Financial Report to Congress

Medical Device User Fee Amendments of 2022

FY 2025

U.S. FOOD & DRUG ADMINISTRATION

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Executive Summary

The Medical Device User Fee Amendments of 2022 (MDUFA) requires the Food and Drug Administration (FDA) to report annually on the financial aspects of MDUFA program implementation. This is the third report under the fifth authorization of MDUFA (MDUFA V) and covers fiscal year (FY) 2025.

The Federal Food, Drug, and Cosmetic (FD&C) Act specifies that the following three legal conditions must be satisfied each year for FDA to collect and spend MDUFA user fees:

1. Within FDA's Salaries and Expenses Appropriation, the amount appropriated for devices and radiological health, excluding fees, each fiscal year must not be more than 1 percent less than $398,566,000, multiplied by an adjustment factor specified in the statute.

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

3. FDA must spend at least as much from appropriated funds, excluding fees, for the review of device applications as it spent in FY 2009, multiplied by an adjustment factor specified in the statute, for costs of the review of device applications plus certain other costs.

Section 704(g)(10) of the FD&C Act also contains a provision that FDA must spend at least as much on medical device establishment inspections as it spent in FY 2002, increased by five percent each fiscal year. If FDA does not satisfy this condition for 2 consecutive years, FDA is prohibited from allowing accredited third parties to conduct certain medical device establishment inspections.

FDA met the three legal conditions in FY 2025, and this report explains how these legal conditions were satisfied. The statements and tables in the report provide data on medical device user fee collections, expenditures, and carryover, as well as comparative data from prior years. FDA also fulfilled the provision regarding spending on medical device inspections, which enables FDA to continue with the third party inspection program.

In FY 2025, FDA had net collections of $420 million in medical device user fees, spent $410 million in user fees for the device review process, and carried $240 million forward for future fiscal years.

MDUFA V user fees and non-user fee appropriations in FY 2025 supported 2,048 full-time equivalents, including salaries and operational expenses, to support the review of device applications. Detailed program accomplishments can be found in the MDUFA Performance Report.[1]

[1] The MDUFA Performance Report is available at https://www.fda.gov/about-fda/fda-track-agency-wide-program-performance/fda-track-medical-device-user-fee-amendments-mdufa-performance-reports.

Report Overview

A. Scope

This financial report addresses the implementation and use of medical device user fees by the Food and Drug Administration (FDA or Agency) during the period of October 1, 2024, through September 30, 2025. It presents the legal conditions that FDA must satisfy to collect and spend medical device user fees each fiscal year and documents how FDA determined that it met those requirements. It also presents information on the spending level for medical device inspections that must be satisfied for FDA to continue the Third Party inspection program and documents how FDA determined that it met that requirement. In addition, this report presents summary statements of fiscal year (FY) 2025 fee collections, obligations of user fees, carryover, and total costs of the process for the review of device applications from both Medical Device User Fee Amendments of 2022 (MDUFA) fees and non-user fee appropriations.

B. Report Requirements

In accordance with section 738A(a)(4) of the Federal Food, Drug, and Cosmetic (FD&C) Act, for FY 2023 through FY 2027, FDA will publish an annual financial report on the implementation of the authority for user fees during each fiscal year and the use by FDA of the fees collected for such fiscal year. The purpose of this report is to meet these requirements.

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

C. User Fee Background and Structure

The Medical Device User Fee and Modernization Act (MDUFMA) was a law passed by the United States Congress in 2002 that allowed FDA to collect fees from medical device manufacturers to help fund the process for the review of device applications. The FD&C Act, as amended by subsequent user fee amendments, authorizes FDA to collect fees from industry to supplement non-user fee appropriations spent on FDA's medical device review process.

MDUFMA was reauthorized in 2007 with the Medical Device User Fee Amendments to the FDA Amendments Act (MDUFA II), in 2012 with the Medical Device User Fee Amendments to the Food and Drug Administration Safety and Innovation Act (MDUFA III), in 2017 with the Medical Device User Fee Amendments to the FDA Reauthorization Act of 2017 (MDUFA IV), and in 2022 with the FDA User Fee Reauthorization Act of 2022 (MDUFA V) with the support of industry, stakeholders, Congress, and the Administration.

The FDA User Fee Reauthorization Act of 2022 includes the fourth reauthorization of MDUFA, also known as MDUFA V, which extends the program from October 1, 2022, through September 30, 2027. This 5-year reauthorization helps ensure continued

funding for FDA from FY 2023 through FY 2027 to support program operations, evaluation, and improvement. Under MDUFA, companies must pay application fees when submitting certain device applications to FDA. Fee-paying applications include premarket approval (PMA) applications; product development protocols (PDPs); premarket reports (PMRs); biologics license applications (BLAs); certain supplements to all of these applications; De Novo classification requests; premarket notification submissions (510(k)s); 30-day notices of changes to manufacturing procedures or methods of manufacture affecting device safety and effectiveness; and requests for classification information under section 513(g) of the FD&C Act. Under MDUFA, firms must pay an annual fee for each "establishment subject to a registration fee" and a fee for periodic reports regarding class III devices. The base fees for a PMA or BLA and for device establishment registration are specified in the statute for each year through FY 2027. Fees for other application types and for periodic reports are fixed by statute as a percentage of the PMA fee for each year.

Over time, MDUFA has been a success, creating a predictable, streamlined review process and dramatically reducing the average time to new medical device approval and clearance. MDUFA V continues to support medical device development oversight and marketing application review for the human medical device regulatory program and deliver tremendous public health benefits by enhancing FDA's capacity to review medical devices so that safe and effective products can come to the market more quickly.

FDA spends MDUFA user fee collections and non-user fee appropriations to hire, support, and maintain personnel for the review of medical device applications to help ensure that safe, effective, and high-quality medical devices are available to the American public. **Exhibit 1** outlines MDUFA V's fee structure.

