Five-Year Financial Plan

Fiscal Years
2024-2025-2026-2027-2028

FY 2024 Version

FOR THE

Animal Drug User Fee Act Program

FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Table of Contents

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 the first year of this commitment.

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 5 years in the current reauthorization period.

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 Regulatory Affairs (ORA), and Headquarters (HQ).

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

Exhibit 1: User Fee Program Components

Component	Mission
CVM	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.
ORA	Protects consumers and enhances public health by maximizing the compliance of FDA-regulated products and minimizing the risk associated with those products.
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

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

FDA leverages the User Fee Financial Management Committee (UFFMC) for user fee governance. The UFFMC 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 ensuring FDA's 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 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 user fee 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. Additionally, FDA established an Enterprise Risk Management (ERM) Program, with an ERM Council as the governance body responsible for providing overall oversight and accountability. For further information regarding the Internal Controls and Enterprise Risk Management, please refer to the User Fee Program's Financial Report.[1]

E. User Fee Background and Structure

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by ADUFA, authorizes FDA to collect fees from industry to supplement non-user fee appropriations that the Agency spends on the process for the review of animal drug applications.

Originally authorized in 2003 (ADUFA I), ADUFA was reauthorized in 2008 (ADUFA II), in 2013 (ADUFA III), in 2018 (ADUFA IV), and most recently in 2023 (ADUFA V). ADUFA V extends the ADUFA program from October 1, 2023, through September 30, 2028. ADUFA V authorizes continued funding for FDA from FY 2024 through FY 2028 to support program operations, evaluation, and improvement. ADUFA V continues to deliver tremendous public health benefits by enhancing FDA's capacity to review new animal drug submissions to help ensure that products coming to the market for the American public will be safe and effective.

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 V establishes a fee structure comprised of the following four types of fees: application fee, product fee, establishment fee, and sponsor fee.

Exhibit 2 outlines the ADUFA V user fee structure.

[1] ADUFA Financial Reports are available at https://www.fda.gov/about-fda/user-fee-financial-reports/adufa-financial-reports.

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 for which safety or effectiveness data are required, 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. Because the definition of "animal drug application" was expanded by ADUFA IV to include applications for conditional approval submitted under section 571 of the FD&C Act, persons submitting such applications are now subject to ADUFA fees, except that fees may be waived in certain circumstances as provided in the statute, including when the drug is solely intended to provide for a minor use or minor species indication.
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 drug 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 an investigational animal drug submission pending at FDA after September 1, 2003. An animal drug sponsor is subject only to one such 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.

The statute specifies at section 740(c) of the FD&C Act how the fees are to be calculated each fiscal year, including annual adjustments that must be made for inflation. The statute also provides for the possibility of annual adjustments for workload and operating reserve. FDA publishes the fee amounts, and the methodology used to calculate these amounts, in the Federal Register each year.[2]

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

[2] 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.

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.[3]

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. Over the next five fiscal years, FDA will focus on implementing the new commitments and changes to the program. Below are some highlights of what FDA will be focusing on over the next five years in the program.

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.
- 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.

[3] https://www.fda.gov/media/116001

- 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 policies 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.

Third-Party Assessment

FDA will engage an independent, third-party to conduct a comprehensive assessment of the process for the review of animal drug applications. The assessment will include consultation with both FDA and industry and the final assessment report will be published on FDA.gov. FDA will convene a public workshop approximately three months after accepting the final assessment report to present the findings of the independent assessment. The assessment report and the public meeting will be completed by December 31, 2025.

Financial Transparency

FDA agreed to publish this ADUFA 5-year financial plan no later than the end of the second quarter of FY 2024 and will publish updates to the 5-year plan no later than the end of the second quarter of each subsequent fiscal year.

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, 2024 (FY 2025), the base will comprise FY 2019 through FY 2023. 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 estimated target revenue amount for each fiscal year. The financial notes referenced in this table can be found in **Appendix B**.

