Public Law 118-42), which the President signed on March 9, 2024 and which specified that $25,000,000 shall be derived from animal generic drug user fees and that animal generic 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. 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.
	Met	The specified minimum level for FY 2025 is $7,581,047. In FY 2025, FDA obligated $13,828,473 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 in FY 2025, the third legal condition was satisfied.

Financial Information

This section provides an overview of the program financials for AGDUFA for FYs 2024 and 2025. These financials include user fee revenue, obligations, carryover, non-user fee appropriations, and full-time equivalents (FTEs).

D. User Fee Program Financials

Table 1 represents a summary of the AGDUFA financial position for FY 2024 and FY 2025.

Table 1: Animal Generic Drug User Fee Program Financials for FYs 2024 and 2025

Budgetary Resources	FY 2024	FY 2025
Total Carryover, Beginning of Year	$53,277,270	$60,003,583
Net Collections	$29,041,501	$29,342,710
Recoveries	$273,489	$89,291
Total Budgetary Resources	**$82,592,260**	**$89,435,584**
Obligations	**FY 2024**	**FY 2025**
Total Payroll	$17,219,390	$16,900,372
Total Operating	$814,577	$559,130
Total Rent	$476,563	$599,347
Total Shared Services	$4,078,147	$3,529,227
Total Obligations	**$22,588,677**	**$21,588,076**
Carryover	**FY 2024**	**FY 2025**
Total Carryover, End of Year	**$60,003,583**	**$67,847,508**

- **Budgetary Resources:** "Total Budgetary Resources" illustrates the total user fee funding (i.e., the existing total carryover, user fee collections, and recoveries). "Net Collections" are the amounts collected during the fiscal year net of refunds that have taken place. Recoveries account for funds de-obligated from prior year obligations. For example, recoveries could include funding from a contract that ended in a prior year and was not expended.

- **Obligations:** **"**Total Obligations" 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 drug applications," as defined in AGDUFA IV. For more information on the allowable and excluded costs and activities, see **Appendix A**.

- **Carryover:** AGDUFA fees collected, appropriated, and not obligated at the end of the fiscal year remain available to support the AGDUFA program in future fiscal years. In this report, such fee funds, plus certain user fee funds

that FDA has collected that are considered unappropriated, are referred to as the "total carryover" or "AGDUFA carryover." See **Section G** for more on carryover.

E. User Fee Revenue

The estimated user fee collections are based on the target revenue (i.e., base revenue adjusted for inflation, workload, and reduction of workload adjustment, as applicable).

FDA assumes, for planning purposes, that net collections will equal the target revenue amount. Net collections may differ from the annual target revenue amount if the actual number of fee-paying units differs from the number of fee-paying units estimated when fees are set each year. See **Collections**, below, for more information.

Table 2 outlines the annual target revenue amount for FY 2024 and FY 2025. The process for setting the annual target revenue is defined in the statute.

Table 2: Animal Generic Drug User Fee Target Revenue for FYs 2024 and 2025

Target Revenue	FY 2024	FY 2025
Base Fee Revenue Amount	$25,000,000	$25,000,000
Inflation Adjustment	$0	$983,500
Workload Adjustment	$0	$0
Reduction of Workload Adjustment by Excess Fees	$0	$0
Final Year Adjustment	N/A	N/A
Target Revenue Total	**$25,000,000**	**$25,984,000**

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

- **Base Fee Revenue Amount:** The base fee revenue amount for AGDUFA IV is specified in section 741(b) of the FD&C Act and is adjusted for the following factors, as applicable: inflation adjustment, workload adjustment, reduction of workload adjustment, and a final year adjustment. The amount after the additional dollar amounts are added becomes the target revenue for each fiscal year.

- **Inflation Adjustment**: The inflation adjustment adjusts the base amount to maintain the purchasing power of fee funds in consideration of inflation. This adjustment is a composite measure that adjusts operating expenses by changes in the Consumer Price Index (CPI) and adjusts payroll-related expenses by changes in FDA's average personnel compensation and benefits amounts.

  For FY 2025, AGDUFA IV had an inflation adjustment of $983,500.