Exhibit 1: MDUFA V Fee Structure

Fee Type	Definition
Premarket application	An application for approval of a device submitted under section 515(c) of the FD&C Act or section 351 of the Public Health Service Act (PHS Act) or a product development protocol described in section 515(f) of the FD&C Act. In general, these are applications providing scientific and regulatory documentation to demonstrate a reasonable assurance that a class III medical device is safe and effective for its intended use.
Premarket report (submitted under section 515(c)(2) of the FD&C Act)	A report submitted under section 515(c)(2) of the FD&C Act. In general, these are applications required for class III devices originally approved for a single use (that is, use on a single patient during a single procedure) that a manufacturer has reprocessed for additional use.
Panel-track supplement	A supplement to an approved premarket application or premarket report under section 515 of the FD&C Act that requests a significant change in design or performance of the device, or a new indication for use of the device, and for which substantial clinical data are necessary to provide a reasonable assurance of safety and effectiveness.

Fee Type	Definition
180-day supplement	A supplement to an approved premarket application or premarket report under section 515 of the FD&C Act that is not a panel-track supplement and requests a significant change in components, materials, design, specification, software, color additives, or labeling. In general, a supplemental application to an approved PMA or premarket report that typically requests approval of a significant change in aspects of a device, such as its design, specifications, or labeling, when a demonstration of a reasonable assurance of safety and effectiveness either does not require new clinical data or requires only limited clinical data.
Real-time supplement	A supplement to an approved premarket application or premarket report under section 515 of the FD&C Act that requests a minor change to the device, such as a minor change to the design of the device, software, sterilization, or labeling, and for which the applicant has requested (and the Agency has granted) a meeting or similar forum to jointly review and determine the status of the supplement.
30-day notice	A notice under section 515(d)(5) that is limited to a request to make a modification to a manufacturing procedure or method of manufacture affecting the safety and effectiveness of the device.
Efficacy supplement (to an approved BLA under section 351 of the PHS Act)	A supplement to an approved premarket application under section 351 of the PHS Act that requires substantive clinical data. In general, these applications provide a supplement to an approved application proposing to make one or more changes to a product, its manufacturing, or its labeling that necessitates the submission of data from significant studies.
510(k) premarket notification submission	A report submitted under section 510(k) of the FD&C Act. In general, a premarket submission made to FDA to demonstrate that a device to be marketed is substantially equivalent to a legally marketed device that is not subject to the PMA review process (i.e., a predicate device).
513(g) request for classification information	A request made under section 513(g) of the FD&C Act for information about the class in which a device has been classified or the requirements applicable to a device.
Annual fee for periodic reporting on a class III device	An annual fee associated with periodic reports required by a premarket application approval order. In general, fee to be paid by sponsors of class III devices for post-approval periodic reports (e.g., annual reports) which are submitted to FDA in accordance with 21 CFR 814.82(a)(7) and 814.84(b).
De Novo classification request	A request made under section 513(f)(2)(A) of the FD&C Act with respect to the classification of a device. In general, these applications request FDA to classify a device for which there is no legally marketed predicate but for which general or general and special controls provide a reasonable assurance of safety and effectiveness.

Fee Type	Definition
Annual establishment registration fee	An annual fee to be paid by an establishment that is registered (or is required to register) with the Secretary of Health and Human Services (delegated to FDA) under section 510 of the FD&C Act because such establishment is engaged in the manufacture, preparation, propagation, compounding, or processing of a device.

The statute specifies how the fees must be calculated each fiscal year, including (1) annual adjustments to the base fees and the total revenue that must be made for inflation, (2) adjustments to base fees to reach the inflation-adjusted total revenue amount, and (3) any applicable performance improvement, hiring, or operating reserve adjustments to establishment registration fees. The fee amounts are to be published in the *Federal Register* each year, typically at the beginning of August.[2]

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

Legal Conditions

The FD&C Act, as amended by MDUFA, specifies that three legal conditions must be satisfied each fiscal year for FDA to collect and spend medical device user fees. **Exhibit 2** describes those legal conditions and provides a brief explanation as to how those legal conditions were met for FY 2025.

[2] See https://www.federalregister.gov/documents/2024/07/31/2024-16883/medical-device-user-fee-rates-for-fiscal-year-2025.

Exhibit 2: MDUFA Legal Conditions

Legal Condition #		Details
1	Description	Within FDA's Salaries and Expenses Appropriation, the amount appropriated for devices and radiological health, excluding fees, each fiscal year must not be more than 1 percent less than $398,566,000, multiplied by an adjustment factor specified in the statute. The specified minimum level for FY 2025 is $438,921,700.
	Condition Was Met	In FY 2025, the final appropriation for the Device and Radiological Health line of FDA's Salaries and Expenses Appropriation (excluding user fees) was $446,660,000. Therefore, the first legal condition was satisfied.
2	Description	The fee amounts FDA may collect for each fiscal year must be specified in that year's user fee appropriation acts.
	Condition Was Met	The Full-Year Continuing Appropriations Act (Division A of The Full-Year Continuing Appropriations and Extensions Act, 2025, Public Law 119-4) which the President signed on March 15, 2025 specified an approval of funding at the level provided for in the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act (Division B of the Consolidated Appropriations Act, 2024, Public Law 118-42), which the President signed on March 9, 2024 and specified that $362,381,000 shall be derived from medical device user fees and that medical device user fees collected in excess of this amount are also appropriated for FDA. Therefore, the second legal condition was satisfied.
3	Description	The third condition requires a minimum spending from appropriations, excluding user fees, on the MDUFA program plus certain specified costs. The minimum spending from appropriations is the amount that FDA spent on the MDUFA program in FY 2009, multiplied by the adjustment factor.
	Condition Was Met	The specified minimum level for FY 2025 is $248,666,863. In FY 2025, FDA spent $272,130,707 from appropriations (exclusive of user fees) on the process for the review of device applications plus certain specified costs. Because FDA spent more than the specified minimum amount from appropriations in FY 2025, the third legal condition was satisfied.

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

Section 704(g)(10) of the FD&C Act also provides that FDA's obligations for medical device establishment inspections must be equal to or greater than the amount spent in FY 2002, increased by five percent each fiscal year. If this condition is not met for 2

consecutive years, FDA is not allowed to use accredited third parties to conduct certain medical device establishment inspections in future years.

That specified minimum level for FY 2025 is $59,664,354. In FY 2025, FDA obligated $64,691,793 from appropriations (exclusive of user fees) for medical device inspections. Because spending on inspections of medical device establishments exceeded the specified minimum level, FDA may permit accredited third parties to conduct certain medical device establishment inspections in future years.

