Financial Report to Congress

Medical Device User Fee Amendments of 2022

FY 2023

U.S. FOOD & DRUG ADMINISTRATION

Table of Contents

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 implementation. This is the first report under the fifth authorization of MDUFA (MDUFA V) and covers fiscal year (FY) 2023.

MDUFA 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.

Section 704(g)(10) of the Federal Food, Drug, and Cosmetic 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 5 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 2023, 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 2023, FDA had net collections of $312 million in medical device user fees, spent $316 million in user fees for the device review process, and carried $249 million forward for future fiscal years.

MDUFA V user fees and non-user fee appropriations in FY 2023 supported 1,865 full-time equivalents, including salaries and operational expenses, to support the review of device applications. Detailed program accomplishments can be found in the FY 2023 MDUFA Performance Report.

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, 2022, through September 30, 2023. It presents the legal conditions that FDA must satisfy to collect and spend medical device user fees each 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) 2023 fee collections, carryover, obligations of user fees, and total costs of the process for the review of device applications from both Medical Device User Fee Amendments (MDUFA) fees and non-user fee appropriations.

B. Report Requirements

In accordance with section 738A(a)(4) of the Federal Food, Drug, and Cosmetic Act (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. Agency Background

FDA is responsible for protecting the public's health by helping to ensure the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices and by ensuring 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 and advancing the public's health. FDA not only helps speed innovations that make medical products more effective and safer but also helps the public get the accurate, science-based information they need 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.

Program Organization

There are four major components that support the MDUFA program: the Center for Devices and Radiological Health (CDRH), the Center for Biologics Evaluation and Research (CBER), 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
CDRH	Protects and promotes the public's health by helping to ensure that patients and providers have timely and continued access to safe, effective, and high-quality medical devices and safe radiation-emitting products.
CBER	Ensures the safety, purity, potency, and effectiveness of biological products including vaccines, allergenics, blood and blood products, and cells, tissues, and gene therapies for the prevention, diagnosis, and treatment of human diseases, conditions, or injury. Regulates medical devices related to licensed blood and cellular products
ORA	Protects consumers and enhances public health by maximizing compliance of FDA-regulated products and minimizing the risk associated with those products. ORA inspects regulated products and manufacturers, conducts sample analyses of regulated products, and reviews imported products offered for entry into the United States.
HQ	Provides FDA-wide program direction and administrative services to ensure FDA's consumer and patient safety programs are effectively and efficiently managed.

User Fee Governance

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

FDA 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 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.

D. User Fee Background and Structure

The FD&C Act, as amended by MDUFA, authorizes FDA to collect fees from industry to supplement non-user fee appropriations that the Agency spends on the process for the review of device applications. 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 ensures 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.

MDUFA V continues to 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 2** outlines MDUFA V's fee structure. I

Exhibit 2: MDUFA V Fee Structure

Fee Type	Definition
Application Fees: *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.
Application Fees: *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.
Application Fees: *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.
Application Fees: *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.
Application Fees: *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
Application Fees: *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.
Application Fees: *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.
Application Fees: *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).
Application Fees: *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.
Application Fees: *Annual fee for periodic reporting on a class III device*	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).
Annual Fees: *Annual establishment registration fee*	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.[1]

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.

Appendix B provides more information on the history of the user fee program.

E. Legal Conditions

The FD&C Act, as amended by MDUFA, specifies that three legal conditions must be satisfied each year for FDA to collect and spend medical device user fees. **Exhibit 3** describes those legal conditions and provides a brief explanation as to how those legal conditions were met for FY 2023.

[1] See https://www.federalregister.gov/documents/2022/10/07/2022-21967/medical-device-user-fee-rates-for-fiscal-year-2023.

Exhibit 3: 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.
	Condition Was Met	In FY 2024, the final appropriation for the Device and Radiological Health line of FDA's Salaries and Expenses Appropriation (excluding user fees) was $449,297,000. 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 Consolidated Appropriations Act, 2023 (Public Law 117-2617), which the President signed on December 29, 2022, made appropriations through September 30, 2023, for the salaries and expenses account of FDA. This act specified that $324,777,000 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.
It 3	Description	The third condition requires a minimum spending from appropriations, excluding user fees, on the MDUFA program. 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	That specified minimum level for FY 2024 is $223,545,692. In FY 2023, FDA spent $399,907,048 from appropriations (exclusive of user fees) on the process for the review of device applications. Because FDA spent more than the specified minimum amount from appropriations in FY 2023, 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 C**.

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 5 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 2023 is $54,117,332. In FY 2023, FDA obligated $56,276,238 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.

F. 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 2022 and FY 2023. These financials include user fee revenues, obligations, carryover, non-user fee appropriations, and full-time equivalents (FTEs).