Table 1: Animal Drug User Fee Target Revenue for FY 2024 through FY 2028

	Notes	FY2024 Actual	FY2025 Estimate	FY2026 Estimate	FY2027 Estimate	FY2028 Estimate
Annual Base Revenue[4]	Note 1	$33,500,000	$33,500,000	$33,500,000	$33,500,000	$33,500,000
Inflation Adjustment	Note 6	$0	$1,318,000	$2,014,000	$2,725,000	$3,449,000
Workload Adjustment	Note 7	$0	$0	$0	$0	$0
Operating Reserve Adjustment		NA	($4,593,000)	($1,371,000)	($1,420,000)	($1,470,000)
Target Revenue Total		**$33,500,000**	**$30,225,000**	**$34,143,000**	**$34,805,000**	**$35,479,000**

All numbers other than Annual Base Revenue have been rounded to the nearest dollar.

Target Revenue: 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. See **Note 1** for a diagram of this process.

- **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 weight operating expenses by changes in the CPI and payroll-related expenses by changes in FDA's average personnel compensation and benefits amounts.

[4] Annual Base Revenue for ADUFA V is specified in the FD&C Act and is not an estimated number.

- **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 may increase the fee revenue amount 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 exceed the operating reserve defined maximum threshold. FDA has estimated that an operating reserve adjustment of ($4,593,000) will be needed for FY 2025, ($1,371,000) for FY 2026, ($1,420,000) for 2027, and ($1,470,000) for 2028 to bring the operating reserves of carryover user fees to less than or equal to the threshold amount. For more information, see **Section J**.

Tables 2a-2c together represent a summary of the estimated ADUFA financial position., Table 2a provides an overview of user fee budgetary resources. Table 2b provides an overview of estimated obligations for which the user fee resources would be used. Table 2c provides an estimate of carryover amounts. Annual updates to this plan will provide actual amounts for the prior fiscal years. The financial notes referenced in this table can be found in **Appendix B**.

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

Target Revenue	Note 1	**$33,500,000**	**$30,225,000**	**$34,143,000**	**$34,805,000**	**$35,479,000**
Net Collections		$33,500,000	$30,225,000	$34,143,000	$34,805,000	$35,479,000
Recoveries	Note 2	$318,000	$318,000	$318,000	$318,000	$318,000
Total Carryover, Beginning of FY		$23,281,801[5]	$20,970,268	$16,695,268	$15,642,268	$14,540,268
Total Budgetary Resources		**$57,099,801**	**$51,513,268**	**$51,156,268**	**$50,765,268**	**$50,337,268**

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

Obligations	Notes	FY2024 Estimate	FY2025 Estimate	FY2026 Estimate	FY2027 Estimate	FY2028 Estimate
Payroll and Operating	Note 3	$29,889,882	$28,373,239	$28,856,464	$29,346,725	$29,841,715
Rent	Note 4	$1,375,525	$1,389,280	$1,403,173	$1,417,205	$1,431,377
Shared Services	Note 5	$4,864,126	$5,055,481	$5,254,363	$5,461,070	$5,675,908
Total Obligations		**$36,129,534**	**$34,818,000**	**$35,514,000**	**$36,225,000**	**$36,949,000**

[5] Total Carryover, Beginning of FY for FY 2024 is the actual amount of carryover from FY 2023.

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

Carryover	Notes	FY2024 Estimate	FY2025 Estimate	FY2026 Estimate	FY2027 Estimate	FY2028 Estimate
Total Carryover, End of Year		**$20,970,364**	**$16,695,268**	**$15,642,268**	**$14,540,268**	**$13,388,2688**
Unappropriated Amounts	Note 9	($2,058,256)	($2,058,256)	($2,058,256)	($2,058,256)	($2,058,256)
Operating Reserve, Set Aside		($7,730,769)	($8,034,923)	($8,195,538)	($8,359,615)	($8,526,692)
Carryover Net of Unavailable and Set Aside, End of Year		**$11,181,339**	**$6,602,089**	**$5,388,474**	**$4,122,397**	**$2,803,320**

All numbers other than Target Revenue in Tables 2a-2c have been rounded to the nearest dollar. Target Revenue has been rounded to the nearest thousand dollars (except Target Revenue for FY 2024, which is set in the FD&C Act and is not an estimate).

Budgetary Resources: The Total Budgetary Resources estimates in **Table 2a** show the sum of user fee funding estimates for each FY. Budgetary resources include net collections, recoveries, and carryover amounts.

Budgetary resources are discussed in more detail in **Section H**.