Changes to Fee Structure and Fee-Setting Mechanisms Under MDUFA V

MDUFA V contains three new potential adjustments that may impact collections, including a performance improvement adjustment, a hiring adjustment, and an operating reserve adjustment. These adjustments must be made by increasing or decreasing the establishment registration base fees.

First, the performance improvement adjustment provides new authority for FDA to increase fee revenue above the statutory annual total revenue amount to support performance improvements in FY 2025, FY 2026 and/or FY 2027 if the Agency meets certain performance goals in FY 2023, FY 2024 and/or FY 2025 in the following four premarket submission areas: PMAs, 510(k)s, De Novos, and Pre-submissions. Second, the hiring adjustment provides for the reduction of base establishment registration fees in FY 2025, FY 2026, and FY 2027, respectively, if specific hiring goal thresholds for FY 2023, FY 2024, and FY 2025, respectively, are not met. Third, the operating reserve adjustment requires FDA to decrease base establishment registration fees for FYs 2023 to 2027 if the amount of the operating reserves of carryover user fees exceeds the designated amount and if such reduction is necessary to provide for not more than that designated amount of operating reserves in the following fiscal year.

Financial Information

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

D. User Fee Financials

Table 1 represents a summary of the MDUFA User Fee financial position for FY 2024 and FY 2025.

Table 1: Medical Device User Fee Budgetary Resources for Fiscal Years 2024 and 2025

Budgetary Resources	Notes	FY 2024	FY 2025
Total Carryover, Beginning of Year		**$248,753,175**	**$226,240,393**
Total Revenue in Statute:		$335,750,000	$350,746,400
Inflation Adjustment		1.079318	1.122491
Inflation-Adjusted Total Revenue		$362,381,000	$393,710,000
Performance Improvement Adjustment		N/A	$17,282,545
Hiring Adjustment		N/A	$0
Operating Reserve Adjustment		$0	$0
Inflation-Adjusted Total Revenue +/- Adjustments	**Note 1**	**$362,381,000**	**$410,992,545**
Net Collections		$346,163,806	$420,108,584
Recoveries	Note 2	$2,340,334	$3,675,474
Total Budgetary Resources		**$597,257,315**	**$650,024,451**
Obligations	**Notes**	**FY 2024**	**FY 2025**
Total Payroll and Operating	Note 3	$309,447,933	$342,035,399
TAP – Non-Add-Funded Thru Carryover		*$13,419,088*	*$13,894,812*
Third Party – Non-Add-Funded Thru Carryover		*$1,600,000*	*$1,600,000*
Total Rent	Note 4	$6,959,098	$7,652,065
Total Shared Services	Note 5	$54,614,910	$60,798,243
Total Obligations		**$371,021,941**	**$410,485,707**
Carryover	**Notes**	**FY 2024**	**FY 2025**
Total Carryover, End of Year		**$226,235,374**[3]	**$239,538,744**

The inflation-adjusted total revenue has been rounded to the nearest thousand dollars.

[3] The FY 2024 end of year carryover balance was understated by $5,019 due to the timing of a payment receipt adjustment. The adjustment is reflected in the FY 2025 beginning of year carryover.

The “Total Budgetary Resources” component of **Table 1** illustrates the total user fee funding (i.e., the existing total carryover, user fee collections, and recoveries). The “Inflation-Adjusted Total Revenue +/- Adjustments” component is the total revenue amount specified in the statute as adjusted for inflation, with the new statutory adjustments for performance improvement, hiring, and operating reserve added or subtracted as applicable.

The **“**Total Obligations” component of **Table 1** shows the actual expenditures of MDUFA fees for FYs 2024 and 2025. The “TAP – Non-Add-Funded Thru Carryover” and “Third Party – Non-Add-Funded Thru Carryover” components are a subset of the “Total Payroll and Operating Obligations” component and represent those obligations towards the Total Product Life Cycle Advisory Program (TAP Pilot) and Third Party review program that FDA funded from the MDUFA carryover in FYs 2024 and 2025. MDUFA fees may only be expended for costs to support the “process for the review of device applications,” as specified in the statute.[4]

The “Total Carryover, Beginning of Year” component of **Table 1** is the total amount of unobligated fee funds at the end of the preceding fiscal year; this amount includes funds subject to set asides and funds that FDA is currently precluded from obligating. The “Total Carryover, End of Year” component is the total amount of unobligated fee funds at the end of the fiscal year; this amount includes funds subject to set asides and funds that FDA is currently precluded from obligating. More details regarding the carryover balance are shown in **Table 6**.

Note 1. Inflation-Adjusted Total Revenue +/- Adjustments (User Fee Revenue Methodology)

This is the total revenue amount specified in the statute as adjusted for inflation, with the new statutory adjustments for performance improvement, hiring, and operating reserve added or subtracted as applicable. These new potential adjustments will not change the total revenue amount but may impact collections only by increasing or decreasing establishment registration base fees. If triggered, these adjustments direct FDA to set fees to either increase or decrease collections above or below the “inflation adjusted total revenue” amount. See **Section E – User Fee Revenue** for an explanation of these adjustments.

Note 2. Recoveries

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.

Note 3. Payroll and Operating Costs

These obligations provide for payroll and operating costs for which MDUFA fees may be expended to support the process for the review of device applications, as set forth in the statute. 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 MDUFA program.

[4] See sections 737(9) and 737(10) of the FD&C Act.

For payroll, Center employees are required to report their time in an activity-based reporting system, which allows FDA to identify activities that user fees can be used to support. See **Appendix A** for a listing of those activities. For operating activities (e.g., certain contracting services), MDUFA fee funds are allocated based on the proportion to which those activities support the MDUFA program.

Note 4. Rent Costs

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 device applications, a portion of those charges is paid from non-user fee appropriations, and a portion is paid from MDUFA fees. Also included in this account are recurring costs that FDA pays directly to non-federal sources under the delegation of direct lease and service authority. These services include the rental of space and all recurring services for building operations such as overtime utilities, janitorial services, guards, and ground maintenance. The amount of rent and rent-related costs each FDA Center pays is directly related to the square footage occupied by that Center.

Note 5. Shared Services Costs

FDA has several shared service programs, supported by the Working Capital Fund (WCF), that provide support for activities across the Agency. **See Appendix C.1** for the full list of organizations.