- **Workload Adjustment:** The workload adjustment calculates the weighted average of the change in the total number of each of the types of applications and submissions specified in the workload adjustment provision in section 741(c)(3)(A) of the FD&C Act.

For FY 2025, the workload adjustment criteria were not satisfied, therefore, there is no workload adjustment.

- **Reduction of Workload Adjustment by Excess Fees:** Under section 741(c)(3)(B) of the FD&C Act, if application of the workload adjustment increases the amount of fee revenue established for the fiscal year, as adjusted for inflation, the fee revenue increase will be reduced by the amount of any excess collections for the second preceding fiscal year, up to the amount of the fee revenue increase for workload.

  For FY 2025, since there was no workload adjustment, there will be no reduction of workload adjustment by excess fees.

Collections

AGDUFA provides for the collection of application fees, product fees, sponsor fees, and JINAD fees. User fee collections are recognized and reported in the year the fee was originally due (referred to as the "cohort year"[3]). Totals reported for each fiscal year are net of any refunds for the cohort year. Net fees collected differ between the fiscal year and the cohort year. Cohort year collections reflect collections for a single cohort year (e.g., FY 2025) and are collected across multiple fiscal years. To ensure the quality of the information provided in this financial report, FDA annually updates prior years' numbers to account for any refunds processed after publication of the report.

Tables 3a and 3b outline AGDUFA collections by fee source and cohort year. **Table 3c** shows the outstanding amounts that are still owed for Cohort Years 2024 and 2025. Once these amounts are collected, they will be recognized as revenue in the corresponding cohort year. Refer to **Section C** for more background and information.

Table 3a: Animal Generic Drug User Fee Collections by Fee Type for Cohort Year 2024

Fees Collected	Estimated†	Actual	% Diff
Application Fees	$2,000,000	$4,886,698	144%
Product Fees	$10,000,000	$10,934,131	9%
Sponsor Fees	$10,000,000	$10,074,919	1%
JINAD Fees	$3,000,000	$3,350,000	12%
Total Collections	**$25,000,000**	**$29,245,748**	**17%**

† Estimated values were taken from the animal generic drug user fee rates published in the FY 2024 *Federal Register* notice.[4]

[3] For example, a fee originally due in FY 2024 but received in 2025 is attributed to FY 2024 cohort year collections.
[4] https://www.federalregister.gov/documents/2023/10/23/2023-23374/animal-generic-drug-user-fee-program-rates-and-payment-procedures-for-fiscal-year-2024.

Table 3b: Animal Generic Drug User Fee Collections by Fee Type for Cohort Year 2025

Fees Collected	Estimated††	Actual	% Diff
Application Fees	$2,946,700	$3,642,909	24%
Product Fees	$10,393,400	$10,490,350	1%
Sponsor Fees	$10,393,400	$10,589,336	2%
JINAD Fees	$2,250,000	$3,200,000	42%
Total Collections	**$25,983,500**	**$27,922,595**	**7%**

†† Estimated values were taken from the animal generic drug user fee rates published in the FY 2025 *Federal Register* notice.[5]

Table 3c: Animal Generic Drug User Fees Receivable by Fee Type in FY 2024 for Cohort Years 2024 and 2025

Fees Receivable	Cohort Year 2024 Actual	Cohort Year 2025 Actual
Application Fees	$0	$0
Product Fees	$16,393	$0
Sponsor Fees	$322,914	$270,236
JINAD Fees	$0	$0
Total Receivables	**$339,307**	**$270,236**

Waivers

Waivers or reductions remain available for abbreviated applications for generic new animal drugs intended solely for a minor use/minor species indication.

F. 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 section 741(k) of the FD&C Act. For more information on the allowable and excluded costs, see **Appendix A.**

Table 4 provides a comparison of user fee obligations by expense category during the past 2 fiscal years.

[5] https://www.federalregister.gov/documents/2024/07/31/2024-16885/animal-generic-drug-user-fee-program-rates-and-payment-procedures-for-fiscal-year-2025.