Obligations: The Total Obligations estimates in **Table 2b** show the 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**.

Obligations are discussed in more detail in **Section I**.

Carryover: The Carryover estimates in **Table 2c** show 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 unappropriated amounts or the operating reserve. Appropriated carryover remains available to support the ADUFA program in future fiscal years.

Carryover is discussed in more detail in **Section J**.

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. This section describes the process for setting the annual target revenue amount and then describes 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 assumes, for planning purposes, that net collections will equal the target revenue amount. In practice, net collections may differ from the 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:** For the purposes of this plan, future year recoveries are estimated to be $318,096 annually. Additional details on recoveries are included in **Note 2.**

- **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 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 Estimate
Application Fees	$6,700,000
Establishment Fees	$8,710,000
Product Fees	$9,045,000
Sponsor Fees	$9,045,000
Total Net Collections	**$33,500,000**

Numbers have been rounded to the nearest dollar.

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 2024 but was paid in FY 2025. This would be reported as a net collection in FY 2025 and a cohort year collection in FY 2024.

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. The financial notes can be found in **Appendix B**.

Table 4: Animal Drug User Fee Obligations by Expense Category for FY 2024 through FY 2028

User Fee Obligations	Notes	FY2024 Estimate	FY2025 Estimate	FY2026 Estimate	FY2027 Estimate	FY2028 Estimate
Payroll & Operating Costs	**Note 3**					
CVM		$28,601,375	$27,059,130	$27,516,242	$27,979,872	$28,465,199
OC		$860,980	$878,031	$895,422	$913,158	$913,747
ORA		$427,527	$436,078	$444,799	$453,695	$462,769
Rent	Note 4	$1,375,525	$1,389,280	$1,403,173	$1,417,205	$1,431,377
Shared Services	Note 5	$4,864,126	$5,055,481	$5,254,363	$5,461,070	$5,675,908
Total Obligations		**$36,129,534**	**$34,818,000**	**$35,514,000**	**$36,225,000**	**$36,949,000**

Numbers have been rounded to the nearest dollar.

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 all payroll and operating costs that support the activities for which ADUFA fees may be expended, as set forth in 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.

  Payroll and operating costs are presented by each major organizational component relevant to the ADUFA program. FDA plans to expend operating resources in FY 2024 for the Third-Party Assessment that is one of the ADUFA V commitments.

  The Payroll and Operating Costs estimates shown in Table 4 are assumed to increase by 2 percent yearly.

- **Rent:** This is paid to the General Services Administration for the federal buildings that FDA occupies, as well as to non-federal sources for direct leases and services (see **Note 4**). Rent is charged at different rates depending on the type and location of the space provided.

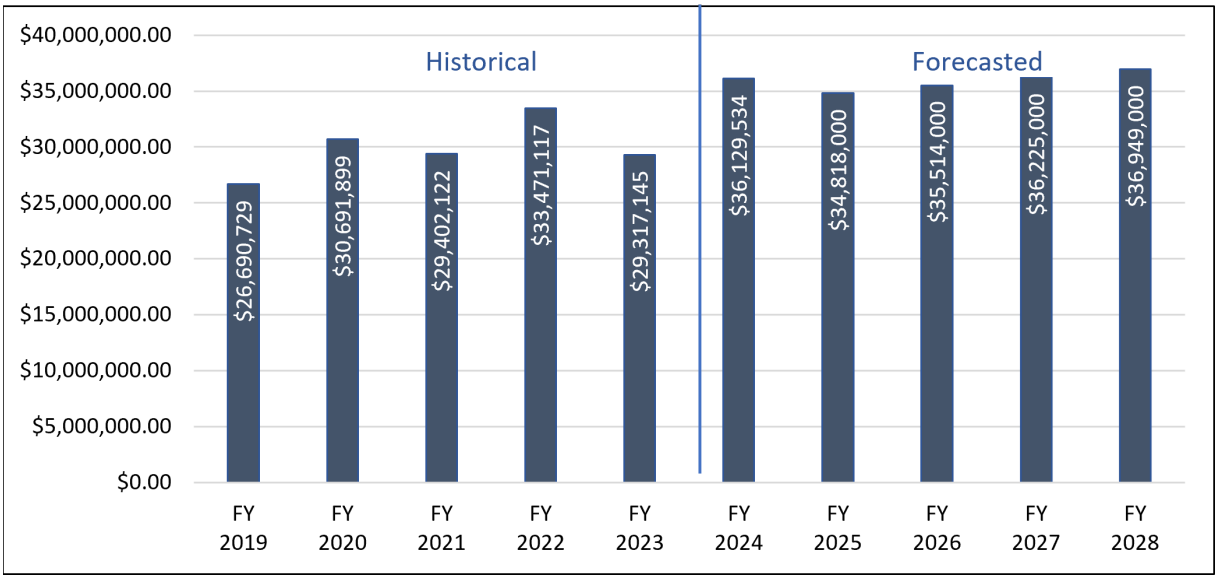
  The rent cost estimates shown in Table 4 are adjusted for inflation using a flat inflation adjustment amount of amount of 1 percent, which reflects recent trends in FDA's rent cost.