E. User Fee Revenue

MDUFA specifies that user fees shall be collected for certain medical device application submissions (which include annual fees for periodic reports) and that annual user fees shall be collected for establishment registrations. In addition, the statute directs FDA to set the fee rate for each application type and for periodic reports as a percentage of the standard fee for a PMA.

MDUFA V further specifies how the fees must be calculated each fiscal year, including (1) annual adjustments to the base fees and the total revenue that must be made for inflation, (2) adjustments to the base fees to reach the inflation-adjusted total revenue amount, and (3) any applicable performance improvement, hiring, or operating reserve adjustments to the establishment registration fees. After the applicable inflation adjustment to fees is complete, FDA is to increase the base fee amounts on a uniform proportionate basis if necessary to achieve the inflation-adjusted total revenue amount.[5] If necessary, after this adjustment, FDA is to further increase the base establishment registration fees to generate the inflation-adjusted total revenue amount.[6]

In addition, as mentioned in **Section C –** *Changes to Fee Structure and Fee-Setting Mechanisms Under MDUFA V*, MDUFA V has three potential new adjustments that may impact collections by increasing or decreasing only the establishment registration

[5] See section 738(c)(2)(D) of the FD&C Act.
[6] See section 738(c)(3) of the FD&C Act.

base fees: (1) the performance improvement adjustment (see section 738(c)(4) of the FD&C Act), (2) the hiring adjustment (see section 738(c)(5)), and (3) the operating reserve adjustment (see section 738(c)(6)). If submissions or registrations are higher than estimated, collections may exceed the inflation-adjusted total revenue amount (+/- adjustments) in a given fiscal year.

Table 2 outlines the inflation-adjusted total revenue amounts +/- adjustments for FYs 2024 and 2025.

Table 2: Medical Device Revenue for Fiscal Years 2024 and 2025

Inflation-Adjusted Total Revenue +/- Adjustments	FY 2024	FY 2025
Total Revenue in Statute	$335,750,000	$350,746,400
Inflation Adjustment	$26,631,019	$42,963,277
Inflation Adjusted Total Revenue		$393,710,000
Performance Improvement Adjustment	N/A	$17,282,545
Hiring Adjustment	N/A	$0
Operating Reserve Adjustment	$0	$0
Inflation Adjusted Total Revenue +/- Adjustments	**$362,381,000**	**$410,993,000**

The inflation-adjusted total revenue +/- adjustments numbers have been rounded to the nearest thousand dollars.

These adjustments are defined below:

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

The applicable inflation adjustment utilized in FY 2025 was 1.122491.

Performance Improvement Adjustment: The performance improvement adjustment provides authority for FDA to increase fee revenue above the statutory annual total revenue amount to support performance improvements in FY 2025, FY 2026, and/or FY 2027 if the Agency meets certain performance goals in FY 2023, FY 2024, and/or FY 2025 in the following four premarket submission areas: PMAs, 510(k)s, De Novos, and Pre-submissions. FDA met the FY 2023 Pre-submission Written Feedback goal, which triggered the performance improvement adjustment for FY 2025. The amount of this adjustment for FY 2025 is $17,282,545.

Hiring Adjustments: The hiring adjustment provides for the reduction of base establishment registration fees in FY 2025, FY 2026, and FY 2027, respectively, if specific hiring goal thresholds for FY 2023, FY 2024, and FY 2025, respectively, are not met. FDA met the specified hiring goal threshold for FY 2023. Accordingly, there was no hiring adjustment for FY 2025.

Operating Reserve Adjustment: For FYs 2023 through 2027, the operating reserve adjustment requires FDA to decrease its base establishment registration fees if the amount of operating reserves of carryover user fees exceeds the designated amount; this requirement is intended to provide for not more than such designated amount of operating reserves in the following fiscal year (see section 738(c)(6) of the FD&C Act).

The designated amount for the operating reserve adjustment is equal to the sum of 13 weeks of operating reserves of carryover user fees plus 1 month of operating reserves. In making this calculation for FYs 2023 through 2026, a total of $118 million is to be excluded from the designated amount and not subject to the decrease; that $118 million is intended to support the MDUFA V commitments for the TAP Pilot and the Third Party review program. Any residual amount of the excluded $118 million that is left unspent at the end of FY 2026 will no longer be excluded when determining if the operating reserves of carryover user fees exceed the designated amount for FY 2027; this residual amount will be subject to the operating reserve adjustment for FY 2027.

Note also that operating reserves do not include user fee funds considered unappropriated or unearned revenue.

No operating reserve adjustment was necessary in FY 2025 because the operating reserve did not exceed the designated amount. The calculations are included in the annual *Federal Register* notice establishing MDUFA fees (i.e., Medical Device User Fee Rates for Fiscal Year 2025), published in July 2024.[7]

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 for each fiscal year are net of any refunds for the cohort year. Net collections differ between the fiscal year and the cohort year. Cohort year collections reflect collections for a single cohort year (e.g., FY 2025) and are collected across multiple fiscal years. Transactions such as late collections or refunds processed in a different fiscal year (e.g., a refund processed during FY 2025 for an FY 2024 payment) will be displayed in **Tables 3a**, **3b**, **3c**, and **3d**. Other data tables, though, use a single fiscal year's data that solely show the activity within that fiscal year. To ensure the quality of the information provided in this financial report, FDA annually updates the prior cohort year's numbers.

Under MDUFA, fees collected, earned, and appropriated but not spent by the end of the fiscal year continue to remain available for FDA to spend in future years, as they are classified as "no-year funding." The funds carried over from year to year are described in **Section G – User Fee Carryover**. Unearned fees are fees received by September 30, 2025, either for applications that had not been submitted to FDA as of September 30, 2025, or for establishment fees received without identification of the remitter.

User fee collections were composed of collections from medical device application submissions (which included annual fees for periodic reports) and annual establishment

[7] MDUFA's *Federal Register* notice for the FY 2025 fee rates can be found at https://www.federalregister.gov/documents/2024/07/31/2024-16883/medical-device-user-fee-rates-for-fiscal-year-2025.

registration user fees under MDUFA V. **Tables 3a**, **3b**, **3c**, and **3d** outline MDUFA collections by fee source and cohort year. Unearned fees are a subset of total collections. Fees receivable is the balance of money due that was not yet collected as of September 30, 2025.