Table 4: Animal Generic Drug User Fee Obligations by Expense Category for FYs 2024 and 2025

User Fee Obligations	FY 2024	FY 2025
Payroll	**$17,219,390**	**$16,900,372**
CVM	$17,219,337	$16,900,372
OII	$0	$0
HQ	$53	$0
Operating	**$814,577**	**$559,130**
CVM	$789,246	$550,486
OII	$0	$0
HQ	$25,331	$8,644
Total Rent	**$476,563**	**$599,347**
Total Shared Services	**$4,078,147**	**$3,529,227**
Total Obligations	**$22,588,677**	**$21,588,076**

- **Payroll and Operating:** These obligations provide for all payroll and operating costs for which AGDUFA fees may be expended to support the process for the review of generic new animal drug applications, as set forth in section 741(g) of the FD&C Act. Such payroll and operating activities include, 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.

  For payroll, Center 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 A** for a listing of those activities. For operating activities (e.g., contracting services), AGDUFA 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 and/or non-user fee appropriations. 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.

- **Rent Costs:** GSA charges rent to FDA for the federal buildings that FDA occupies. This rent is charged at different rates depending on the type and location of the space provided. Because rent is an allowable support cost for the process for the review of generic new animal drug applications, 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 utilities, janitorial services, guards, and ground maintenance.

- **Shared Services:** FDA has several shared service organizations, located within the Working Capital Fund (WCF), that provide support across the user fee programs, such as human resources and information technology (IT) support. **Appendix C.1** provides a full list of what is contained in the WCF.

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 generally increased over time and the percentage spent by each FDA organizational component has remained steady.

Table 5: Generic New Animal Drug Review Process Historical Trend of Total Costs by Organization as of September 30 of Each Fiscal Year

	FY 2021	FY 2022	FY 2023	FY 2024	FY 2025
CVM Spent ($)	$27,315,733	$31,744,205	$36,155,307	$36,601,810	$32,048,176
CVM Percentage (%)	91%	92%	91%	91%	90%
OII Spent ($)	$159,534	$182,489	$389,914	$395,803	$540,904
OII Percentage (%)	1%	1%	1%	1%	2%
HQ Spent ($)	$2,541,166	$2,708,260	$2,998,217	$3,017,366	$2,827,469
HQ Percentage (%)	8%	8%	8%	8%	8%
Total Spent	**$30,016,433**	**$34,634,954**	**$39,543,438**	**$40,014,979**	**$35,416,549**

Numbers have been rounded to the nearest dollar and nearest percentage.

G. User Fee Carryover

AGDUFA fees collected, appropriated, and not obligated at the end of the fiscal year, remain available to support the AGDUFA program in future fiscal years. In this report, such fee funds, plus certain user fee funds that FDA has collected that are considered unappropriated, are referred to as the "total carryover" or "AGDUFA carryover."

Maintaining an appropriate level of carryover 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 activities related to the process for the review of generic new animal drug applications under such financial constraints. FDA may also set aside available user fee funds in the carryover for certain purposes, including, for example, future year refund allowances.

When setting fees for the final fiscal year of AGDUFA IV (i.e., FY 2028), FDA is authorized to increase fees, if necessary, to provide up to 3 months of operating reserve of carryover user fees for the first 3 months of FY 2029. If FDA has carryover balances in excess of 3 months of such operating reserve, then such adjustment will not be made. This includes all available fee funds, including set asides for future fiscal years, but excludes $2,363,711 in collections that are considered unappropriated and therefore currently unavailable for obligation (see **Table 6** and **Appendix C.2**). As this operating reserve adjustment does not apply until the final year of AGDUFA IV (i.e., FY 2028), any amount held as carryover for FY 2024, 2025, 2026, or 2027 is at the request of the program Center.

The net change in AGDUFA carryover each year is equal to net collections minus net obligations. This is demonstrated best in **Table 7b** below.

Table 6 provides the AGDUFA carryover at the end of FY 2024 and 2025.

Table 6: AGDUFA Carryover for FYs 2024 and 2025

Carryover	FY 2024	FY 2025
Total Carryover, End of Year	**$60,003,583**	**$67,847,508**
Unappropriated Amounts	($2,363,711)	($2,363,711)
Total Available Carryover, End of Year	**$57,639,872**	**$65,483,797**
Future Year Refunds Allowance, Set Aside	($100,000)	($100,000)
Final Year Operating Reserve (FY 2028 only)	N/A	N/A
Carryover Net of Unavailable and Set Aside, End of Year	**$57,539,872**	**$65,383,797**

- **Total Carryover, End of Year –** This is the total amount of unobligated fee funds at the end of the fiscal year.

