Five-Year Financial Plan

Fiscal Years
2024-2025-2026-2027-2028

FY 2026 Version

FOR THE

Animal Drug User Fee Act Program

FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Five-Year Plan Overview

A. Scope

The purpose of the Five-Year Financial Plan is to communicate the anticipated financial position of the Animal Drug User Fee Act (ADUFA) program over the current five-year authorization period (ADUFA V). This document addresses the plan for implementation and use of ADUFA user fees by the Food and Drug Administration (FDA or the Agency) during the period of October 1, 2023, through September 30, 2028.

B. Five-Year Plan Commitment

In accordance with Animal Drug User Fee Act Reauthorization Performance Goals and Procedures Fiscal Years 2024 through 2028 (ADUFA V Commitment Letter), Section V.B, FDA will publish an ADUFA five-year financial plan no later than the second quarter of fiscal year (FY) 2024. FDA will publish updates to the five-year plan no later than the second quarter of each subsequent fiscal year. The purpose of this document is to meet these commitments.

C. Updates to the Five-Year Plan

All estimates in the plan are subject to review and reassessment each fiscal year as the actual amounts for appropriations, obligations, and collections for the previous fiscal year become available. The five-year financial plan provides the baseline from which future changes will be made. Updates to the five-year financial plan will occur on an annual basis and cover the five years in the current reauthorization period.

Management Discussion

D. 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 helping to ensure 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. FDA helps to speed innovations that make medical products more effective, safe, and affordable and helps the public get accurate, science-based information needed to use medical products and consume foods to maintain and improve their health. FDA similarly plays a significant role in the nation's counterterrorism capability. FDA fulfills this responsibility by helping to ensure the security of the food supply and by fostering the development of medical products to respond to deliberate and naturally emerging public health threats.

The Center for Veterinary Medicine (CVM) is responsible for regulating animal drugs, veterinary devices, and food for animals. CVM evaluates new animal drug applications for target animal and human food safety and effectiveness; monitors the safety of animal drugs, foods, and devices on the market; evaluates animal food additives for safety; 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, honeybees, and birds, and for minor uses (infrequent and limited) in the major species: cattle, pigs, chickens, dogs, cats, horses, and turkeys. In furtherance of the Agency's mission to promote and protect the health of humans and animals, CVM also takes steps to help facilitate access to safe, effective, and innovative products, including animal food products, that can address existing, novel, and emerging animal health challenges.

Program Organization

There are three major FDA components that support the ADUFA program: the Center for Veterinary Medicine (CVM), the Office of Inspections and Investigations (OII), 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	Protects and promotes the health of humans and animals from a One Health perspective 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.
OII	Conducts rigorous, transparent, and science-based inspections and investigations, providing real-time evidence and insight essential in empowering fact-based regulatory decisions to protect public health.
HQ	Provides FDA-wide program direction and administrative services to ensure FDA's consumer and patient safety programs are effectively and efficiently managed.

User Fee Governance

Strong financial governance is needed because of the Agency's expanding level of user fees, the required reporting of FDA's performance commitments associated with these fees, and the need for FDA to convey how these user fee programs are executed. These include 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's user fee governance process leverages the User Fee Financial Management Committee (UFFMC), which 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 UFFMC 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 compliance with statutory provisions that authorize FDA to collect and spend user fees. The UFFMC 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 program workload. The UFFMC advises the Executive Committee and other Center- and Office-level bodies on a variety of financial and performance-related topics.

Working Capital Fund/Cost Allocation

FDA utilizes a Cost Allocation and Recovery framework as part of the financial management of user fee resources. Congress authorized FDA to establish a Working Capital Fund (WCF) to finance centralized services (see Pub. L. No. 115-141, Div. A, § 722 (2018)). The WCF benefits the financial management of Agency funds by:

- Increasing transparency through defining administrative activities performed for Centers and Offices and allocating costs based on Agency usage.
- Strengthening accountability by improving the tracking and management of administrative costs, including costs charged to user fees for administrative services.
- Promoting efficiency by optimizing customer usage and improving the management of shared administrative costs over time.
- Leveraging the WCF governance structure to ensure FDA leadership engagement in decision making is relative to administrative costs, efficiency opportunities, recapitalization, and burden on all funding sources – including user fees.