Table 3a: Medical Device User Fee Collections by Fee Source for Cohort Year 2024

Fees Collected	Estimated †	Actual	% Diff
Application Fees	$113,255,576	$112,490,666	-1%
Registration Fees	$249,143,415	$236,154,220	-5%
Total Collections	**$362,398,991**	**$348,644,886**	**-4%**

† Estimated values were taken from the Medical Device User Fee Rates for Fiscal Year 2024 at https://www.federalregister.gov/documents/2023/07/28/2023-15919/medical-device-user-fee-rates-for-fiscal-year-2024.

Table 3b: Medical Device User Fee Collections by Fee Source for Cohort Year 2025

Fees Collected	Estimated †	Actual	% Diff
Application Fees	$126,609,887	$142,117,495	12%
Registration Fees	$267,101,820	$282,186,265	6%
Total Collections	**$393,711,707**	**$424,303,760**	**8%**

† Estimated values were taken from the Medical Device User Fee Rates for Fiscal Year 2025 at https://www.federalregister.gov/documents/2024/07/31/2024-16883/medical-device-user-fee-rates-for-fiscal-year-2025.

Table 3c: Medical Device Unearned Fees by Fee Source for Cohort Years 2024 and 2025

Unearned Fees	Cohort Year 2024	Cohort Year 2025
Application Fees	$3,799,048	$10,871,398
Registration Fees	$2,196,372	$1,948,720
Total Unearned Fees	**$5,995,420**	**$12,820,118**

Table 3d: Medical Device User Fees Receivable by Fee Source for Cohort Years 2024 and 2025

Fees Receivable	Cohort Year 2024 Actuals	Cohort Year 2025 Actuals
Application Fees	$1,862,746	$1,709,714
Registration Fees	$91,927	$213,472
Total Receivables	**$1,954,673**	**$1,923,186**

F. Total MDUFA Program Costs

The MDUFA program is supported by both user fees and non-user fee appropriations. MDUFA fees may be expended only for costs necessary to support the

"process for the review of device applications," as specified in the statute. For more information on the allowable and excluded costs, see **Appendix A**. In addition, FDA calculates the total MDUFA program costs based on what is allowable under "the process for the review of device applications."

For historical context, **Table 4** provides the total amounts (from user fees and non-user fee appropriations) spent by FDA and by each FDA organization on the MDUFA program for the past 5 fiscal years.

Table 4: MDUFA Program Historical Trend of Total Costs by Organization as of September 30 for Fiscal Years 2021-2025

Category	FY 2021	FY 2022	FY 2023	FY 2024	FY 2025
CDRH Spent ($)	$431,620,290	$532,061,725	$608,248,689	$548,922,120	$578,061,950
CDRH Percentage (%)	83%	85%	85%	85%	85%
CBER Spent ($)	$42,036,545	$43,561,256	$51,035,711	$44,537,181	$44,473,711
CBER Percentage (%)	8%	7%	7%	7%	7%
OII Spent ($)	$10,093,225	$12,540,499	$15,461,981	$15,559,055	$14,764,722
OII Percentage (%)	2%	2%	2%	2%	2%
HQ Spent ($)	$35,719,285	$37,655,059	$41,617,554	$41,992,862	$45,316,031
HQ Percentage (%)	7%	6%	6%	6%	6%
Total Spent	**$519,469,345**	**$625,818,539**	**$716,363,935**	**$651,011,218**	**$682,616,414**

Focusing specifically on the user fee component of total MDUFA program costs, **Table 5** provides a comparison breakout of user fee obligations by expense category during the past 2 fiscal years.

Table 5: Medical Device User Fee Obligations by Expense Category for Fiscal Years 2024 and 2025

User Fee Obligations	FY 2024	FY 2025
Payroll and Operating		
CDRH	$282,662,843	$313,732,491
CBER	$16,063,200	$12,930,268
OII	$1,820,440	$2,488,637
HQ	$8,901,450	$12,884,003
Total Rent	$6,959,098	$7,652,065
Total Shared Services	$54,614,910	$60,798,243
Total Obligations	**$371,021,941**	**$410,485,707**

Total obligations include payroll and operating, rent, and shared services costs. The details of each component of total obligations are described above in **Section D - User Fee Financials**.

G. User Fee Carryover

MDUFA fees collected, earned, appropriated, and not obligated at the end of the fiscal year remain available to support the MDUFA program in future fiscal years. Such fee

funds, plus certain user fee funds that FDA has collected that are considered unearned, unappropriated, or otherwise subject to restrictions, are referred to in this report as the "total carryover" or "MDUFA carryover."

Maintaining an appropriate level of carryover enables FDA to mitigate financial risks to the program, including, for example, the risk of under collecting fees and the financial challenges associated with any potential lapse in appropriations, so that FDA can continue performing activities related to the medical device user fee process under such financial constraints. FDA may also set aside available user fee funds in the carryover for certain purposes, including, for example, for processing future year refunds.

The statute requires at least a 1-month operating reserve to be maintained at the end of each fiscal year. The net change in carryover each year is equal to net collections minus net obligations, which is demonstrated best in **Table 6**.

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

Table 6: MDUFA Carryover by Fiscal Year

Carryover	FY 2024	FY 2025
Total Carryover, End of Year	$226,235,374	$239,538,744
Unearned Fee Revenue	($65,193,572)	($70,957,814)
Unappropriated Amounts	($26,680,243)	($26,680,243)
Total Appropriated	**$134,361,559**	**$141,900,687**
Future Year Refunds Allowance, Set Aside	($2,373,000)	($2,413,000)
One-Month Reserve	($34,249,379)[8]	($39,847,157)
Subtotal	**$97,739,180**	**$99,640,530**
Carryover Set Aside for MDUFA V Commitments (TAP &Third Party), End of Year	($95,759,331)	($80,264,519)
Carryover Net of Unavailable and Set Aside, End of Year	**$1,979,849**	**$19,376,011**

These terms are defined below:

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

Unearned Fee Revenue: Unearned fees are fees received by September 30, 2025, for applications that had not been submitted to FDA as of September 30, 2025, or for establishment fees received without identification of the remitter.