- **Unappropriated Amounts –** FDA's AGDUFA carryover includes $2,363,711 in fee collections that are considered unappropriated and therefore currently unavailable for obligation. This amount is the cumulative total of fee collections that exceeded the annual level of AGDUFA fees appropriated for a given year, prior to a technical fix that was added to the appropriations language to ensure that all fee collections would be considered appropriated.

- **Future Year Refunds Allowance, Set Aside –** FDA maintains a small amount to provide for any refunds, as a matter of prudent operations. For that purpose, a total of $100,000 in fee funds available for obligation is being set aside annually. See **Appendix C.3** for additional details.

- **Final Year Operating Reserve –** In FY 2028, FDA has the authority to hold up to 3 months (12 weeks) of operating reserves for the process for the review of abbreviated applications for generic new animal drugs for the beginning of FY 2029.

- **Carryover Net of Unavailable and Set Aside, End of Year –** This is the total carryover, less any carryover funds subject to set asides or subject to any restrictions that currently preclude FDA from obligating the carryover funds.

The operations in FY 2025 resulted in a net increase of the carryover of $7,843,925, from $60,003,583 at the end of FY 2024 to $67,847,508 at the end of FY 2025. This increase in carryover is due to CVM obligating less AGDUFA funds than the FY 2025 net collections, driven primarily by excess collections of application fees.[6]

Tables 7a and 7b reflect the historical amount of carryover, fees collected, and fees obligated during the previous and current reauthorization periods.

[6] To calculate the available carryover by week, the FY 2026 target revenue amount is divided by 52 weeks in a year to generate the 1-week operating amount. The total available carryover is then divided by the 1-week operating amount.

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

	AGDUFA I (FY 2009-2013)	AGDUFA II (FY 2014-2018)	AGDUFA III (FY 2019-2023)
Total Carryover, Beginning of FY	**$0**	**$8,546,799**	**$10,800,810**
Net Collections	$29,641,950	$48,190,167	$135,134,268
Recoveries	$0	$203,538	$588,932
Total Obligations	($21,095,151)	($46,139,693)	($93,246,740)
Total Carryover, End of FY	**$8,546,799**	**$10,800,810**	**$53,277,270**

Table 7b: Animal Generic Drug User Fee Carryover for AGDUFA IV

Category	FY 2024	FY 2025
Total Carryover, Beginning of FY	**$53,277,270**	**$60,003,583**
Net Collections	$29,041,501	$29,342,710
Recoveries	$273,489	$89,291
Total Obligations	($22,588,677)	($21,588,076)
Total Carryover, End of FY	**$60,003,583**	**$67,847,508**

- **Recoveries:** These account for funds de-obligated from prior year obligations. For example, recoveries could include funding from a contract that ended in a prior year and was not expended.

H. 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 $7,581,047 for FY 2025.

The "non-user fee spending trigger amount" is determined by multiplying the base amount spent on the generic new animal drug review process in FY 2008 ($5,510,000) by the adjustment factor for the fiscal year. See **Appendix B.1** for more details on the adjustment factor.

Table 8 provides the total amount spent on the AGDUFA program for the past 5 fiscal years, as well as the dollar amount and percentages derived from user fee and non-user fee appropriations.

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

Funding Source	FY 2021	FY 2022	FY 2023	FY 2024	FY 2025
Non-User Fee Appropriations Obligated: Total ($)	$9,437,145	$12,885,768	$19,822,560	$17,426,303	$13,828,473
Non-User Fee Appropriations Obligated: Percent (%)	31%	37%	50%	44%	39%
User Fee Funds Obligated: Total ($)	$20,579,287	$21,749,185	$19,720,878	$22,588,677	$21,588,076
User Fee Funds Obligated: Percent (%)	69%	63%	50%	56%	61%
Total Obligated	**$30,016,432**	**$34,634,954**	**$39,543,437**	**$40,014,979**	**$35,416,549**

