Financial Report to Congress

Animal Drug User Fee Act

FY 2025

U.S. FOOD & DRUG
ADMINISTRATION

Table of Contents

Executive Summary

The Animal Drug User Fee Act of 2003 (ADUFA), as amended, requires the Food and Drug Administration (FDA) to report to Congress annually on the financial aspects of ADUFA implementation. This is the second report under the fifth authorization of ADUFA (ADUFA V) and covers fiscal year (FY) 2025.

ADUFA specifies that the following three legal conditions must be satisfied each year for FDA to collect and spend ADUFA user fees:

1. FDA's overall Salaries and Expenses appropriation (excluding user fees) must be equal to, or greater than, FDA's FY 2003 Salaries and Expenses Appropriation (excluding user fees), multiplied by the adjustment factor.

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

3. FDA must spend at least as much from appropriated funds (excluding user fees) for the review of animal drug applications as it spent in FY 2003, multiplied by the adjustment factor.

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

In FY 2025, FDA had net collections of $30 million in animal drug user fees, spent $32 million in user fees for the animal drug review process, and carried $21 million forward for future fiscal years.

ADUFA user fees and non-user fee appropriations in FY 2025 supported 341 full-time equivalents, including salaries and operational expenses, to support the process for the review of animal drug applications. Detailed program accomplishments can be found in the ADUFA Performance Report.[1]

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

Report Overview

A. Scope

This financial report addresses the implementation and use of animal drug user fees by the Food and Drug Administration (FDA or Agency) during the period of October 1, 2024, through September 30, 2025. The report presents the legal conditions that FDA must satisfy to collect and spend animal 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, user fee obligations, and total costs of the process for the review of animal drug applications from both Animal Drug User Fee Act of 2003 (ADUFA) fees and non-user fee appropriations.

B. Report Requirements

In accordance with section 740A(c) 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.

Section 740A(b) of the FD&C Act requires FDA 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 extend FDA's requirements for financial reports through FY 2028.

C. User Fee Background and Structure

Under ADUFA, FDA assesses and collects fees from animal drug sponsors to help fund the animal drug review process. The FD&C Act, as amended by ADUFA, 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 animal drug applications.

ADUFA was enacted in 2003, reauthorized in 2008 (ADUFA II), 2013 (ADUFA III), 2018 (ADUFA IV), and most recently in 2023 (ADUFA V) via the Animal Drug and Animal Generic Drug User Fee Amendments of 2023. ADUFA V authorizes continued user fee funding for FDA from FY 2024 through FY 2028 to support program operations, evaluation, and improvement. FDA spends ADUFA user fee collections and non-user fee appropriations to hire, support, and maintain personnel for the review of animal drug applications. ADUFA has delivered public health benefits by enhancing FDA's capacity to review animal drug submissions so that safe and effective products can be brought to the market.

The fee structure remains unchanged from ADUFA IV with four types of fees: application fee, product fee, establishment fee, and sponsor fee. The proportions of target revenue derived from each type of user fee are application fees: 20 percent, product fees: 27 percent, establishment fees: 26 percent, and sponsor fees: 27 percent.

Exhibit 1 outlines the ADUFA V fee structure.

Exhibit 1: ADUFA V Fee Structure

Fee Type	Definition
Application: (FD&C Act Section 740(a)(1))	Each person that submits an animal drug application or a supplemental animal drug application shall be subject to an application fee. The term "animal drug application" means an application for approval of any new animal drug submitted under section 512(b)(1) or an application for conditional approval of a new animal drug submitted under section 571 of the FD&C Act. As the definition of “animal drug application” includes applications for conditional approval submitted under section 571 of the FD&C Act, such applications are subject to ADUFA fees. Fees may be waived in certain circumstances.
Product: (FD&C Act Section 740(a)(2))	Each person named as the applicant in an animal drug application or supplemental animal drug application for an animal product submitted for listing under section 510 of the FD&C Act, and who had an animal drug application or supplemental animal drug application pending at FDA after September 1, 2003, shall pay an annual fee for each such animal drug product.
Establishment: (FD&C Act Section 740(a)(3))	The establishment fee must be paid annually by the person who: (1) owns or operates, directly or through an affiliate, an animal drug establishment; (2) is named as the applicant in an animal drug application or supplemental animal drug application for an animal drug product submitted for listing under section 510 of the FD&C Act; (3) had an animal drug application or supplemental animal drug application pending at FDA after September 1, 2003; and, (4) whose establishment engaged in the manufacture of the animal drug product during the fiscal year.
Sponsor: (FD&C Act Section 740(a)(4))	The sponsor fee must be paid annually by each person who meets the definition of “animal drug sponsor” within that fiscal year and who had an animal drug application, supplemental animal drug application, or investigational animal drug submission pending at FDA after September 1, 2003. An animal drug sponsor is subject to only one fee each fiscal year. A person meets the definition of “animal drug sponsor” if that person is named as the applicant in an animal drug application, except for an application that has been withdrawn by the applicant or for which approval has been withdrawn by FDA, or if that person has submitted an investigational animal drug