Unappropriated Amounts: FDA's MDUFA carryover includes $26,680,243 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 MDUFA fees appropriated for a given year, prior to a technical fix that

[8] Updated to include the performance improvement adjustment, as appropriate.

was added to the appropriations language to ensure that all fee collections would be considered appropriated. See **Appendix C** for additional details.

Future Year Refunds Allowance, Set Aside: FDA maintains a small amount to provide for any refunds as a matter of prudent operations. For that purpose, a total of $2,413,000 in fee funds available for obligation is being set aside annually. See **Appendix C.4** for additional details.

One-Month Reserve: FDA may use unobligated carryover from fees collected in previous fiscal years to ensure that sufficient fee revenues are available in that fiscal year, so long as FDA maintains unobligated carryover of not less than 1 month of operating reserves for the first month of the next fiscal year.

Carryover Set Aside for MDUFA V Commitments (TAP & Third Party): Per MDUFA V, a certain amount of carryover will be excluded from the designated amount within the operating reserves and not subject to the operating reserve adjustment. This amount is set aside and intended to support the TAP Pilot and Third Party review program.

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

The FY 2025 operations resulted in a net increase in the total end-of-year carryover balance of $13,303,370, from $226,235,374 at the end of FY 2024 to $239,538,744 at the end of FY 2025. The increase in the total carryover balance is a result of FDA over collecting by $13.3M compared to the sum of the inflation-adjusted total revenue amount and the performance improvement adjustment.

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

Table 7a: Historical Medical Device User Fee Carryover by Reauthorization Period

Category	MDUFA I (FY 2003 - 2007)	MDUFA II (FY 2008 - 2012)	MDUFA III (FY 2013 - 2017)	MDUFA IV (FY 2018 – 2022)
Total Carryover, Beginning of Year	**$0**	**$10,862,872**	**$53,216,730**	**$109,444,020**
Net Collections	$144,018,382	$312,851,252	$658,306,967	$1,231,415,394
Recoveries	$0	$0	$540,100	$9,665,452
Obligations	($133,155,510)	($270,497,394)	($602,619,777)	($1,099,793,823)
Total Carryover, End of Year	**$10,862,872**	**$53,216,730**	**$109,444,020**	**$252,026,792**

Table 7b: Medical Device User Fee Carryover for Current Reauthorization Period

Category	FY 2023	FY 2024	FY 2025
Total Carryover, Beginning of Year	$252,026,792	$248,753,175	$226,240,393
Net Collections	$311,810,191	$346,163,806	$420,108,584
Recoveries	$1,373,080	$2,340,334	$3,675,474
Obligations	($316,456,888)	($371,021,941)	($410,485,707)
Total Carryover, End of Year	**$248,753,175**	**$226,235,374**[9]	**$239,538,744**

H. Non-User Fee Appropriations

For FDA to obligate user fees collected under MDUFA, a certain amount of non-user fee appropriations must be spent on the process for the review of device applications plus certain other costs during that fiscal year. This amount is often referred to as a "non-user fee spending trigger." The spending trigger was $240,860,200 for FY 2024 and $248,666,863 for FY 2025.

The non-user fee spending trigger amount is determined by multiplying the amount spent from appropriations exclusive of user fees on the medical device review process in FY 2009 ($223,545,692) times the adjustment factor applicable to the fiscal year (1.112376 for FY 2025). See **Appendix B** for more details on the adjustment factor.

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

Table 8: Historical Trend of MDUFA Program Costs by Funding Source as of September 30 for Fiscal Years 2021 to 2025

Funding Source	FY 2021	FY 2022	FY 2023	FY 2024	FY 2025
Non-User Fee Appropriations Obligated: Total ($)	$269,569,602	$292,946,693	$399,907,048	$279,989,277	$272,130,707
Non-User Fee Appropriations Obligated: Percent (%)	52%	47%	56%	43%	40%
User Fee Funds Obligated: Total ($)	$249,899,743	$332,871,845	$316,456,888	$371,021,941	$410,485,707
User Fee Funds Obligated: Percent (%)	48%	53%	44%	57%	60%
Total Obligated	**$519,469,345**	**$625,818,538**	**$716,363,936**	**$651,011,218**	**$682,616,414**

[9] The FY 2024 end of year carryover balance was understated by $5,019 due to the timing of a payment receipt adjustment. The adjustment is reflected in the FY 2025 beginning of year carryover.

I. Full-Time Equivalents

"FTE employment," as defined by section 85 of the Office of Management and Budget (OMB) Circular A-11, reflects the total number of regular straight-time hours—not including overtime or holiday hours—worked by employees, divided by the number of compensable hours applicable to each fiscal year. Annual leave, sick leave, compensatory time off, and other approved leave categories are considered "hours worked" for purposes of defining FTE employment.

As it relates to MDUFA specifically, FTEs are referred to as "Process FTEs," which are how FDA measures a paid staff year devoted to the MDUFA program. In **Table 9**, FTEs do not represent an accounting of individual people, but rather an estimate of labor hours expended on MDUFA activities. FTEs are distributed throughout the FDA component organizations based on the amount of work conducted to support MDUFA.

Table 9 presents total Process FTE levels, paid from user fee and non-user fee appropriations, that support the MDUFA program. The data cover the past 5 fiscal years and are arranged by FDA's organizational components (CDRH, CBER, OII, and HQ). Staff in the consolidated shared services organizations (e.g., procurement, IT services, etc.) are included in the FTE levels for various components.

Table 9: Historical Trend of Medical Device User Fee Total Process FTEs Utilized by Organizations as of September 30 for Fiscal Year 2021 to 2025

Fiscal Year	FY 2021	FY 2022	FY 2023	FY 2024	FY 2025
CDRH	1,365	1,476	1,575	1,730	1,719
CBER	124	127	129	120	131
OII	40	46	54	54	50
HQ	90	101	107	103	148
Total	**1,619**	**1,750**	**1,865**	**2,007**	**2,048**

Numbers have been rounded.