Internal Controls

The Department of Health and Human Services (HHS) provides guidance to its operating divisions (OpDivs) to implement The Federal Managers' Financial Integrity Act of 1982 (FMFIA) through its FMFIA Guidelines, which is intended to strengthen internal controls and accounting systems. OpDivs, including FDA, are responsible for developing and maintaining internal control and compliance programs that include programmatic and operational controls, as well as reporting controls to support sound financial management.

E. 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 Federal Food, Drug, and Cosmetic Act (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 2 outlines the ADUFA V user fee structure.

Exhibit 2: ADUFA V Fee Structure

Fee Type	Definition
Application (Section 740(a)(1) of the FD&C Act)	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 (Section 740(a)(2) of the FD&C Act)	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 (Section 740(a)(3) of the FD&C Act)	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 (Section 740(a)(4) of the FD&C Act)	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.[1]

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.

F. Forward View

FDA developed the enhancements for ADUFA V in accordance with the statutory process then in effect. Information on the ADUFA V commitments can be found on FDA's website.[2]

The ADUFA V Commitment Letter continues many commitments from ADUFA IV and introduces new enhancements to the program. ADUFA V also made changes to the fee-setting mechanisms. During the current authorization, FDA is focusing on implementing the new commitments and changes to the program. Below are some highlights.

Highlights of New Programmatic Enhancements in ADUFA V

ADUFA V provides continued funding to the FDA to implement new enhancements to the program while sustaining existing commitments. The funding supports the core aspect of the ADUFA program:

- Provides predictable timelines for evaluating animal drug applications and submissions.
- Facilitates the review of animal drug applications/submissions to better meet the therapeutic needs of animals.
- Facilitates the review of animal drugs used in food animal production to help protect both human and animal health.
- Facilitates the development and evaluation of innovative and novel animal drugs and indications.

The funding also supports the following programmatic enhancements:

- If a sponsor requests a virtual pre-submission conference with FDA, they can request to receive written responses to their questions posed in the meeting request at least six days in advance.
- To increase engagement with stakeholders, the Agency will provide up to 8 hours annually for a public education session intended for the animal drug industry.

[1] See the ADUFA user fee rates archive at https://www.fda.gov/industry/fda-user-fee-programs/animal-drug-user-fee-act-adufa, under the Regulations and Federal Register Documents topic.
[2] https://www.fda.gov/media/116001

- To increase transparency, the Agency will report new metrics in FDA-TRACK and in the annual ADUFA performance report.

- In consultation with both the Agency and industry, a third-party will conduct a comprehensive assessment of the process for the review of animal drug applications and FDA will report on the results in a public forum.

- The Agency and industry will explore several areas, including Animal Drug Availability Act (ADAA) combination medicated feeds, the drug residue analytical method trial process, clock stops during review of sentinel submissions, and methods of FDA feedback to sponsors on product development plans. These explorations may result in additional activities.

- The Agency will continue to facilitate the timely scheduling and conduct of foreign preapproval inspections through the voluntary notification process and will work to implement the mutual recognition agreements between the US and the EU and the US and the UK for foreign GMP inspections.

- The Agency will clarify and/or expand the use of H submissions in several areas:

    - Supporting information for pre-submission conferences and INAD protocols without data submissions
    - Dosage characterization
    - Raw data submissions

- The Agency will publish both a revised guidance for industry and a policy and procedures manual (P&P) related to the Chemistry, Manufacturing, and Controls (CMC) Technical Sections.

Enhancing Management of User Fee Resources in ADUFA V

FDA is committed to enhancing management of ADUFA resources and ensuring ADUFA user fee resources are administered and allocated in an efficient manner. FDA will also continue activities to promote transparency of the use of financial resources in support of the ADUFA program.

Workload Adjustment

During reauthorization negotiations, FDA and industry agreed on changes to the workload adjuster, and Congress enacted the following:

- The base years were changed to a rolling average comprising the five most recently completed fiscal years. For example, beginning October 1, 2025 (FY 2026), the base will comprise FY 2020 through FY 2024. At the start of each fiscal year thereafter, the base will be adjusted upward by one year on the upper and lower ends of the range.

- The workload adjustment will be made when it is greater than 3 percent for a second fiscal year during the authorization period, and any year thereafter through FY 2028.