	submission that has not been terminated or otherwise rendered inactive by FDA.

Section 740(c) of the FD&C Act specifies how the fees must be calculated each fiscal year, including annual adjustments that must be made beginning in FY 2025 for inflation, workload, and operating reserve. The fee amounts are published in the *Federal Register* each year, typically at the beginning of August.[2]

ADUFA 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 ADUFA, specifies three legal conditions that must be satisfied each year for FDA to collect and spend animal 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 factor are included in **Appendix B.**

[2] See https://www.federalregister.gov/documents/2024/07/31/2024-16894/animal-drug-user-fee-rates-and-payment-procedures-for-fiscal-year-2025.

Exhibit 2: ADUFA 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 $3,530,150,000 (excluding user fees). FDA's FY 2003 Salaries and Expenses Appropriation (excluding user fees) was $2,331,229,785 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, 2024 (Division B of the Consolidated Appropriations Act, 2024, Public Law 118-42), which the President signed on March 9, 2024 and which specified that $33,500,000 shall be derived from animal drug user fees and that animal drug user fees collected in excess of this amount, if any, are appropriated for FDA. Therefore, the second legal condition was satisfied.
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 animal drug applications. This specified minimum is the amount FDA spent on the process for the review of animal drug applications from appropriations (exclusive of user fees) in FY 2003, multiplied by an adjustment factor specified in the statute. Under ADUFA, this legal 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 $55,574,241. In FY 2025, FDA obligated $66,813,958 from appropriations (exclusive of user fees) for the process for the review of animal drug applications. Because FDA spent more than the specified minimum amount from appropriations in FY 2025, the third legal condition was satisfied.

Financial Information

This section provides an overview of the program financials for ADUFA 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 ADUFA financial position for FY 2024 and FY 2025.

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

Budgetary Resources	FY 2024	FY 2025
Total Carryover, Beginning of Year	$23,281,801	$22,384,596
Net Collections	$32,998,286	$30,198,459
Recoveries	$451,092	$69,753
Total Budgetary Resources	**$56,731,179**	**$52,652,808**
Obligations	**FY 2024**	**FY 2025**
Total Payroll	$23,570,113	$24,564,135
Total Operating	$4,408,708	$1,621,949
Total Rent	$1,375,525	$1,452,288
Total Shared Services	$4,992,237	$4,421,655
Total Obligations	**$34,346,583**	**$32,060,027**
Carryover	**FY 2024**	**FY 2025**
Total Carryover, End of Year	**$22,384,596**	**$20,592,781**

- **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 ADUFA fee funds broken out by major expense categories. ADUFA fees may be expended only for costs to support the "process for the review of animal drug applications," as defined in ADUFA V. For more information on the allowable and excluded costs and activities, see **Appendix A**.

- **Carryover:** ADUFA fees collected, appropriated, and not obligated at the end of the fiscal year remain available to support the ADUFA 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 "ADUFA 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 any potential lapse in appropriations, so that FDA can continue performing animal drug application reviews under such financial constraints. The operating reserve adjustment detailed below will ensure that FDA will achieve that goal. 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 operating reserve, 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.

Table 2 outlines the annual target revenue amount for FYs 2024 and 2025. The process for setting the annual target revenue is defined in section 704(c) of the FD&C Act.

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

Target Revenue	FY 2024	FY 2025
Annual Base Fee Revenue Amount	$33,500,000	$33,500,000
Inflation Adjustment	$0	$1,317,890
Workload Adjustment	$0	$0
Operating Reserve Adjustment	N/A	($6,310,919)
Target Revenue Total	**$33,500,000**	**$28,507,000**

Target Revenue Total is rounded to the nearest thousand dollars.