G. User Fee Financials

Table 1 represents a summary of the MDUFA User Fee financial position for FY 2022 and FY 2023. The financial notes referenced in this table can be found in **Appendix D.**

Table 1: Medical Device User Fee Collections, Obligations and Carryover for Fiscal Years 2022 and 2023

Budgetary Resources	Notes	FY 2022	FY 2023
Total Carryover, Beginning of Year		**$322,958,046**	**$252,026,792**
Total Revenue in Statute:		$213,687,660	$312,606,000
Inflation Adjustment		1.139385	1.038935
Inflation-Adjusted Total Revenue		$ 243,473,000	$324,777,000
Performance Improvement Adjustment		n/a	n/a
Hiring Adjustment		n/a	n/a
Operating Reserve Adjustment		n/a	$0
Inflation-Adjusted Total Revenue +/- Adjustments	**Note 1**	**$243,473,000**	**$324,777,000**
Net Collections		$260,321,107	$311,810,191
Recoveries	Note 2	$1,619,483	$1,373,080
Total Budgetary Resources		**$584,898,636**	**$565,210,063**
Obligations	**Notes**	**FY 2022**	**FY 2023**
Total Payroll and Operating	Note 3	$291,192,160	$264,760,276
TAP – Non-Add-Funded Thru Carryover			*$5,621,581*
Third Party – Non-Add-Funded Thru Carryover			*$1,600,000*
Total Rent	Note 4	$13,961,213	$11,665,308
Total Shared Services	Note 5	$27,718,472	$40,031,304
Total Obligations		**$332,871,845**	**$316,456,888**
Carryover	**Notes**	**FY 2022**	**FY 2023**
Total Carryover, End of Year		**$252,026,792**	**$248,753,175**

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

- **Budgetary Resources:** The Total Budgetary Resources component of **Table 1** illustrates the sum of the total user fee funding (i.e., the existing total carryover and additional user fee collections). 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. Please refer to the financial notes in **Appendix D** for more details and definitions of each adjustment. The Net Collections component is the actual amounts collected including refunds during the fiscal year.

- **Obligations:** The obligations component of **Table 1** shows the actual expenditures of MDUFA fees for FYs 2022 and 2023. 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 (TPLC) Advisory Program (TAP Pilot) and Third Party review program that FDA funded from the MDUFA carryover in FY 2023. MDUFA fees may only be expended for costs to support the "process for the review of device applications," as specified in the statute.[2]

- **Carryover:** 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**.

MDUFA V 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.[3] If necessary, after this adjustment, FDA is to further increase the base establishment registration fees to generate the inflation-adjusted total revenue amount.[4]

In addition, as mentioned in **Section F – 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

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

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

[4] 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)), only the last of which is potentially applicable in FY 2023. If submissions or registrations are higher than estimated, collections may exceed the inflation-adjusted total revenue amount in a given fiscal year. FDA has applied the applicable adjustments to calculate the inflation-adjusted total revenue +/- adjustments amount, shown in **Table 1**, for annual fee setting.

H. User Fee Revenue

Table 2 outlines the inflation-adjusted total revenue +/- adjustments amounts for FYs 2022 and 2023. The financial notes referenced in this table can be found in **Appendix D**.

Table 2: Medical Device Revenue for Fiscal Years 2022 and 2023

Inflation-Adjusted Total Revenue +/- Adjustments	Notes	FY 2022	FY 2023
Total Revenue in Statute		$213,687,660	$312,606,000
Inflation Adjustment	Note 6	$29,784,854	$12,171,315
Performance Improvement Adjustment	Note 7	n/a	n/a
Hiring Adjustment	Note 8	n/a	n/a
Operating Reserve Adjustment	Note 9	n/a	$0
Inflation Adjusted Total Revenue +/- Adjustments	**Note 1**	**$243,473,000**	**$324,777,000**

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

Cohort Year
The year in which user fee collections are originally due and reported. For example, a fee originally due in FY 2023 but received in FY 2024 is attributed to FY 2023's collections.

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. These base fee amounts for each application type are adjusted for inflation and then, if necessary, further increased to generate the inflation-adjusted total revenue amount rounded to the nearest thousand dollars. After this adjustment, FDA shall, if necessary, further increase the base establishment registration fees to generate the inflation-adjusted total revenue amount. As mentioned in **Section F – Changes to Fee Structure and Fee-Setting Mechanisms Under MDUFA V**, MDUFA V has three new potential adjustments that may impact collections

by increasing or decreasing only the establishment registration base fees. Only the operating reserve adjustment was potentially applicable in FY 2023.

User fee collections are 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 2023) across multiple fiscal years. Transactions such as late collections or refunds processed in a different fiscal year (e.g., a refund processed during FY 2023 for an FY 2022 payment) will be displayed in **Tables 3a – 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 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 J – User Fee Carryover**. Unearned fees are fees received by September 30, 2023, either for applications that had not been submitted to FDA as of September 30, 2023, or for establishment fees received without identification of the remitter.

Increase in Collections
The primary factor in the increase in collections from FY 2022 to FY 2023 was the increase in the total revenue amount from MDUFA IV to MDUFA V.

User fee collections were composed of collections from medical device application submissions (which included annual fees for periodic reports) and annual establishment 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, 2023.

Table 3a: Medical Device User Fee Collections by Fee Source for Cohort Year 2022

Fees Collected	Estimated †	Actual	% Diff
Application Fees	$79,896,132	$75,241,600	(6%)
Registration Fees	$182,798,329	$184,760,257	1%
Total Collections	**$262,694,461**	**$264,001,857**	**(1%)**

Numbers have been rounded to the nearest dollar.