Operating Reserve Adjustment

Carryover user fees for the process for the review of animal drug applications will be used to fund the third-party assessment described above and any ADUFA V negotiated, one-time IT enhancements.

Additionally, FDA and industry agreed on a new adjustment beginning in FY 2025 to adjust fee revenue amounts to provide an operating reserve of carryover user fees for the process of the review of animal drug applications of not less than 12 weeks and not more than 16 weeks. The enacted provision reduces the operating reserve to the 16-week maximum, as phased in over the 5-year lifecycle of ADUFA V: 22 weeks for fiscal year 2025, 20 weeks for fiscal year 2026, 18 weeks for fiscal year 2027, and 16 weeks for fiscal year 2028.

Financial Information

This section provides an overview of the financial outlook for ADUFA for the FY 2024 through FY 2028 authorization period including budgetary resources, obligations, carryover, and non-user fee appropriations requirements. The forecasts included in this section are driven by the initiatives and goals as outlined in the Forward View section of this plan.

G. User Fee Program Financial Summary

Table 1 outlines the target revenue amount for each fiscal year. See **Appendix B** for more information.

Table 1: Animal Drug User Fee Target Revenue for Fiscal Years 2024 – 2028

	FY2024 Actual	FY2025 Actual	FY2026 Actual	FY2027 Estimate	FY2028 Estimate
Annual Base Revenue	$33,500,000	$33,500,000	$33,500,000	$33,500,000	$33,500,000
Inflation Adjustment	$0	$1,317,890	$3,002,505	$4,663,368	$7,657,956
Workload Adjustment	$0	$0	$0	$0	$0
Operating Reserve Adjustment	N/A	($6,310,853)	($350,639)	$0	$0
Target Revenue Total	**$33,500,000**	**$28,507,037**	**$36,151,866**	**$38,163,368**	**$41,157,956**

The process for setting the annual target revenue is defined in section 740(b) of the FD&C Act and is described below.

Annual Base Revenue: The base revenue for FY 2024 – FY 2028 is specified in section 740(b)(1) of the FD&C Act ($33,500,000) and for FY 2025 – FY 2028 is adjusted annually for the factors described below.

Inflation Adjustment: The inflation adjustment, specified in section 740(c)(2) of the FD&C Act, adjusts the base revenue to maintain the purchasing power of fee funds in consideration of inflation. The adjustment is a composite of factors that adjusts operating expenses by changes in the CPI and payroll-related expenses by changes in FDA's average personnel compensation and benefits amounts. The estimated inflation adjustments for future years are set to match the most recent fiscal year percent increase. The inflation adjustment made each fiscal year after fiscal year 2025 will be applied on a compounded basis to the revenue amount calculated for the most recent previous fiscal year.

Operating Reserve Adjustment: The operating reserve adjustment was established in section 704(c)(4) of the FD&C Act to provide a mechanism to support the management of a reasonable amount of fee funds carried over from year to year. Beginning in FY 2025, ADUFA V provides for an operating reserve adjustment to allow FDA to further adjust the fee revenue amount (after adjustment for inflation and workload) as necessary to maintain a specified operating reserve of carryover user fees. FDA is required to increase the fee revenue amount, if necessary to maintain a 12-week minimum. If FDA has an excess operating reserve, FDA will decrease the fee revenue

amount so that FDA has 22 weeks of operating reserve for FY 2025, 20 weeks for FY 2026, 18 weeks for FY 2027, and 16 weeks for FY 2028.

The current estimated total carryover, end of year amounts for FY 2025 through FY 2028 exceeds the operating reserve defined maximum threshold. FDA has set an operating reserve adjustment of ($6,310,853) for FY 2025 and ($350,639) for FY 2026 and estimates no adjustment will be needed for 2027 and 2028. These adjustments are intended to bring the operating reserves of carryover user fees to less than or equal to the threshold amount in FY 2026 and maintain the statutory thresholds for FY's 2027 and 2028. For more information, see **Section J**.

Tables 2a-2c together outline the ADUFA financial position. **Table 2a** provides an overview of user fee budgetary resources. **Table 2b** provides an overview of obligations for which the user fee resources would be used. **Table 2c** provides carryover amounts. Annual updates to this plan provide actual amounts for the prior fiscal years.