I. Full-Time Equivalents

"FTE employment" (often referred to as "staff year"), as defined by Office of Management and Budget (OMB) Circular 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 **Table 9** 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 fiscal years and are arranged by FDA organizational components (CVM, OII, and HQ). Staff in the consolidated shared service programs (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 2021	FY 2022	FY 2023	FY 2024	FY 2025
CVM	121	129	137	150	131
OII	1	1	1	1	2
HQ	6	7	8	7	9
TOTAL	**128**	**137**	**146**	**158**	**142**

Management Assurance

The FDA maintains a strong internal control culture in order to support data-driven decision making, reliable financial forecasting, accountability for resource use and to ensure compliance with laws, including:

- Federal Managers' Financial Integrity Act (FMFIA) – This act requires agencies to establish internal controls that provide reasonable assurance of effective and efficient operations, compliance with applicable laws, and reliable financial reporting. This act requires agencies to comply with federal financial management systems requirements, ensuring that transactions are properly recorded, and financial reports are reliable.

- Office of Management and Budget (OMB) Circular A-123 – It sets the standards for internal controls and requires agencies to implement internal control assessments, including the management of risks and ensuring accountability.

- Government Accountability Office (GAO) Standards for Internal Control (Green Book) – Provides the framework for designing, implementing, and operating an effective internal control system within the federal government.

- Improper Payments Elimination and Recovery Act (IPERA) – IPERA requires agencies to identify and reduce improper payments and recover overpayments when they occur.

- Federal Information Security Modernization Act (FISMA) – Addresses internal controls related to information security, ensuring the protection of federal information systems.

Additionally, FDA established a council to govern oversight and accountability:

- User Fee Financial Management Committee (UFFMC): The UFFMC oversees and ensures FDA's compliance with sound financial management practices and statutory provisions governing user fees, providing oversight for resource needs, financial planning, and forecasting. The CFO serves as the Chairman, a Program Representative serves as the Program Vice Chairman, and voting members include all Center Directors from across the Agency.

Appendices

A. Allowable and Excluded Activities for AGDUFA

Section 741(k)(11) 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:

Exhibit 3: Included Activities

Included Activities	
1. The activities necessary for the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions. 2. 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. 3. The inspection of animal drug establishments and other facilities undertaken as part of [FDA's] review of pending animal drug applications, supplemental animal drug applications, and investigational animal drug submissions. 4. Monitoring of research conducted in connection with the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions.	5. The development of regulations and policy related to the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions. 6. Development of standards for products subject to review. 7. Meetings between [FDA] and the animal drug sponsor. 8. A 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. 9. The activities necessary for implementation of the United States and European Union Mutual Recognition Agreement for Pharmaceutical Good Manufacturing Practice Inspections, the United States and United Kingdom Mutual Recognition Agreement Sectoral Annex for Pharmaceutical Good Manufacturing Practices, and other mutual recognition agreements, with respect to animal drug products subject to review, including implementation activities prior to and following product approval.

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 incurred in connection with this process for the following activities:

Exhibit 4: Included Expenses

Included Expenses
1. Officers and employees of FDA; FDA contractors; advisory committees consulted with respect to the review of specific abbreviated animal drug applications, supplemental abbreviated 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.
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.
4. Collecting fees under this section of the [FD&C Act] and accounting for resources allocated for the review of abbreviated animal drug applications, supplemental abbreviated animal drug applications, and investigational animal drug submissions.

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

Exhibit 5: Excluded Expenses

Excluded Expenses
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.

B. Conditions for Assessment and Use of Fees

B.1. Adjustment Factor

To determine whether the legal conditions are satisfied, FDA must calculate and incorporate "adjustment factors" (as defined in section 741(k)(2) of the FD&C Act as amended) 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 CPI for all urban consumers (all items; United States city average) for October of the preceding fiscal year divided by

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

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

For the first legal condition, this adjustment factor formula applies as reflected in section 741(f)(1) of the FD&C Act. Thus, the adjustment factor is the CPI for all urban consumers (all items; United States city average) for October of the preceding fiscal year divided by such Index for October 2002.