† Estimated values were taken from the Medical Device User Fee Rates for Fiscal Year 2022 at https://www.federalregister.gov/documents/2021/08/02/2021-16408/medical-device-user-fee-rates-for-fiscal-year-2022.

Table 3b: Medical Device User Fee Collections by Fee Source for Cohort Year 2023

Fees Collected	Estimated †	Actual	% Diff
Application Fees	$108,798,923	$111,367,725	2%
Registration Fees	$228,143,316	$205,610,339	(10%)
Total Collections	**$336,942,239**	**$316,978,065**	**(6%)**

Numbers have been rounded to the nearest dollar.

† Estimated values were taken from the Medical Device User Fee Rates for Fiscal Year 2023 at https://www.federalregister.gov/documents/2022/10/07/2022-21967/medical-device-user-fee-rates-for-fiscal-year-2023.

Table 3c: Medical Device Unearned Fees by Fee Source for Cohort Years 2022 and 2023

Unearned Fees	Cohort Year 2022	Cohort Year 2023
Application Fees	$2,674,183	$11,727,256
Registration Fees	$2,909,601	$4,284,975
Total Unearned Fees	**$5,583,784**	**$16,012,231**

Numbers have been rounded to the nearest dollar.

Table 3d: Medical Device User Fees Receivable by Fee Source for Cohort Years 2022 and 2023

Fees Receivable	Cohort Year 2022 Actuals	Cohort Year 2023 Actuals
Application Fees	$2,156,294	$1,765,360
Registration Fees	$74,581	$59,429
Total Receivables	**$2,230,875**	**$1,824,789**

Numbers have been rounded to the nearest dollar.

I. 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.

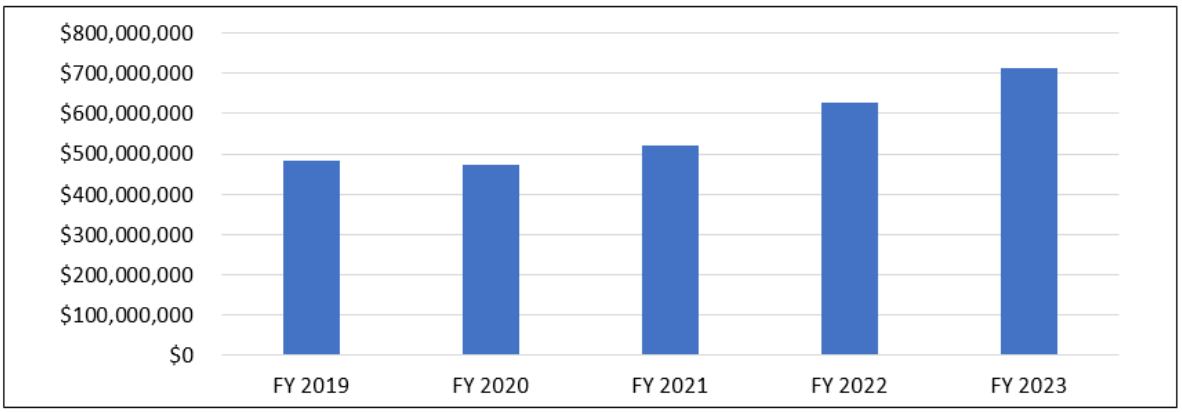
Table 4: MDUFA Program Historical Trend of Total Costs by Organization as of September 30 Fiscal Year

CATEGORY	FY 2019	FY 2020	FY 2021	FY 2022	FY 2023
CDRH Spent($)	$385,201,127	$377,702,623	$431,620,290	$532,061,725	$608,248,689
CDRH Percentage(%)	80%	80%	83%	85%	85%
CBER Spent($)	$49,038,852	$52,009,143	$42,036,545	$43,561,256	$51,035,711
CBER Percentage(%)	10%	11%	8%	7%	7%
ORA Spent($)	$10,829,248	$11,036,341	$10,093,225	$12,540,499	$15,461,981
ORA Percentage(%)	2%	2%	2%	2%	2%
HQ Spent($)	$38,269,145	$30,895,317	$35,719,285	$37,655,059	$41,617,554
HQ Percentage(%)	8%	7%	7%	6%	6%
Total Spent	**$483,338,372**	**$471,643,425**	**$519,469,345**	**$625,818,538**	**$716,363,936**

Numbers have been rounded to the nearest dollar.

Exhibit 4 provides an illustration of historical MDUFA obligations over the past 5 fiscal years.

Exhibit 4: Historical MDUFA Program Obligations for Fiscal Year



As demonstrated by this exhibit, the MDUFA program's costs in FY 2023 increased from FY 2022 and previous years' levels. This increase was due to an increase in hiring and FDA's required level of staff effort towards MDUFA process activities, an increase in MDUFA-related payroll costs, and spending associated with new MDUFA V commitments areas, such as the TAP Pilot. In FY 2023, the MDUFA program obligated funds to support meeting MDUFA V's commitments, such as improving the premarket process, developing infrastructure, and enhancing the Agency's scientific and regulatory review. Specifically, resources were used to support the following key areas:

- Pre-submissions
- Review enhancement and infrastructure
- Independent assessments
- Quality management
- Patient science and engagement

- Real-world evidence (RWE)
- Standards
- Digital health
- International harmonization
- TAP Pilot

Details of these areas can be found in the FY 2023 MDUFA Performance Report to Congress.