Management Assurance

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

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

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

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

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

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

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

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

Appendices

A. Allowable and Excluded Costs for MDUFA

Section 737(9) of the FD&C Act defines in general terms the activities that are included in the "process for the review of device applications." In summary, costs related to the following activities have been attributed to the "process for the review of device applications" under this definition:

Exhibit 3: Included Activities

	Included Activities
Section 737(9)(A) - The activities necessary for the review of PMAs, PMRs, supplements, and premarket notification submissions.	These activities include, but are not limited to, the following: 1. 510(k)s - Traditional/supplements/abbreviated/specials (third party and non-third party) 2. PMAs (includes amendments, supplements, and annual reports) 3. Modular PMAs (shell, modules, amendments, and supplements) 4. PDPs (including amendments, supplements, and annual reports) 5. Premarket reports (amendments, supplements, and annual reports) 6. Reclassification Petitions 7. Class II exemption petitions 8. BLAs and BLA supplements (applications subject to section 351 of the PHS Act) 9. Pre-submissions (review of the submission and any correspondence) 10. Recruitment and use of outside experts during the review process 11. Obtaining advisory committee input (e.g., convened meetings, homework assignments) 12. Resolution of product jurisdictional issues 13. Dispute resolution/appeals 14. IT support for review activities 15. Recruitment of review staff 16. Training and professional development of staff 17. Quality management 18. Independent assessment activities

Section 737(9)(B) - The issuance of action letters that allow marketing of devices or which set forth in detail the specific deficiencies in such applications, reports, supplements, or submissions and, when appropriate, the actions necessary to place them in condition for approval.	These activities include, but are not limited to, the following: 1. The issuance of deficiency letters 2. Meetings with applicants to discuss such letters 3. Review of the responses
Section 737(9)(C) - The inspection of manufacturing establishments and other facilities undertaken as part of the Secretary's review of pending premarket applications, premarket reports, and supplements.	These activities include, but are not limited to, the following: 1. The review of manufacturing information submitted in PMAs 2. Preapproval current good manufacturing practices (GMP) inspections 3. Resolution of any identified GMP issues
Section 737(9)(D) - Monitoring of research conducted in connection with the review of such applications, reports, supplements, submissions, and De Novo classification requests.	For the types of applications identified above, these monitoring activities include, but are not limited to, the following: 1. Conduct of bioresearch monitoring inspections (both "for cause" and preapproval) of sponsors, institutional review boards, and clinical investigators 2. Adverse event and complaint investigations related to ongoing clinical trials 3. Good Laboratory Practice inspections (21 CFR part 58)
Section 737(9)(E) - Review of device applications subject to section 351 of the PHS Act for an investigational new drug application (IND) under section 505(i) or for an Investigational Device Exemption (IDE) under section 520(g) and activities conducted in anticipation of the submission of such applications under section 505(i) and 520(g).	These activities include, but are not limited to, the following: 1. Review of the IDEs (original, amendments, and supplements) 2. Review of INDs (amendments, supplements, and safety reports) 3. Pre-submissions (review of the submission and any meetings or correspondence) 4. Study risk determinations 5. Determination/Agreement meetings

Section 737(9)(F) - The development of guidance document, policy documents, or regulations to improve the process for the review of premarket applications, premarket reports, supplements, premarket notification submissions, and De Novo classification requests.	These activities include, but are not limited to, the following: 1. Development of device-specific, cross-cutting, special control, and program-related guidance documents 2. Standard Operating Procedures
Section 737(9)(G) - The development of voluntary test methods, consensus standards, or mandatory performance standards under section 514 in connection with the review of applications, reports, supplements, or submissions and related activities.	This includes, but is not limited to, national and international standards development and coordination related to the review of premarket applications, as well as certain ASCA and patient science and engagement activities.
Section 737(9)(H) - The provision of technical assistance to device manufacturers in connection with the submission of such applications, reports, supplements, submissions, or requests.	These activities include, but are not limited to, the following: 1. Informal consultation via phone, meetings, e-mail, and facsimile 2. Meetings between FDA and applicants, such as Pre-submission meetings, Determination/Agreement meetings, meetings with TAP Pilot participants, and meetings to discuss deficiencies in premarket applications 3. Use of outside experts in the review of premarket applications 4. Review of labeling prior to approval of a premarket application or supplement 5. FDA-sponsored conferences/workshops related to premarket submissions 6. Staff participation at non-FDA meetings related to such applications
Section 737(9)(I) - Any activity undertaken under section 513 or 515(i) in connection with the initial classification or reclassification of a device or under section 515(b) in connection with any requirement for approval of a device.	These activities include, but are not limited to, the following: 1. Reclassification petitions 2. De Novo classification request 3. The review of requests for information submitted under section 513(g) 4. The “call” for PMAs for pre-amendments devices

Section 737(9)(J) - Evaluation of post-market studies required as a condition of approval of a premarket application or premarket report under section 515 or a premarket application under section 351 of the PHS Act.	These activities include, but are not limited to, the following: 1. Protocols for post-market studies 2. Modifications to such protocols 3. Data collected under the protocol 4. Labeling changes (instructions for use, warnings, precautions, etc.), if needed as a result of the review of the data
Section 737(9)(K) - Compiling, developing, and reviewing information on relevant devices to identify safety and effectiveness issues for devices subject to premarket applications, premarket reports, supplements, premarket notification submissions, or De Novo classification requests.	These activities include, but are not limited to, the following: 1. Epidemiology studies 2. Post-marketing problem identification/resolution, including reports filed under the Medical Device Report regulation 3. RWE and real-world data

Section 737(10) of the FD&C Act defines the "costs of resources allocated for the process for the review of device applications" as the expenses in connection with this process for:

Exhibit 4: Included Expenses

Included Expenses
1. Officers and employees of FDA, FDA contractors, advisory committees, and costs related to such officers, employees, and committees, and to contracts with such contractors 2. Management of information, and the acquisition, maintenance, and repair of computer resources 3. Leasing and necessary scientific equipment 4. Collecting user fees and accounting for resources allocated for the review of premarket applications, premarket reports, supplements, and submissions

The MDUFA program excludes costs related to the following:

Exhibit 5: Excluded Activities

Excluded Activities
1. Enforcement policy and regulation development 2. Third Party inspection program 3. Post-approval compliance actions and activities unrelated to PMA Conditions of Approval and investigations of safety and effectiveness issues for devices subject to FDA's regulation 4. Post-approval activities relating to: ○ Promotion and advertising ○ International coordination/Mutual Recognition Agreement work ○ International standards development ○ Liaison/outreach and manufacturing assistance ○ Device tracking ○ Inspections unrelated to the review of covered applications ○ Export/import activities unrelated to the conduct of a clinical trial ○ Research related to future products ○ All activities conducted under the Mammography Quality Standards Act, radiation safety authorities of the FD&C Act (sections 531 et seq.), and the Clinical Laboratory Improvement Amendments of 1988

B. Conditions for Assessment and Use of Fees

Introduction

The FD&C Act, as amended by MDUFA, specifies three legal conditions that must be met each fiscal year for FDA to collect and spend medical device user fees. This appendix describes these conditions and the applicable adjustment factor, as set forth in the FD&C Act.