Table 2a: Animal Drug User Fee Budgetary Resources, Fiscal Years 2024 – 2028

Budgetary Resources	FY2024	FY2025	FY2026	FY2027	FY2028
	Actual	Actual	Estimate	Estimate	Estimate
Target Revenue	$33,500,000	$28,507,000	$36,152,000	$38,163,000	$41,158,000
Net Collections	$32,998,286	$30,198,459	$36,151,866	$38,163,368	$41,157,956
Recoveries	$451,092	$69,753	$376,000	$258,000	$258,000
Total Carryover, Beginning of FY	$23,281,801	$22,384,596	$20,592,781	$17,732,162	$14,135,278
Total Budgetary Resources	**$56,731,179**	**$52,652,808**	**$57,120,647**	**$56,153,530**	**$55,551,234**

Table 2b: Animal Drug Obligations Paid by User Fees, Fiscal Years 2024 – 2028

Obligations	FY2024	FY2025	FY2026	FY2027	FY2028
	Actual	Actual	Estimate	Estimate	Estimate
Payroll	$23,570,113	$24,564,135	$28,480,892	$30,914,924	$33,573,873
Operating	$4,408,708	$1,621,949	$4,713,280	$4,782,217	$4,860,367
Rent	$1,375,525	$1,452,288	$1,517,645	$1,600,818	$1,625,487
Shared Services	$4,992,237	$4,421,655	$4,676,668	$4,720,293	$4,604,018
Total Obligations	**$34,346,583**	**$32,060,027**	**$39,388,485**	**$42,018,252**	**$44,663,745**

Table 2c: Animal Drug User Fee Carryover, Fiscal Years 2024 – 2028

Carryover	FY2024	FY2025	FY2026	FY2027	FY2028
	Actual	Actual	Estimate	Estimate	Estimate
Total Carryover, End of Year	**$22,384,596**	**$20,592,781**	**$17,732,162**	**$14,135,278**	**$10,887,489**
Unappropriated Amounts	($2,058,256)	($2,058,256)	($2,058,256)	($2,058,256)	($2,058,256)
Carryover Net of Unappropriated Amounts, End of Year	**$20,326,340**	**$18,534,525**	**$15,673,906**	**$12,077,022**	**$8,829,233**

Budgetary Resources: Total Budgetary Resources is 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 been issued.

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. See **Section H** for more detail on budgetary resources.

Obligations: The Total Obligations in **Table 2b** show the actual or planned expenditures of user fees for FY 2024 through FY 2028, divided into major expense categories. ADUFA fees may be expended only 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, see **Appendix A**. See **Section I** for more details on obligations.

Carryover: The Carryovers in **Table 2c** show actual or estimated total and net carryover of user fees for FY 2024 through FY 2028. Total carryover includes ADUFA fees collected, appropriated or unappropriated, and not obligated at the end of the fiscal year. Net carryover does not include the unappropriated amounts. Appropriated carryover remains available to support the ADUFA program in future fiscal years. See **Section J** for more details on carryover.

H. Budgetary Resources

Budgetary resources include net collections (collections net of any refunds), recoveries, and carryover amounts. Net collections are a function of the annual target revenue amount, and the number of fees paid. Where **Section G** describes the process for setting the annual target revenue amount, this section will describe the estimated total budgetary resources.

Annual updates to this plan will update the actual revenue amount for the current fiscal year and the actual collections amount from the preceding fiscal years.

Net Collections: FDA generally assumes, for planning purposes, that net collections will equal the target revenue amount. Net collections represent the total collections minus any refunds that occurred during the fiscal year, regardless of the year the fee was due. In practice, 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.

Recoveries: Recoveries account for funds returned to the Agency in the form of de-obligations of prior year obligations. For example, recoveries could include funding from a contract that ended in a prior FY and was not expended. For the purposes of this plan, future year recoveries are estimated to be $376,000 for FY 2026 and adjusted as necessary for subsequent fiscal years.

Total Carryover, beginning of FY: Total carryover represents the balance of unspent ADUFA fee funds at the beginning of the fiscal year. The total carryover at the end of one fiscal year equals the total carryover at the beginning of the subsequent fiscal year. Carryover is discussed in more detail in **Section J**.

Table 3 presents the actual and estimated total annual ADUFA fee collections by fee type and cohort year. Refer to **Section E** for more background and information on the ADUFA V fee structure.