- **Annual Base Fee Revenue Amount:** The base fee revenue amount for ADUFA V is specified in section 740(b) of the FD&C Act and is adjusted each fiscal year for the following factors, as applicable: inflation adjustment, workload adjustment, and operating reserve adjustment. The amount after any adjustments becomes the target revenue amount 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, ADUFA V had an inflation adjustment of $1,317,890.

- **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 740(c)(3) of the FD&C Act. This section specifies that the workload adjustment must be greater than three percent for a second fiscal year within ADUFA V before FDA can add the adjustment.

  Because ADUFA V does not adjust for workload until FY 2025, there was no workload adjustment for FY 2024, and for FY 2025, the workload adjuster was below the three percent threshold. Therefore, there is no workload adjustment for FY 2025.

- **Operating Reserve Adjustment:** After the adjustments for inflation and workload, as applicable, section 740(c)(4) of the FD&C Act requires FDA to increase the fee revenue amount for the fiscal year, if necessary to provide an operating reserve of not less than 12 weeks, or decrease the fee revenue amount for the fiscal year, if necessary to provide 22 weeks of operating reserves for FY 2025, 20 weeks for FY 2026, 18 weeks for FY 2027, and 16 weeks for FY 2028.

  For FY 2025, ADUFA V had an operating reserve adjustment of ($6,310,919).

Collections

ADUFA provides for the collection of application fees, product fees, establishment 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"[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 ADUFA 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 regarding these changes.

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

Fees Collected	Estimated†	Actual	% Diff
Application Fees	$6,700,000	$8,204,076	22.4%
Product Fees	$9,045,000	$9,107,529	0.7%
Establishment Fees	$8,710,000	$8,187,400	-6.0%
Sponsor Fees	$9,045,000	$8,278,470	-8.5%
Total Collections	**$33,500,000**	**$33,777,475**	**0.8%**

† Estimated values were taken from the animal drug user fee rates for FY 2024.[4]

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

Fees Collected	Estimated††	Actual	% Diff
Application Fees	$5,701,000	$7,271,683	27.5%
Product Fees	$7,697,000	$7,643,370	-0.7%
Establishment Fees	$7,412,000	$7,411,994	0.0%
Sponsor Fees	$7,697,000	$7,145,446	-7.2%
Total Collections	**$28,507,000**	**$29,472,493**	**3.4%**

†† Estimated values were taken from the animal drug user fee rates for FY 2025.[5]

[3] For example, a fee originally due in FY 2024 but received in 2025 is attributed in FY 2024 cohort year collections.
[4] See https://www.govinfo.gov/content/pkg/FR-2023-10-23/pdf/2023-23373.pdf.
[5] See https://www.govinfo.gov/content/pkg/FR-2024-07-31/pdf/2024-16894.pdf.

Table 3c: Animal 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	$0	$10,705
Establishment Fees	$0	$157,702
Sponsor Fees	$2,146,270	$2,613,220
Total Receivables	**$2,146,270**	**$2,781,627**

Waivers

Fees may be waived or reduced under the waiver and reduction provisions in section 740(d) of the FD&C Act. ADUFA directs FDA to waive or reduce one or more fees in five different circumstances:

- the assessment of the fee would present a significant barrier to innovation because of limited resources available to the person or other circumstances;
- the fees to be paid by the person will exceed the anticipated present and future costs incurred by FDA in conducting the process for the review of animal drug applications for such person;
- the animal drug application or supplemental animal drug application is intended solely to provide for use of the animal drug in: a Type B medicated feed (as defined in section 558.3(b)(3) of title 21, Code of Federal Regulations (21 CFR 558.3(b)(3)) or any successor regulation) intended for use in the manufacture of Type C free-choice medicated feeds; or a Type C free-choice medicated feed (as defined in 21 CFR 558.3(b)(4) or any successor regulation);
- the animal drug application or supplemental animal drug application is intended solely to provide for a minor use or minor species indication; or,
- the sponsor involved is a small business submitting its first animal drug application to FDA for review.

F. User Fee Obligations

ADUFA fees may be expended only for costs to support the "process for the review of animal drug applications," as defined in section 739(8) of the

FD&C Act. For more information on 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.