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

Table 5: Medical Device User Fee Obligations by Expense Category for Fiscal Years 2022 and 2023

User Fee Obligations	Notes	FY 2022	FY 2023
Payroll and Operating	Note 3		
CDRH		$265,904,935	$238,396,261
CBER		$12,809,884	$14,263,635
ORA		$2,223,725	$1,731,907
HQ		$10,253,616	$10,368,473
Total Rent	Note 4	$13,961,213	$11,665,308
Total Shared Services	Note 5	$27,718,472	$40,031,304
Total Obligations		**$332,871,845**	**$316,456,888**

Numbers have been rounded to the nearest dollar.

Total obligations include payroll and operating, rent, and shared services costs. The details of each component of total obligations are as follows:

- **Payroll and Operating:** These obligations provide for payroll and operating costs that support the allowable activities for which MDUFA fees may be expended, 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.

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

- **Shared Services:** FDA contains several shared services organizations that provide support across the user fee programs, such as human resources and IT.

J. 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 fee amounts and the risk of a lapse in appropriations.

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 2022 and FY 2023. The financial notes can be found in **Appendix D**.

Table 6: MDUFA Carryover by Fiscal Year

Carryover	Notes	FY 2022	FY 2023
Total Carryover, End of Year		$252,026,792	$248,753,175
Unearned Fee Revenue	Note 10	($53,933,164)	($62,498,454)
Unappropriated Amounts	Note 11	($26,680,243)	($26,680,243)
Total Appropriated		**$171,413,385**	**$159,574,478**
Future Year Refunds Allowance, Set Aside		($2,000,000)	($2,000,000)
One-Month Reserve	Note 12	($27,064,750)	($30,198,417)
Subtotal		**$142,348,635**	**$127,376,061**
Carryover Set Aside for MDUFA V Commitments (TAP &Third Party), End of Year		n/a	$110,778,419
Carryover Net of Unavailable and Set Aside, End of Year		**$142,348,635**	**$16,597,642**

Numbers have been rounded to the nearest dollar.

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.

- **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 was added to the appropriations language to ensure that all fee collections would be considered appropriated. See **Note 11** for additional details.

- **Unearned Fee Revenue:** Unearned fees are fees received by September 30, 2023, for applications that had not been submitted to FDA as of September 30, 2023, or for establishment fees received without identification of the remitter.

- **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 million in fee funds available for obligation is being set aside annually.

- **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 2023 operations resulted in a net decrease in the total end of year carryover balance of $3,273,617 from $252,026,792 at the end of FY 2022 to $248,753,175 at the end of FY 2023. The slight decrease in the total carryover balance is a result of FDA returning a portion of its FY 2023 MDUFA funds, which were not obligated, to the carryover that was offset by under-collecting compared to the Agency's inflation adjusted total revenue amount. The under-collecting can be attributed to a decrease in the number of establishment registrations compared to the establishment registrations that occurred during the pandemic. Finally, FDA spent, in accordance with the MDUFA V agreement, a portion of the existing MDUFA carryover to support the TAP Pilot and the Third Party Review program.

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

is equal to the sum of 13 weeks of operating reserves of carryover user fees plus one 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 calculating whether 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 2023 because the operating reserve did not exceed the designated amount. As shown in **Table 6**, FDA spent $7,221,581 of the $118 million excluded from the designated amount and not subject to the decrease to fund the TAP Pilot and the Third Party Review programs in FY 2023, leaving $110,778,419 remaining to be excluded from the designated amount and not subject to the decrease at the end of FY 2023.

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

	NOTES	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	Note 2	$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**

Numbers have been rounded to the nearest dollar.

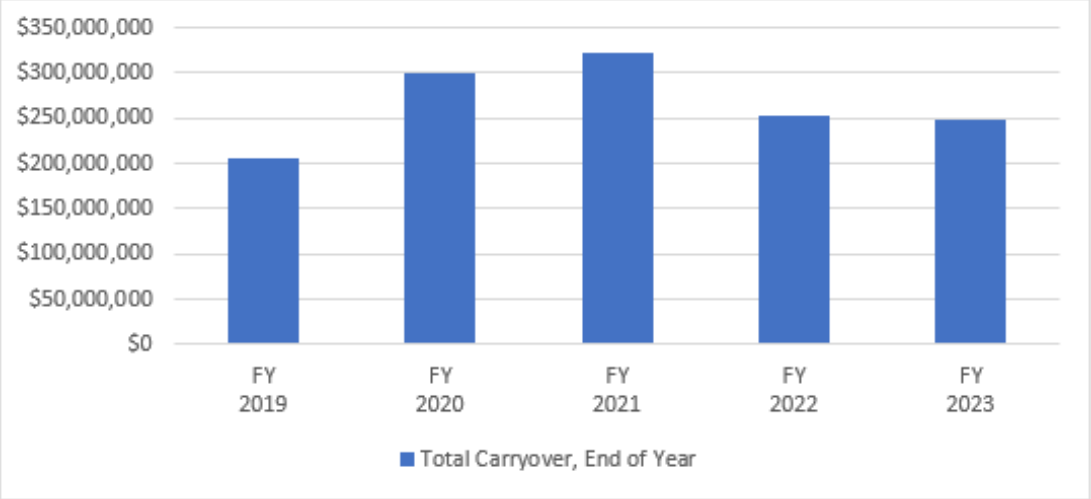
Table 7b: Historical Medical Device User Fee Carryover for Current Reauthorization Period