Table 3: ADUFA V Fee Collections by Fee Type and Cohort Year

Fee Type	Cohort Year 2024 Actual	Cohort Year 2025 Actual	Cohort Year 2026 Estimate
Application Fees	$8,204,076	$7,271,683	$7,230,400
Establishment Fees	$8,187,400	$7,411,994	$9,399,520
Product Fees	$9,107,529	$7,643,370	$9,761,040
Sponsor Fees	$8,278,470	$7,145,446	$9,761,040
Total Net Collections	**$33,777,475**	**$29,472,493**	**$36,152,000**

Cohort Year Collections: User fee collections are generally recognized and reported in the year that the fee was originally due (referred to as the "cohort year"). Totals reported are after any refunds for the cohort year. To ensure the quality of the information provided in this financial plan, FDA annually updates prior years' numbers to account for any collections or refunds processed after publication of the report.

The annual updates to this plan will provide the actual Net Collections amounts by cohort year for the preceding year(s) as well as an updated estimated amount for the following year.

Net Collections vs. Cohort Year Collections: User fee collections are reported in two different ways:

- **Net Collections:** Net collections are the actual dollar amounts collected in a fiscal year, regardless of the fiscal year the fee was due. **Table 2a** reports net collections.

- **Cohort Year Collections:** Cohort year collections represent the fiscal year for which the fee was originally due. **Table 3** reports cohort year collections.

Example: Assume a fee was due in FY 2025 but was paid in FY 2026. This would be reported as a net collection in FY 2026 and a cohort year collection in FY 2025.

I. User Fee Obligations

ADUFA fees may be expended only for certain 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 the allowable and excluded costs, see **Appendix A.**

Table 4 provides a breakout of planned user fee obligations by expense category for the five years represented in this plan. The annual updates to this plan will provide actual amounts for the preceding fiscal year, as well updated estimated amounts for the remaining fiscal years.

Table 4: Animal Drug User Fee Obligations by Expense Category for Fiscal Years 2024 – 2028

User Fee Obligations	FY2024 Actual	FY2025 Actual	FY2026 Forecast	FY2027 Forecast	FY2028 Forecast
Payroll	**$23,570,113**	**$24,564,135**	**$28,480,892**	**$30,914,924**	**$33,573,873**
CVM	$22,610,914	$23,707,997	$27,630,003	$29,989,533	$32,567,390
HQ	$541,162	$346,777	$490,309	$533,309	$580,118
OII	$418,037	$509,361	$360,580	$392,082	$426,366
Operating	**$4,408,708**	**$1,621,949**	**$4,713,280**	**$4,782,217**	**$4,860,367**
CVM	$4,110,836	$1,538,171	$4,279,729	$4,332,749	$4,389,152
HQ	$297,872	$0	$433,551	$449,468	$471,215
OII	$0	$83,778	$0	$0	$0
Rent	**$1,375,525**	**$1,452,288**	**$1,517,645**	**$1,600,818**	**$1,625,487**
Shared Services	**$4,992,237**	**$4,421,655**	**$4,676,668**	**$4,720,293**	**$4,604,018**
Total Obligations	**$34,346,583**	**$32,060,027**	**$39,388,485**	**$42,018,252**	**$44,663,745**

Total Obligations include payroll and operating, rent, and shared services costs funded by ADUFA fee funds. Non-user fee funds supporting the ADUFA program are not included here. The details of each component of Total Obligations are as follows:

- **Payroll and Operating Costs:** These obligations provide for certain payroll and operating costs for which ADUFA fees may be expended to support the process for the review of animal drug applications, as defined in the statute. These allowable 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. See **Appendix A** for a listing of those activities. The payroll and operating costs associated with the ADUFA program are based on obligations attributed to CVM, OII, and HQ.

  Center employees are required to report their time in an activity-based reporting system. This allows FDA to ensure that user fee funds are supporting only allowable activities.

  For operating activities (e.g., certain contracting services), user fee funds are allocated based on the proportion to which those activities support allowable animal drug activities. If an operating activity solely supports the process for the review of animal drug applications, it can be fully funded by ADUFA fees (and/or non-user fee appropriations). If the operating activity supports multiple user fee programs, ADUFA fees may fund the activity up to the proportion of the benefit from such activity that accrues to allowable animal drug activities.