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

User Fee Obligations	FY 2024	FY 2025
Payroll	**$23,570,113**	**$24,564,135**
CVM	$22,610,913	$23,707,997
OII	$418,038	$346,777
HQ	$541,162	$509,361
Operating	**$4,408,709**	**$1,621,949**
CVM	$4,110,837	$1,538,171
OII	$0	$0
HQ	$297,872	$83,778
Total Rent	**$1,375,525**	**$1,452,288**
Total Shared Services	**$4,992,237**	**$4,421,655**
Total Obligations	**$34,346,584**	**$32,060,027**

- **Payroll and Operating:** These obligations provide for all payroll and operating costs for which ADUFA fees may be expended to support the process for the review of animal drug applications, as set forth in section 739(8) 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 ADUFA 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), ADUFA fee funds are allocated based on the proportion to which those activities support the ADUFA program. If an operating activity solely supports ADUFA, it will be fully funded by the program and/or non-user fee appropriations. If the operating activity is shared, ADUFA 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 animal drug applications, a portion of those charges is paid from non-user fee appropriations, and a portion is paid from ADUFA 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 programs, 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 ADUFA program for the past 5 years, including both user fee and non-user fee appropriation obligations. As illustrated by the table, costs generally have increased over time, and the percentage spent by each FDA organizational component has remained steady.

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

CATEGORY	FY 2021	FY 2022	FY 2023	FY 2024	FY 2025
CVM Spent ($)	$83,331,213	$86,840,311	$89,046,378	$92,689,402	$89,863,788
CVM Percentage (%)	90%	90%	91%	91%	91%
OII Spent ($)	$1,840,469	$2,287,239	$2,088,445	$2,272,713	$1,817,961
OII Percentage (%)	2%	2%	2%	2%	2%
HQ Spent ($)	$7,141,820	$7,029,063	$7,077,743	$6,761,213	$7,192,236
HQ Percentage (%)	8%	7%	7%	7%	7%
Total Spent	**$92,313,502**	**$96,156,613**	**$98,212,566**	**$101,723,328**	**$98,873,985**

G. User Fee Carryover

ADUFA fees collected, appropriated, and not obligated at the end of the fiscal year remain available to support the ADUFA 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 "ADUFA 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 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, operational reserves.

Section 740(c)(4) of the FD&C Act establishes a cap of 16 weeks of operating reserves of carryover user fees that can be maintained by the end of FY 2028 (with a step-down plan from FY 2025 to FY 2028) and a minimum amount of 12 weeks throughout ADUFA V. For operating reserve adjustment purposes, carryover user fees include all available fee funds, but exclude $2,058,256 in collections that are considered unappropriated and therefore currently unavailable for obligation (see **Table 6** and **Appendix C.2**).

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

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

Table 6: ADUFA Carryover for FYs 2024 and 2025

Carryover	FY 2024	FY 2025
Total Carryover, End of Year	**$22,384,596**	**$20,592,781**
Unappropriated Amounts	($2,058,256)	($2,058,256)
Total Available Carryover, End of Year	**$20,326,340**	**$18,534,525**

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

- **Unappropriated Amount –** FDA's ADUFA carryover includes $2,058,256 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 ADUFA 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.

- **Carryover Net of Unappropriated Amount, End of Year –**

  The operations in FY 2025 resulted in a net decrease of the carryover of $1,791,815, from $22,384,596 at the end of FY 2024 to $20,592,781 at the end of FY 2025. This decrease in carryover is due to CVM obligating more ADUFA funds than the FY 2025 net collections and allows the ADUFA V program to

remain within the required carryover minimum/maximum for the operating reserve (see section 740(c)(4) of the FD&C Act).

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

Table 7a: Historical Animal Drug User Fee Carryover by Reauthorization Period

Category	ADUFA I (FY 2004 - 2008)	ADUFA II (FY 2009 - 2013)	ADUFA III (FY 2014 - 2018)	ADUFA IV (FY 2019 - 2023)
Total Carryover, Beginning of FY	$0	$4,029,812	$11,959,322	$15,845,573
Net Collections	49,077,860	$89,279,716	$113,861,017	$155,290,612
Recoveries	$0	$0	$457,080	$1,718,627
Total Obligations	($45,048,048)	($81,350,206)	($110,431,847)	($149,573,012)
Total Carryover, End of FY	**$4,029,812**	**$11,959,322**	**$15,845,573**	**$23,281,800**

Table 7b: Animal Drug User Fee Carryover for ADUFA V

Category	FY 2024	FY 2025
Total Carryover, Beginning of FY	**$23,281,801**	**$22,384,596**
Net Collections	$32,998,286	$30,198,459
Recoveries	$451,092	$69,753
Obligations	($34,346,583)	($32,060,027)
Total Carryover, End of FY	**$22,384,596**	**$20,592,781**

- **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 ADUFA, a certain minimum amount of non-user fee appropriations must be spent on the process for the review of animal drug applications during that fiscal year. This is often referred to as a "non-user fee spending trigger." The non-user fee spending trigger for FY 2025 was $55,574,241, less than the $66,813,958 for non-user fee appropriations obligated for FY 2025, meaning the trigger was met.