Category	Notes	FY 2023
Total Carryover, Beginning of Year		$252,026,792
Net Collections		$311,810,191
Recoveries	Note 2	$1,373,080
Obligations		($316,456,888)
Total Carryover, End of Year		**$248,753,175**

Exhibit 5 provides a historical perspective of carryover for the last five fiscal years. The MDUFA carryover has historically included a larger proportion of funds

considered unavailable for obligation due to the high levels of unearned fee revenue (**Note 10**).

Exhibit 5: Historical Carryover by Fiscal Year



K. 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 during that fiscal year. This amount is often referred to as a "non-user fee spending trigger." The spending trigger was $240,801,184 for FY 2022 and $223,545,692 for FY 2023.

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. In year one of the reauthorization cycle, the adjustment factor is 1.0, and thus no inflation is applied. See **Note 13** 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 Year 2019 to 2023

Funding Source	FY 2019	FY 2020	FY 2021	FY 2022	FY 2023
Non-User Fee Appropriations Obligated: Total ($)	$336,156,785	$267,178,191	$269,569,602	$292,946,693	$399,907,048
Non-User Fee Appropriations Obligated: Percent (%)	70%	57%	52%	47%	56%
User Fee Funds Obligated: Total ($)	$147,181,587	$204,465,234	$249,899,743	$332,871,845	$316,456,888
User Fee Funds Obligated: Percent (%)	30%	43%	48%	53%	44%
Total Obligated	**$483,338,372**	**$471,643,425**	**$519,469,345**	**$625,818,538**	**$716,363,936**

Numbers have been rounded to the nearest dollar.

L. 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 (i.e., CDRH, CBER, ORA, and HQ). Staff in the consolidated shared services organizations (e.g., facilities, procurement, IT services, etc.) are included in the FTE levels for various components.

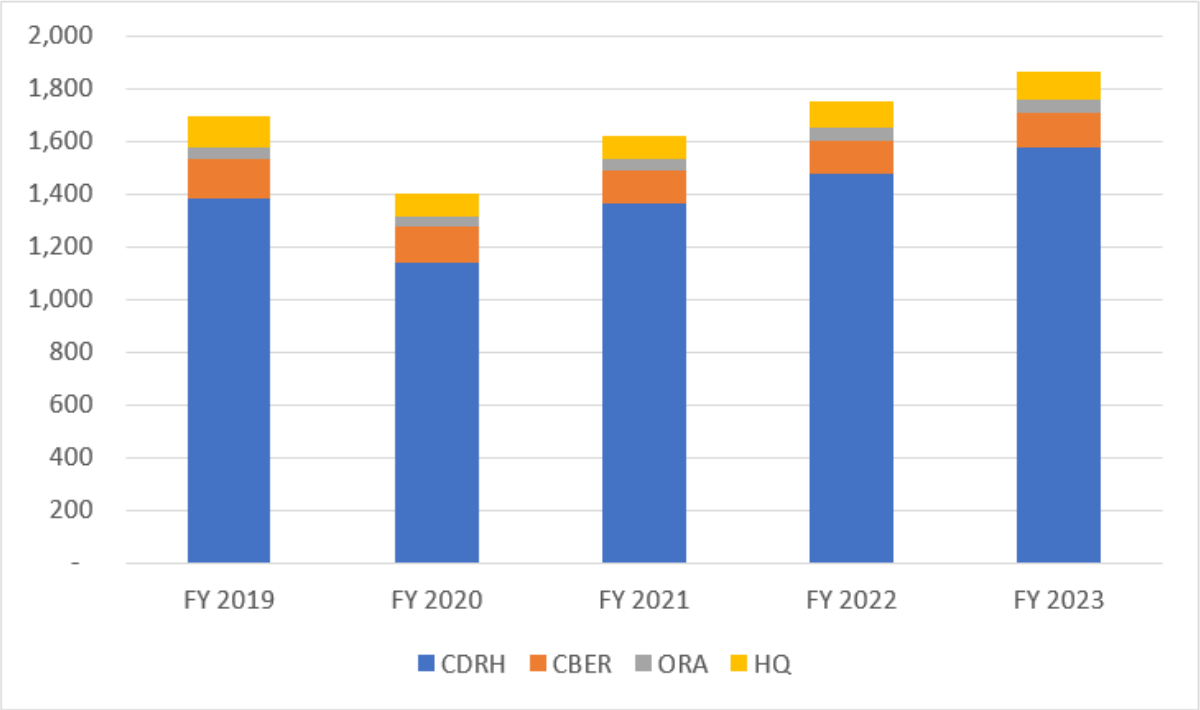
Table 9: Historical Trend of Medical Device User Fee Total Process FTEs Utilized by Organizations as of September 30 Fiscal Year 2019 to 2023

Fiscal Year	FY 2019	FY 2020	FY 2021	FY 2022	FY 2023
CDRH	1,381	1,136	1,365	1,476	1,575
CBER	153	137	124	127	129
ORA	43	40	40	46	54
HQ	115	86	90	101	107
Total	**1,692**	**1,399**	**1,620**	**1,750**	**1,865**

Numbers have been rounded.