Adjustment Factor

To determine whether the legal conditions are satisfied, FDA must calculate and incorporate an "adjustment factor" (defined in section 737(11) of the FD&C Act) to calculate both the non-user fee appropriations trigger in section 738(g)(1)(A) and the non-user fee spending trigger in section 738(h)(2)(A)(ii). The FD&C Act states:

> The term "adjustment factor" applicable to a fiscal year is the Consumer Price Index for all urban consumers (all items; United States city average) for October of the preceding fiscal year divided by such Index for October 2021.

The CPI for October 2023, the October of the fiscal year preceding FY 2025, was 307.671. The CPI in October 2021 was 276.589. Dividing the CPI of October 2023 by 276.589 yields an adjustment factor of 1.112376 for FY 2025.

Legal Conditions

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

Exhibit 6: Legal Conditions

Legal Condition #	FD&C Act Section	Details
1	738(g)(1)	With respect to the amount that, under the salaries and expenses account of the Food and Drug Administration, is appropriated for a fiscal year for devices and radiological products, fees may not be assessed under subsection (a) for the fiscal year, and the Secretary is not expected to meet any performance goals identified for the fiscal year, if—(A) the amount so appropriated for the fiscal year, excluding the amount of fees appropriated for the fiscal year, is more than 1 percent less than $398,566,000 multiplied by the adjustment factor applicable to such fiscal year; or (B) fees were not assessed under subsection (a) for the previous fiscal year.
2	738(h)(2)(A)(i)	The fees authorized by this section—(i) subject to subparagraph (C), shall be collected and available in each fiscal year in an amount not to exceed the amount specified in appropriation Acts, or otherwise made available for obligation, for such fiscal year.
3	738(h)(2)(A)(ii)	The fees authorized by this section— (ii) shall be available – (II) for fiscal year 2025 and each subsequent fiscal year, to defray the costs of the resources allocated for the process for the review of device applications (including such costs for an additional number of full-time equivalent positions in HHS to be engaged in such process), only if the sum of the amounts allocated by the Secretary for such costs, excluding costs paid from fees collected under this section, plus other costs for the maintenance, renovation, and repair of facilities and acquisitions, maintenance, and repair of fixtures, furniture and other necessary materials and supplies in connection with the process for the review of device applications, is no less than the amount allocated for such costs, excluding any such costs paid from fees collected under this section, for fiscal year 2009 multiplied by the adjustment factor.

C. Supplemental Financial Information

C.1. Shared Services Costs

Office of Digital Transformation: Provides the vision and leadership in IT, data, and cybersecurity needed to advance FDA's mission and strategic priorities.

Office of Equal Employment Opportunity: Promotes a work environment that ensures equal employment opportunity and fosters a professional culture that values and empowers individuals so they can participate and contribute to their fullest potential.

Office of Ethics and Integrity: Protects the integrity of FDA's programs and operations by promoting an ethical culture and ensuring compliance with applicable federal ethics laws.

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

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

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

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

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

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

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

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

C.2. Unappropriated Amounts

The unappropriated amount is the amount that FDA collected in user fees in excess of the amount specified in appropriations acts prior to FY 2013. **Table 10** outlines the excess user fees by fiscal year.

Table 10: Medical Device User Fees Collected, Collection Amounts Specified in Appropriations Acts, and Excess Amounts (Excluding Unearned Revenue) as of September 30, 2025

Fiscal Year	Collections Realized	Collection Amount Specified In Appropriation Acts	Amount In Excess Of Collection Amount Specified In Appropriation Acts
2009	$56,962,601	$52,547,000	$4,415,602
2010	$63,699,312	$57,014,000	$6,685,312
2011	$69,720,145	$61,860,000	$7,860,145
2012	$65,324,184	$57,605,000	$7,719,184
Total			**$26,680,243**

C.3. Unearned Fee Revenue

Unearned fees are fees received by September 30, 2025, either for applications that had not been submitted to FDA as of September 30, 2025, or for establishment registration fees received without identification of the remitter. FDA is unable to obligate unearned revenue until applications or establishment registrations pertaining to these funds are submitted to FDA. The total unearned revenue as of September 30, 2025, was $70,957,814. **Table 11** outlines the total collections excluding unearned fee revenues for the last 2 cohort years.

Table 11: Medical Device User Fees Collected, Excluding Unearned Fee Revenue, for Cohort Years

Fees Collected	FY 2024	FY 2025
Collections	$348,644,886	$424,303,761
Unearned Fee Revenue	($5,995,420)	($12,820,118)
Total Collections	**$342,649,466**	**$411,483,643**

C.4. Future Year Refunds Allowance, Set Aside

If an application is refused for filing, FDA shall refund 75 percent of the fee. If an application is withdrawn before filing, FDA shall refund 75 percent of the fee. If an application is withdrawn before first action, FDA may return some or all of the fee. The amount of the refund, if any, shall be based on the level of effort already expended on the review of such application, report, or supplement. FDA shall have sole discretion to refund a fee or portion of the fee (see section 738(a)(2)(D) of the FD&C Act).

Table 12 outlines the actual refunds on earned MDUFA fees by fiscal year that are used to calculate the 3-year average for the estimated refund set aside.

Table 12: Medical Device User Fee Estimated Future Year Refunds Allowance, Set Aside

Estimated Refunds Set Aside	FY 2022	FY 2023	FY 2024	3-Year Average
Actual Refunds	($2,262,066)	($2,498,262)	($2,477,611)	($2,412,646)

The FY 2025 actual refunds for MDUFA totaled $1,869,185.

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