- **Rent:** The General Services Administration 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. Since rent is an allowable support cost for the process for the review of animal drug applications, a portion of those charges is paid from ADUFA fees.

- **Shared Services:** FDA has several shared service programs supported by the WCF that provide support for activities across the Agency, such as human resources and information technology (IT). **Appendix B.1.** provides a full list of what is contained in the WCF.

J. User Fee Carryover

ADUFA fees collected, appropriated, and not obligated at the end of the fiscal year remain available to FDA to support the ADUFA program in future fiscal years.

Maintaining an appropriate level of carryover enables FDA to mitigate financial risks to the ADUFA program, including, for example, the risk of under collecting fees and the risk of 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 set aside available user fee funds in the carryover for certain purposes, including, for example, for processing future year refunds.

The net change in the carryover each year is equal to total budgetary resources minus total obligations. This value can be calculated using the values in **Tables 2a** and **2b** above.

Table 5 provides actual or estimated ADUFA carryover balances at the end of each fiscal year. Estimates are updated with actual amounts in future Five-Year Financial Plan annual updates.

Table 5: ADUFA Carryover by Fiscal Year

Carryover	FY2024 Actual	FY2025 Actual	FY2026 Estimate	FY2027 Estimate	FY2028 Estimate
Total Carryover, End of Year	$22,384,596	$20,592,781	$17,732,162	$14,135,278	$10,887,489
Unappropriated Amounts, Unavailable	($2,058,256)	($2,058,256)	($2,058,256)	($2,058,256)	($2,058,256)
Carryover, Net of Unavailable	$20,326,340	$18,534,525	$15,673,906	$12,077,022	$8,829,233

These terms are defined as follows:

- **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 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. Additional details on Unappropriated Amounts are included in **Appendix B.5.**

- **Carryover, Net of Unavailable:** This is the total carryover less any funds subject to restrictions that currently preclude FDA from obligating the carryover funds.

Current estimates indicate the carryover (net of unavailable) at the end of FY 2025 and 2026 will exceed the operating reserve decrease thresholds shown in **Table 6**. The carryover (net of unavailable) amounts shown in **Table 5** and **Table 6** for FY 2025 and 2026 reflect that an estimated operating reserve adjustment has been made, reducing the Target Revenue amounts. **Table 1** shows the reduced Target Revenue amounts. Looking forward into ADUFA V, the operating reserve adjustment will be used, as needed, to ensure carryover remains between the minimum 12-week and the maximum levels specified in section 740(c)(4) of the FD&C Act. See **Table 6** below for the operating reserve adjustment threshold amounts.

Table 6: ADUFA Operating Reserve Adjustment Thresholds for Fiscal Years 2024 – 2028

Operating Reserve	FY2024 Actual	FY2025 Actual	FY2026 Actual	FY2027 Estimate	FY2028 Estimate
Operating Reserve Adjustment Increase Threshold (weeks)	N/A	12	12	12	12
Operating Reserve Adjustment Increase Threshold ($)	N/A	$8,034,887	$8,423,772	$8,806,846	$9,498,000
Carryover Net of Unavailable, End of Year	**$20,326,340**	**$18,534,525**	**$15,673,906**	**$12,077,022**	**$8,829,233**
Operating Reserve Adjustment Decrease Threshold (weeks)	N/A	22	20	18	16
Operating Reserve Adjustment Decrease Threshold ($)	N/A	$14,730,626	$14,039,620	$13,210,269	$12,664,000

K. Non-User Fee Appropriations

For FDA to obligate user fees collected under ADUFA, a certain amount of non-user fee appropriations must be spent on the process for the review of animal drug applications during a fiscal year. This is often referred to as a "non-user fee spending trigger."[4] **Table 7** presents the actual and forecasted non-user fee spending triggers for FY 2024 through FY 2028.

Table 7: Minimum Allocation of ADUFA Non-User Fee Appropriations by Fiscal Year

FY2024 Actual	FY2025 Actual	FY2026 Actual	FY2027 Actual	FY2028 Estimate
$53,829,548	$55,574,241	$57,018,007	$58,606,998	$59,779,138

The non-user fee spending trigger amount is determined by multiplying the base amount of non-user fee appropriations spent on the process for the review of animal drug applications in FY 2003 ($32,748,000), by the adjustment factor applicable to that fiscal year. See **Appendix B 2-4** for more details.