- **Shared Services:** FDA has several shared service organizations that provide support across the user fee programs, such as human resources and information technology (IT). Shared services are located within the Working Capital Fund (WCF). **Note 5** provides a full list of what is contained in the WCF.

  FY 2024 Shared Service estimates shown in Table 4 include small, proportionate increases to support the growth of the program.

Exhibit 3 below provides an illustration of historical ADUFA IV obligations and projected ADUFA V needs.

Exhibit 3: Historical and Forecasted User Fee Obligations by Fiscal Year



As demonstrated by this graph, annual ADUFA V obligations are expected to be commensurate to the annual ADUFA IV obligations, adjusted for inflation. FDA plans to expend more operating resources in FY 2024 for the Third-Party Assessment that is an ADUFA V commitment.

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 estimates of ADUFA carryover balances at the end of each fiscal year. Estimates will be updated with actual amounts in future Five-Year Financial Plan annual updates.

Table 5: ADUFA Carryover by Fiscal Year

Carryover	Notes	FY2024 Estimate	FY2025 Estimate	FY2026 Estimate	FY2027 Estimate	FY2028 Estimate
Total Carryover, End of Year		**$20,970,364**	**$16,695,268**	**$15,642,268**	**$14,540,268**	**$13,388,268**
Unappropriated Amounts, Unavailable		($2,058,256)	($2,058,256)	($2,058,256)	($2,058,256)	($2,058,256)
Carryover, Net of Unavailable		$18,912,108	14,637,012	13,584,012	12,482,012	11,330,012
Operating Reserve, Set Aside		($7,730,769)	($8,034,923)	($8,195,538)	($8,359,615)	($8,526,692)
Carryover Net of Unavailable and Set Aside, End of Year		**$11,181,339**	**$6,602,089**	**$5,388,474**	**$4,122,397**	**$2,803,320**