The non-user fee spending trigger amount is determined by multiplying the amount spent on the animal drug review process in FY 2003 times the adjustment factor for the applicable fiscal year. See **Appendix B.1** for details on the adjustment factor.

Table 8 provides the total amount spent on the ADUFA 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 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 ($)	$62,911,379	$62,685,496	$68,895,421	$67,376,744	$66,813,958
Non-User Fee Appropriations Obligated: Percent (%)	68%	65%	70%	66%	68%
User Fee Funds Obligated: Total ($)	$29,402,122	$33,471,117	$29,317,145	$34,346,583	$32,060,027
User Fee Funds Obligated: Percent (%)	32%	35%	30%	34%	32%
Total Obligated	**$92,313,501**	**$96,156,613**	**$98,212,566**	**$101,723,328**	**$98,873,985**

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 ADUFA, an FTE is referred to as a "Process FTE," which is the measure of a paid staff year devoted to the ADUFA program. In the table below, an FTE does not represent an accounting of individual people but rather an estimate of labor hours expended on ADUFA 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 ADUFA 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	331	327	315	324	312
OII	7	9	7	8	7
HQ	18	18	18	16	23
TOTAL	**356**	**354**	**340**	**348**	**341**

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 Costs and Activities for ADUFA

Section 739(8) of the FD&C Act defines the phrase "process for the review of animal drug applications" to mean the following activities of FDA with respect to the review of animal drug applications, supplemental animal drug applications, and investigational animal drug 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 739(9) of the FD&C Act defines the phrase “costs of resources allocated for the process for the review of animal drug applications” 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]; contractors of [FDA]; advisory committees consulted with respect to the review of specific animal drug applications, supplemental animal drug applications, or investigational animal drug submissions; and costs related to such officers, employees, committees, and contractors, including costs for travel, education, and recruitment and other personnel activities.
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 section 740 [of the FD&C Act] and accounting for resources allocated for the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions.

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

Exhibit 5: Excluded Expenses

Excluded Expenses
1. Review of abbreviated new animal drug applications.
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 ADUFA program.
6. Research unrelated to the ADUFA 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 an "adjustment factor" (as defined in section 739(10) of the FD&C Act) in the assessment of the first and third legal conditions. Section 739(10) of FD&C Act states:

> The term "adjustment factor" applicable to a fiscal year refers to the formula set forth in section 735(8) [of the FD&C Act] with the base or comparator month being October 2002.

In turn, section 735(8) of the FD&C Act defines "adjustment factor" as follows:

> The term "adjustment factor" applicable to a fiscal year is the Consumer Price Index for all urban consumers (all items; United States city average) for October of the preceding fiscal year divided by such Index for October 1996.

This adjustment factor formula applies to ADUFA V, except that the base month is October 2002, as reflected in section 739(10) of the FD&C Act. Thus, the adjustment factor that applies to ADUFA V 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 the sixth decimal place) for FY 2025.

B.2. Legal Conditions

Exhibit 6 below 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	740(f)(1)	Fees may not be assessed under subsection (a) [of section 740 of the FD&C Act] for a fiscal year beginning after fiscal year 2003 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	740(g)(2)(A)(i)	The fees authorized by [section 740 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	740(g)(2)(A)(ii)	The fees authorized by [section 740 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 animal drug applications (including increases in such costs for an additional number of full-time equivalent positions in the Department of Health and Human Services to be engaged in such process) over such costs, excluding costs paid from fees collected under this section, for fiscal year 2003 multiplied by the adjustment factor.

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	$154,700
2005	$165,101
2006	$0
2007	$1,738,455
2008	$0
2009	$0
2010	$0
2011	$0
2012	$0
Total	**$2,058,256**

C.3. Future Year Refunds Allowance

If an application is withdrawn after it is filed, FDA may refund the fee or a portion of the fee if no substantial work was performed on the application after the application was filed. If an application is refused for filing, FDA refunds 75 percent of the fee.

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 740(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 any refunds or adjustments that occurred during that fiscal year.

The FY 2025 actual refunds amount for ADUFA was $319,069.

This report was prepared by FDA's Office of Financial Management.
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