[4] This requirement is met if an amount that is not more than 3 percent below the minimum level is spent (see sections 740(g)(2)(A)(ii) and 740(g)(2)(B) of the FD&C Act).

Challenges, Risk, and Mitigation

As is the case with most agency 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 only estimate 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 the 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; these contingency plans help ensure FDA is able to move forward in the best interests of the program.

Uncertainty of User Fees 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 financial planning challenges for the program since 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. 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. Additionally, fluctuations in industry submissions from year to year can change the total user fee collections.

Lapse in Non-User Fee Appropriations: FDA is mitigating this risk to the program by maintaining a certain level of ADUFA fee collections as a carryover. FDA considers a reasonable range of carryover for the ADUFA program to maintain in anticipation of these risks to be 22 weeks for FY 2025, 20 weeks for FY 2026, 18 weeks for FY 2027 and 16 weeks for FY 2028. FDA notes this reasonable range is higher for ADUFA than for some other FDA user fee programs. This is because ADUFA is a much smaller program, as measured by workload or planned expenditures, and small shifts in submissions could have a significant impact on workload and the requisite funding needed to maintain operations. This reserve can be used to help support program operations in the event of a lapse in appropriations.

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 target revenue. When FDA under-collects user fees, it leverages its carryover to maintain continuity in operations. FDA monitors collections throughout the fiscal year, and the UFFMC and other FDA senior leaders determine how to mitigate any instances when user fee collection deviates from forecasted estimates.

Strategic Challenges: In FY 2026, FDA will spend user fees to continue enhancing the new animal drug review process, focusing on improving the efficiency, quality, and predictability of the program. Some challenges FDA faces in FY 2026 include managing increasingly complex applications and submissions, maintaining a staff with needed review expertise, and implementing program enhancements to include: public educational seminars, new processes for virtual pre-submission conferences and other

submission types, newly agreed upon public-facing metrics, and continued support of an all-electronic review environment and IT modernizations, Agency systems consolidation, and enhancements needed to provide a more efficient review process.

Appendices

A. Allowable and Excluded Costs and Activities for the ADUFA Program

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:

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 the [HHS] Secretary'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 the Agency and the animal drug sponsor. 8. 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 U.S. and European Union Mutual Recognition Agreement for Pharmaceutical Good Manufacturing Practice Inspections, and the U.S. 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 in connection with the process for the review of animal drug applications for:

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 the 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. 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:

Excluded Activities
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. Supplemental Financial Information

B.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 2026 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.

B.2. Inflation Adjustment

The fee revenue amounts established in ADUFA V for FY 2025 and subsequent fiscal years are subject to adjustment to account for inflation. The inflation adjustment adjusts the annual fee revenue amounts specified in the ADUFA statute to maintain the purchasing power of fee funds despite inflation. The adjustment is made to the non-payroll-related portion by changes in the CPI and adjusts the payroll-related portion by changes in FDA's average personnel compensation and benefits.

The adjustment amount for FY 2026 is $3,002,505.

B.3. Workload Adjustment

The fee revenue amounts established in ADUFA V for FY 2025 and subsequent fiscal years are also subject to adjustment to reflect changes in FDA's workload for the process for the review of animal drug applications. A workload adjustment will be applied to the inflation-adjusted fee revenue amount (section 740(c)(3) of the FD&C Act).

To apply the workload adjustment, ADUFA V specifies that FDA shall calculate the weighted average of the change in the total number of each of the five types of applications and submissions specified in the workload adjustment provision (i.e., animal drug applications, supplemental animal drug applications for which data with respect to safety or effectiveness are required, manufacturing supplemental animal drug applications, investigational animal drug study submissions, and investigational animal drug protocol submissions submitted).

No adjustment will be made until after the workload reaches greater than 3% for a second year in the authorization and any year thereafter through FY 2028. No adjustment was made for FY 2026.

B.4. Minimum Non-User Fee Appropriations Adjustment Factor

FDA must calculate and incorporate an adjustment factor when calculating the minimum non-user fee appropriations for the purpose of section 740(g)(2)(A)(ii). During ADUFA V, the following adjustment factor is applied: 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 2002. (See section 739(10) of the FD&C Act.)

B.5. 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 8** outlines the excess user fees by fiscal year.

Table 8: 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**

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