The CPI for October 2023, the October of the fiscal year preceding FY 2025 (beginning on October 1, 2024), was 311.380. The CPI for October 2002 was 181.3. Dividing the CPI of October 2023 by the CPI of October 2002 yields an adjustment factor of 1.717485 (rounded to six decimal places) for FY 2025.

For the third legal condition, this adjustment factor formula applies as reflected in section 741(g)(2)(A)(ii) of the FD&C Act. Thus, the adjustment factor is the CPI for all urban consumers (all items; United States city average) for October of the preceding fiscal year divided by such Index for October 2007.

The CPI for October 2023, the October of the fiscal year preceding FY 2025 (beginning on October 1, 2024), was 311.380. The CPI for October 2007 was 208.936. Dividing the CPI of October 2023 by the CPI of October 2007 yields an adjustment factor of 1.490313 (rounded to the sixth decimal place) for FY 2025.

B.2. Legal Conditions

Exhibit 6 provides the details regarding each legal condition, as quoted from the FD&C Act.

Exhibit 6: 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 [FDA] 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 [FDA] 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] 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 new generic 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 2008 multiplied by the adjustment factor.

C. Supplemental Financial Information

C.1. Shared Service Costs

FDA has several shared service programs, supported by the WCF, that provide support for activities across the Agency. The shared service programs in FY 2025 include:

- **Office of Digital Transformation:** Provides the vision and leadership in IT, data, and cybersecurity needed to advance FDA's mission and strategic priorities.
- **Office of Equal Employment Opportunity:** Promotes a work environment that ensures equal employment opportunity and fosters a professional culture that values and empowers individuals so they can participate and contribute to their fullest potential.
- **Office of Ethics and Integrity:** Protects the integrity of FDA's programs and operations by promoting an ethical culture and ensuring compliance with applicable federal ethics laws.
- **Office of Facilities, Engineering, and Mission Support Services:** Provides FDA employees with office and laboratory facilities.

- **Office of Finance, Budget, and Acquisitions:** Leads FDA's budget, acquisitions, and financial management functions while ensuring the financial integrity of FDA's resources.

- **Office of Human Capital Management:** Provides human resource services that promote collaboration and a work environment that is characterized by open communication, personal accountability, trust, and mutual respect.

- **Office of Management and Enterprise Services:** Provides strategic and tactical enterprise-wide services through development and implementation of administrative policies, programs, and initiatives.

- **Office of Occupational Safety and Health:** Reinforces FDA's expectations for workplace health and safety, laboratory safety and security, laboratory quality and efficiency, enhances communications among FDA safety staff, and provides program support.

- **Office of Planning, Evaluation and Risk Management:** Partners with FDA's leaders to achieve organizational excellence by improving program performance, governance, operational efficiency, and risk management.

- **Office of Security and Passport Operations:** Develops and implements the Agency-wide security policies and programs by providing leadership and guidance to managers and staff on all aspects of security. Delivers efficient passport and visa services and administers vital security functions that contribute to the Agency's mission of protecting public health by enhancing the safety and security of all personnel, facilities, and information.

- **Office of Talent Solutions:** Provides high quality and efficient solutions that enable FDA to hire a talented and qualified workforce.

C.2. Unappropriated Amounts

The "unappropriated amount" is the amount that FDA collected in user fees in excess of the amount specified in appropriation acts prior to FY 2013. FDA's ability to access and obligate these collections remains uncertain. **Table 10** outlines the excess user fees by fiscal year.

Table 10: Unappropriated Amounts as of September 30, 2025.

Fiscal Year	Amount in Excess of Collection Amount Specified in Appropriation Acts
2004	$0
2005	$0
2006	$0
2007	$0
2008	$0
2009	$268,071
2010	$0
2011	$0
2012	$2,095,640
Total	**$2,363,711**

C.3. Future Year Refunds Allowance

If a sponsor pays the fee for an abbreviated application that 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).

Refunds impact net fee collections for each fiscal year. These net collections reflect the amount of fees collected net of any refunds or adjustments that occurred during that fiscal year. The FY 2025 actual refunds for AGDUFA was $50,000.

This report was prepared by FDA's Office of Financial Management.
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This report is available on FDA's website at https://www.fda.gov.