Exhibit 6 provides the historical trend of FTE distributions and levels across FDA's organizations for the past 5 fiscal years.

Exhibit 6: Historical Medical Device User Fee Process FTE Levels by FDA's Organizations



As demonstrated by this graph, MDUFA Process FTEs increased in FY 2023. This increase was attributed to a surge in hiring in accordance with the MDUFA V agreement and an increased level of staff effort supporting MDUFA process activities, while new Emergency Use Authorization submissions related to COVID-19 decreased.

M. Internal Controls

The Federal Managers' Financial Integrity Act of 1982 (FMFIA) is intended to strengthen internal controls and accounting systems. The Office of Management and Budget (OMB) Circular A-123, Management's Responsibility for Enterprise Risk Management and Internal Control implements the FMFIA requirements. FMFIA requires that management establish and maintain effective internal control to achieve the following objectives:

1. effective and efficient operations
2. reliable reporting
3. compliance with applicable laws and regulations

The Department of Health and Human Services (HHS) provides guidance to its operating divisions (OpDivs) to implement FMFIA through its FMFIA Guidelines. 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. The Government Accountability Office's Standards for Internal Control in the Federal Government (Green Book) states: "Management is responsible for an effective internal control system. As part of this responsibility, management sets the entity's objectives, implements controls, and evaluates the internal control system." OMB Circular A-123 requires an annual internal control assessment, and FMFIA requires the head of each executive agency to report annually on the effectiveness of the internal controls and any identified material weaknesses in those controls.

In alignment with FMFIA, OMB Circular A-123, OMB Circular A-11, the Green Book, and HHS guidelines, FDA established an Enterprise Risk Management (ERM) Program, with an ERM Council (ERMC) as the governance body responsible for providing overall oversight and accountability. The ERMC's purview includes deciding on and managing the Agency's Enterprise Risk Profile and ensuring integration with FDA's FMFIA, budget formulation, and strategic planning activities. The ERMC has senior executive representatives from each FDA Center and Office and is chaired by the FDA's Chief Operating Officer, with a Center Director as Co-Chair and the FDA's Chief Financial Officer (CFO) as President Pro Tempore. FDA's ERM Program supports the ERMC in managing the Agency's Enterprise Risk Profile, facilitates risk response planning, collaborates with Center and Office senior leaders and staff in conducting a range of analyses to manage risks, and provides communications and training opportunities that promote a risk-informed culture.

Additionally, FDA has an established Senior Assessment Team (SAT) to act as the governance body responsible for providing oversight and accountability for FDA's internal control over reporting, including overseeing the FMFIA and OMB Circular A-123 assessments, and for fostering an environment that promotes strong internal

controls and reduces the risk of fraud, waste, and abuse. The SAT is chaired by FDA's CFO and co-chaired by the Deputy CFO and Director of the Office of Financial Management, as well as a Program Co-Chair who is a Center Deputy Executive Officer appointed by the CFO. The SAT members are representatives from each FDA Center and Office.

FDA's internal control program includes integrated management controls covering the OMB Circular A-123 appendices. Specifically:

1. Reporting controls to include business and IT controls are implemented in accordance with Appendix A, Management of Reporting and Data Integrity Risk;

2. Charge card controls are implemented in accordance with Appendix B, A Risk Management Framework for Government Charge Card Programs.

3. Controls over financial disbursements are implemented in accordance with Appendix C, Requirements for Payment Integrity Improvement; and

4. Financial system controls are implemented in accordance with Appendix D, Compliance with the Federal Financial Management Improvement Act of 1996.

In FY 2023, FDA's annual assessment of internal controls included tests of 94 business and IT controls across nine major transaction cycles and 21 transaction sub-cycles to identify recommendations to strengthen internal controls and compliance. This assessment included 11 IT controls related to the User Fee System. Further, in FY 2023, FDA enhanced its integration with HHS, to focus on IT controls, align with HHS standardized IT controls guidance, and collaborate overall with HHS (see Appendices A and B of OMB Circular A-123).

Annually, FDA conducts an improper payments risk assessment and performs improper payment testing to assess financial disbursements. In FY 2022, FDA completed the FDA FY22 Improper Payments risk assessment to identify FDA Programs that were susceptible to significant improper payments. Six FDA Programs—including Foods, Human Drugs, Biologics, CURES Activities, Reimbursable Program (Federal Sources), Opioids – IMF Programs—were deemed to not be susceptible to significant improper payments. The Biologics Program and the Devices and Radiological Health Program were selected for improper payments transactional testing. Neither the Biologics nor the Devices and Radiological Health Programs were found to be susceptible to significant improper payments.

The Unified Financial Management System (UFMS) FDA-set-of-books—which is the Integrated Budget, and Acquisition Planning Systems (IBAPS) —and the User Fee System are compliant with HHS guidelines and with OMB Circular A-123 Appendix D, Compliance with the Federal Financial Management Improvement Act of 1996

FDA has also implemented other internal control procedures, including the performance of Organizational Risk Reviews, which are reviews of targeted financial and non-financial management processes to identify potential recommendations to enhance

internal controls. Also, FDA maintains a Continuous Monitoring Program to oversee the timely implementation of corrective action plans for any deficiencies identified through any of its control assessments.