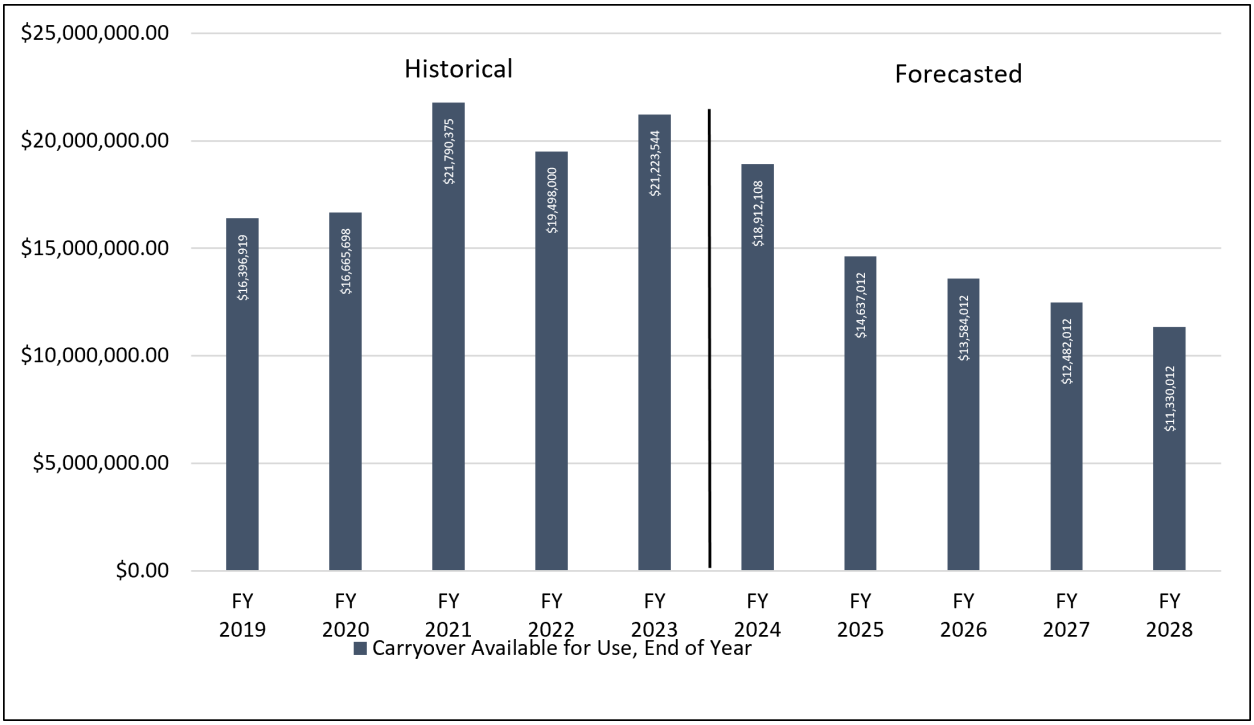
Numbers are rounded to the nearest dollar.

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.
- **Carryover, Net of Unavailable:** This is the total carryover less any funds subject to restrictions that currently preclude FDA from obligating the carryover funds.
- **Operating Reserve, Set Aside:** This is 12 weeks of carryover funds, as allowed to be maintained at the end of the fiscal year (see section 740(c)(4)(A)(i) of the FD&C Act).
- **Carryover Net of Unavailable and Set Aside, End of Year:** This is the total carryover less any carryover funds subject to set asides, or subject to any restrictions that currently preclude FDA from obligating the carryover funds.

Exhibit 4 below shows the historical trend of carryover in ADUFA IV and the forecasted carryover in ADUFA V. The forecasted values reflect the use of the operating reserve adjustment for FY 2025, FY 2026, FY 2027, and FY 2028.

Exhibit 4: Historical and Forecasted Carryover (Net of Unavailable) by Fiscal Year



Current estimates indicate the carryover (net of unavailable) at the end of each FY 2025 through 2028 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, FY 2026, FY 2027, and FY 2028 reflect that the estimated operating reserve adjustments have 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 FY 2024 through FY 2028

Operating Reserve	FY2024 Estimate	FY2025 Estimate	FY2026 Estimate	FY2027 Estimate	FY2028 Estimate
1-Week Operating Amount	$644,231	$669,577	$682,962	$696,635	$710,558
Operating Reserve Adjustment Increase Threshold (weeks)	n/a	12	12	12	12
Operating Reserve Adjustment Increase Threshold ($)	n/a	$8,034,923	$8,195,538	$8,359,615	$8,526,692
Operating Reserve Adjustment Decrease Threshold (weeks)	n/a	22	20	18	16
Operating Reserve Adjustment Decrease Threshold ($)	n/a	$14,730,692	$13,659,231	$12,539,423	$11,368,923
Carryover (Net of Unavailable), End of FY	**$18,912,108**	**$14,637,012**	**$13,584,012**	**$12,482,012**	**$11,330,012**

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."[6] **Table 7** presents the 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	FY2025 Estimate	FY2026 Estimate	FY2027 Estimate	FY2028 Estimate
$53,829,558	$55,574,240	$56,685,725	$57,819,439	$58,975,828

Numbers have been rounded to the nearest dollar.

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 **Note 8** for more details on the adjustment factor.