As a component of HHS, FDA's financial data is presented in HHS's consolidated financial statements. The FY 2022 HHS audit found that FDA's financial statements fairly present, in all material respects, the consolidated financial position of HHS as of September 30, 2022, and 2021, and related notes are in accordance with generally accepted accounting principles in the United States. Further, FDA's FY 2023 Assurance Statements found no material weaknesses or financial system nonconformances.

N. Risks and Challenges

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 assume 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 that total appropriation comes in considerably lower than anticipated. Below is a listing of foreseeable risks associated with the collections and obligations of funds for which FDA has identified contingency plans to help move forward in the best interest of the program.

- **Under-Executing Planned Spend:** Historically, MDUFA budgetary resources have been under-spent due to the uncertainty around the timing of user fee revenue availability, non-user fee spending trigger requirements, and difficulties with hiring. In this first year of the current 5-year cycle, FDA put more emphasis on the initial planning of initiatives in order to reduce variance in its planned allocations versus actual expenditures.

- **Uncertainty of 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 planning challenges as non-user fee fund levels are often uncertain for much of the fiscal year. With Continuing Resolutions (CR) becoming more prevalent, FDA has been required to spend at or slightly below levels from the prior authorized fiscal year during the CR period, thus limiting its ability to spend the non-user fee appropriations from the onset.

- **Lapse in Non-User Fee Appropriations:** In MDUFA V, FDA can maintain at least 1 month of an operating reserve so it can continue program operations in the event of a shutdown.

- **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 targeted revenue. When FDA under-collects user fees, it leverages its carryover to maintain continuity in operations. When FDA over-collects, the carryover may increase without additional planned expenditures being identified to obligate those funds towards, and FDA may have to decrease base establishment registration fee amounts, in order to reduce the size of its operating reserves, if the new operating reserve adjustment in MDUFA V is triggered. The changes in the fee structure and minimization of clean-up billing are meant to mitigate these risks in MDUFA V. FDA monitors collections throughout the fiscal year, and the UFFMC and other FDA senior leaders determine how to mitigate any instances when the user fee revenue deviates from the forecasted estimates.

  Section 3309 of the Consolidated Appropriations Act, 2023 amended section 738(a)(3)(B) of the FD&C Act by adding a new provision for small businesses reporting $1 million or less of gross receipts or sales; this new provision authorizes FDA to grant, beginning on October 1, 2024, a waiver of the registration fee (excluding establishments registering for the first time) to establishments proving "financial hardship." FDA will estimate the volume of establishments that may qualify for the fee waiver to prepare for its FY 2025 fee setting. There is a risk that the actual impact of the waiver may differ from preliminary estimates, leading to potential under- or over-collecting in the initial implementation year of FY 2025.

In addition to these mitigation strategies, FDA continued to implement IBAPS to enable greater and more timely insight into budget activity across the Agency. IBAPS improves the accuracy and availability of budget and acquisition information that enables FDA to better plan, forecast, track, and analyze the data to make better informed decisions about the best use of its resources.

Strategic Challenges

Under the MDUFA V agreement, many of the substantive areas subject to commitments under MDUFA IV have continued, including, but not limited to, reviewing premarket medical device applications; quality management; enhancing digital health; using RWE in regulatory decision-making; enhancing patient science and engagement efforts that support premarket review; the Accreditation Scheme for Conformity Assessment (ASCA) regarding testing standards, which will transition from a pilot to a program; and advancing the international harmonization of regulatory standards and practices as they relate to the premarket review process.

However, FDA is implementing several new commitments under MDUFA V. FDA is establishing the TAP Pilot, which is designed to enhance early premarket engagement between the FDA and industry to improve industry's understanding of FDA's regulatory expectations, facilitate better strategic planning and risk management over the total product life cycle, and improve the quality of premarket applications submitted for review. The MDUFA V commitments also include a new construct regarding enhanced performance metrics for Pre-Submissions, De Novo Classification requests, 510(k)s,

and PMAs. If FDA meets specified performance goals in FY 2023, FY 2024 and/or FY 2025, this will trigger add-on payments to supplement FDA's resources to support enhanced performance goals in FY 2025, FY 2026 and/or FY 2027.

To achieve the new commitments set forth in the MDUFA V agreement, FDA plans to add 273 hires supported by MDUFA V fees and 118 TAP Pilot hires supported by (1) the MDUFA carryover balance through FY 2026 and (2) the MDUFA V fees in FY 2027. In addition, if FDA meets the enhanced performance goals, FDA plans to increase the number of hires, which would be supported by additional MDUFA fee collections.

FDA will continue striving to improve its ability to attract, hire, and retain the top scientific talent required for medical device review. MDUFA V includes additional resources for FDA to continue to utilize the hiring and pay authorities provided through the 21st Century Cures Act (Cures Act). The Cures Act pay authority enables the Agency to better compete with the private sector to recruit and retain highly qualified staff.