[6] 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

Financial Risks and Mitigation

As is the case with all financial programs, there are certain financial risks and challenges that exist with FDA's user fee programs. These risks and challenges can vary from program to program, with some being in FDA's control and some out of FDA's control. An example of a shared financial risk across all user fee programs is that FDA cannot obligate funds in advance of receiving the funds, either through appropriated user fee collections or non-user fee appropriations. FDA can 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 2024, 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 2024 include managing increasingly complex applications and submissions, and implementing program enhancements to include: public educational seminars, new processes for virtual pre-submission conferences and other submission types, a draft guidance for industry on raw data requirements, newly agreed upon public-facing metrics, a comprehensive third-party assessment of the animal drug applications review process, and continued support of an all-electronic review environment and the IT modernizations and enhancements needed to provide a more efficient review process.

Appendices

A. Allowable and Excluded Costs 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:

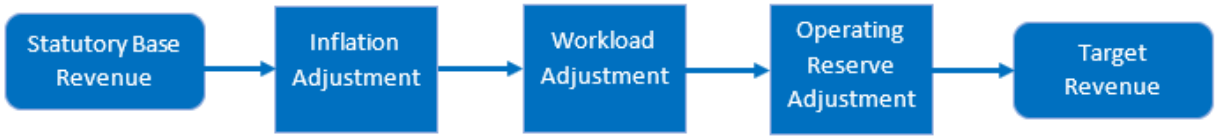
Excluded Activities
1. Review of abbreviated new animal drug applications. 2. Enforcement policy development. 3. Post-approval surveillance and compliance activities. 4. Post-approval activities relating to the review of advertising. 5. Inspections unrelated to the ADUFA program. 6. Research unrelated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

B. Financial Notes

Note 1. Annual Target Revenue Methodology

Exhibit 5 is a flowchart that outlines the Annual Target Revenue Methodology.

Exhibit 5: ADUFA Annual Target Revenue Methodology



The inflation, workload, and operating reserve adjustments apply beginning in FY 2025.

Note 2. 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.

Note 3. Payroll and Operating Costs

Payroll and operating costs associated with the ADUFA program are based on obligations attributed to CVM, ORA, and HQ.

For payroll, employees are required to report their time in an activity-based time 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), 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. 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.

Note 4. Rent Costs

GSA charges rent to FDA for the federal buildings that FDA occupies. Rental rates vary based on the type and location of the space provided. Because rent is an essential support cost for the process for the review of 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. The amount of rent and rent-related costs each Center pays is directly related to the square footage occupied by that Center.

Note 5. Shared Service Costs

FDA has several shared service organizations, located within the WCF, that provide support across the user fee programs. The shared service organizations in FY 2024 include:

- FDA Central: Provides for Center-wide and Agency-wide services such as telecommunications, training, printing, mail and document management, IT systems, employee health units, and other support and miscellaneous services.

- Office of Acquisitions and Grants Services: Manages contracts, grants, and other agreements.

- Office of Equal Employment Opportunity: Promotes an inclusive work environment that ensures equal employment opportunity and fosters a culture that values diversity and empowers individuals.

- Office of Facilities, Engineering, and Mission Support Services: Provides FDA employees with office and laboratory facilities.

- Office of Financial Management: Provides financial managerial services and policy guidance.

- Office of Digital Transformation: Provides the information, communication, and knowledge infrastructure and services that enhance, transform, and sustain the ability of FDA to protect and promote the public health. Provides support to all FDA employees requesting administrative, IT, facilities, human resources, or other employee services.

- Division of Budget Execution and Control: Initiates, monitors, and analyzes FDA's budget resources. The Agency's budget is comprised of several appropriation accounts including Salaries and Expenses, Revolving Fund for Color Certification and other Services, Cooperative Research and Development Agreement, Contingency Fund, Building and Facilities, and Royalties.

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

- Office of Security 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. Administers vital security functions that contribute to the Agency's mission of protecting the public health by enhancing the safety and security of all personnel, facilities, and information.

- Office of Laboratory Safety: Reinforces FDA's expectations for safety and laboratory security, enhances communications among FDA's safety staff, and provides program support.

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

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

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

- 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.

Note 6. 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.

ADUFA V does not adjust for inflation until FY 2025; there is no inflation adjustment for FY 2024.

Note 7. 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).

ADUFA V does not start calculating for a workload adjustment until FY 2025 and there is no workload adjustment for FY 2024. 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.

Note 8. 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.)

Note 9. 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 2010. FDA's ability to access and obligate these collections remains uncertain.