If FDA fails to meet the applicable hiring thresholds in FY 2023, FY 2024 and/or FY 2025, the new MDUFA V hiring adjustment will be triggered and establishment registration fee amounts will be decreased to reduce total fee collections in FY 2025, FY 2026 and/or FY 2027 by the statutorily prescribed "hiring adjustment amount." FDA met the applicable threshold in FY 2023, so no hiring adjustment will be imposed in FY 2025.

Beginning in FY 2023, FDA began the transition into a "post-pandemic" framework by developing both transition and final guidance documents to facilitate the public's timely access to medical devices after the public health emergency ended.[5] With the May 11, 2023, declaration of the end of that emergency, FDA's focus shifted to its completion of overdue MDUFA IV submissions as well as to meeting MDUFA V goals. FDA has reduced the volume of overdue MDUFA IV submissions by over 50 percent and is on track to meet all MDUFA V goals. This focus on MDUFA process activities, coupled with new MDUFA V efforts, resulted in an overall increase in MDUFA process costs and FTEs from FYs 2022 to 2023.

FDA continues to modernize and streamline the premarket review process by transitioning to electronic submissions and standardized templates to increase reviewers' productivity. The voluntary eSTAR Pilot program provided electronic submission functionality and standardized templates for 510(k)s. Additional templates for De Novo requests and Pre-submissions have been developed and are currently being piloted for use.

[5] See https://www.govinfo.gov/content/pkg/FR-2023-03-13/pdf/2023-05094.pdf.

Appendices

A. Allowable and Excluded Costs for the MDUFA Program

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:

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; and 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; and 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; and 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; and 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; and 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; and 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; and 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 requests; 3. The review of requests for information submitted under section 513(g); and 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; and 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; and 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:

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, maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, scientific equipment, and other necessary materials and supplies; and 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:

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: o Promotion and advertising; o International coordination/Mutual Recognition Agreement work; o International standards development; o Liaison/outreach and manufacturing assistance; o Device tracking; o Inspections unrelated to the review of covered applications; o Export/import activities unrelated to the conduct of a clinical trial; o Research related to future products; and o 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. User Fee Program History

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 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 human medical device review process. FDA spends MDUFA fee revenues 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.

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. 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.

C. 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) in the assessments of the first and third conditions. 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 Consumer Price Index (CPI) for October 2021, the October of the fiscal year preceding FY 2023, was 276.589. The CPI in October 2021 was 276.589. Dividing the CPI of October 2021 by 276.589 yields an adjustment factor of 1.00 for FY 2023.

Legal Conditions

Exhibit 7 provides the details regarding each legal condition, as quoted from the FD&C Act.

Exhibit 7: 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 $398,566,00 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 to defray increases in the costs of the resources allocated for the process for the review of device applications (including increases in such costs for an additional number of full-time equivalent positions in HHS to be engaged in such process) over such costs, excluding costs paid from fees collected under this section, for fiscal year 2009 multiplied by the adjustment factor.

D. Financial Notes

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 **Notes 7, 8 and 9** for an explanation of these adjustments.

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 year and was not expended.

Note 3. Payroll and Operating Costs

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

Note 4. Rent Costs

GSA charges rent to FDA for the federal buildings that FDA occupies. This rent is charged at different rates depending on the type and location of the space provided. Since rent is an essential 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.

The statutory definitions pertaining to allowable costs for the user fee program changed as of October 1, 2023. Those statutory definitions determine whether user fees can be obligated towards these costs.

Specifically, section 738(g)(3) of the FD&C Act was amended to limit the authorities of section 737(10)(C) to include only expenditures for leasing and necessary scientific equipment. The impact of the change means that certain costs related to facilities, fixtures, furniture, materials, and supplies will no longer be able to be funded by MDUFA user fee funds.

Note 5. Shared Service Costs

- **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, and 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. Applicable 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 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 2023 was 1.139385 percent.

Note 7. 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.

Note 8. Hiring Adjustment

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.

Note 9. 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 is equal to the sum of 13 weeks of operating reserves of carryover user fees plus one 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 10. Unearned Fee Revenue

Unearned fees are fees received by September 30, 2023, either for applications that had not been submitted to FDA as of September 30, 2023, 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, 2023, was $62,498,454. **Table 10** outlines the total collections excluding unearned fee revenues for the last 2 cohort years.

Table 10: Medical Device User Fees Collected, Excluding Unearned Fee Revenue, for Cohort Years

Fees Collected	FY 2022	FY 2023
Inflation-adjusted Total Revenue	**$243,473,000**	**$324,777,000**
Collections	$259,972,820	$316,978,065
Unearned Fee Revenue	($5,583,784)	($16,012,231)
Total Collections	**$254,389,036**	**$300,965,834**

Numbers have been rounded to the nearest dollar.

Note 11. 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 11** outlines the excess user fees by fiscal year.

Table 11: Medical Device User Fees Collected, Collection Amounts Specified in Appropriations Acts, and Excess Amounts (Excluding Unearned Revenue) as of September 30,2023

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	$4,415,601
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**

Numbers have been rounded to the nearest dollar.

Note 12. One-Month Reserve

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

Note 13. Minimum Non-User Fee Appropriations and Spending Adjustment Factor

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."

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