Five-Year Financial Plan

Five Years
2023-2024-2025-2026-2027
FY 2026 Update

FOR THE

Medical Device User Fee Amendments Program

FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Five-Year Plan Overview

A. Scope

The purpose of the Five-Year Financial Plan is to communicate the anticipated financial position of the Medical Device User Fee Amendments (MDUFA) program, and to communicate how FDA plans to utilize user fee resources to execute the MDUFA V commitments and statutory requirements. The MDUFA program was reauthorized by the FDA User Fee Reauthorization Act of 2022, which includes the reauthorization of the Medical Device User Fee Amendments of 2022 (MDUFA V) program over the current five-year authorization period.

This document addresses the plan for 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, 2027.

B. Five-Year Plan Commitments

In accordance with MDUFA Performance Goals and Procedures, Fiscal Years 2023 through 2027, Title IV, Section B, FDA published the first MDUFA five-year financial plan by the end of the second quarter of fiscal year (FY) 2023. FDA committed to publishing updates to the five-year plan no later than the end of the second quarter of each subsequent fiscal year. The purpose of this document is to meet this commitment. This plan update includes information as of the end of Fiscal Year 2025.

C. Updates to the Five-Year Plan

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

Management Discussion

D. Organization Background

FDA is responsible for protecting the public'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 safer and more effective but also helps the public get the accurate, science-based information needed to use medical products and consume foods to maintain and improve their health. In addition, FDA similarly plays a significant role in the nation's counterterrorism capability. FDA fulfills this responsibility by ensuring the security of the food supply and by fostering development of medical products to respond to deliberate and naturally emerging public health threats.

Program Organization

There are four major organizational 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 Inspections and Investigations (OII), and Headquarters (HQ).

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

Exhibit 1: User Fee Program Components

Component	Mission
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	Protects and advances the public health by helping to ensure that biological products are safe, effective, and are available to patients.
OII	Conducts rigorous, transparent, and science-based inspections and investigations, providing real-time evidence and insight essential in empowering fact-based regulatory decisions to protect public health.
HQ	Provides FDA-wide program direction and administrative services to ensure FDA's consumer and patient safety programs are effectively and efficiently managed.

User Fee Governance

Strong financial governance is needed because of 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. This 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 Agency-level bodies on a variety of financial and performance-related topics.

Working Capital Fund/Cost Allocation

FDA utilizes a Cost Allocation and Recovery framework as part of the financial management of user fee resources. Congress authorized FDA to establish a Working Capital Fund (WCF) to finance centralized services (see P.L. 115-141). The WCF benefits the financial management of Agency funds by:

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

E. User Fee Background and Structure

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the FDA User Fee Reauthorization Act of 2022, 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 five-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.

Exhibit 2: 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.
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

Fee Type	Definition
	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, a 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.
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

Fee Type	Definition
	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 60 days before the start of each fiscal year.

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.

F. Forward View

MDUFA was reauthorized by Congress based on the recommendations developed through a consultative process involving FDA with device industry representatives, patient and consumer advocates, health care professionals, and other public stakeholders in 2020 and 2021, as required by statute. Information including meeting minutes and MDUFA V commitments is available here: Medical Device User Fee Amendments 2022 (MDUFA V) | FDA.
During FY 2025 FDA experienced staffing reductions and restructuring that reflected changes from the previously planned staffing levels assumed under MDUFA V. FDA maintained planned performance levels in most areas by prioritizing public health and MDUFA review activities, reassigning staff to address critical workload needs, and employing contract resources where appropriate. FDA is working to return to planned staffing levels during the remainder of MDUFA V and will continue to focus on meeting MDUFA commitments while maintaining its public health responsibilities.

Discussion of Workload and Other Activities in MDUFA

Under the MDUFA V user fee agreement, many of the substantive areas subject to commitments under MDUFA IV have continued, including but not limited to, the review of premarket medical device applications, the continuing improvement of the Third Party review program, the use of real-world evidence in regulatory decision making, the enhancement of patient science and engagement efforts that support premarket review, the Accreditation Scheme for Conformity Assessment (ASCA) regarding testing standards, and the advancement of digital health regulatory standards and practices as they relate to the premarket review process.

In addition, FDA has been implementing several new commitments under MDUFA V. FDA established the Total Product Life Cycle Advisory Program (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. FDA also implemented new commitments to advance international harmonization of premarket regulatory practices.

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. See **Section H**, which provides more detail on these adjustments.

Efforts to Enhance Financial Management

MDUFA Five-Year Financial Plan

FDA published a MDUFA five-year financial plan at the end of the 2nd quarter of FY 2023. This initial financial plan included the MDUFA V annual hiring targets. No later than the end of the 2nd quarter of each subsequent fiscal year, FDA committed to publish updates to the five-year plan as of the end of the prior fiscal year. This document satisfies that commitment. The annual updates include the following information:

- The number of new MDUFA V hires by Office
- The number of new MDUFA V hires made from outside the Center, as well as the number of new MDUFA V hires made from current Center employees (if any)
- The number of unfilled new MDUFA V hires
- The changes in the personnel compensation and benefit costs for the process for the review of medical device applications that exceed the amounts provided by the personnel compensation and benefit costs portion of the inflation adjustment
- An accounting of appropriated user fee funds included in the operating reserves at the end of each fiscal year, as well as the carryover balance of user fee funds that are considered unappropriated or unearned and therefore not included in the operating reserves

- An accounting of the amount excluded from the designated amount within the operating reserves, which is intended to support the Third Party Review program and the TAP Pilot

Independent Assessment of MDUFA Workforce Metrics

FDA retained a qualified, independent contractor with expertise in assessing public sector workforce data analysis and reporting to conduct an assessment of current methodologies and data/metrics available to represent the MDUFA workforce. This included assessment of positions (filled/vacant) and MDUFA process FTEs, including the subset funded by user fees, for each applicable FDA Center and Office.

The assessment was published on the FDA website in March 2025 and can be found here Independent Assessment of MDUFA Workforce Metrics. The report included the contractor's findings from the assessment and recommendations for improved methodologies to represent MDUFA FTE resources, including the subset funded by user fees.

Time Reporting

FDA will continue to perform complete time reporting such that data from time reporting can be used to conduct workload analysis and capacity planning.

Financial Information

This section provides an overview of the financial outlook for MDUFA through the FY 2023 - FY 2027 reauthorization period including user fee revenue, obligations, carryover, and planned hiring. The forecasts included in this section are driven by the initiatives and goals as outlined in the Forward View section of this plan.

G. User Fee Program Financial Summary

Table 1a represents a summary of the forecasted MDUFA financial position, as it relates to user fee resources (collections and carryover). **Table 1b** provides an overview of planned obligations for which the user fee resources would be used and **Table 1c** provides the projected End of Year carryover balance. Annual updates to this plan will provide actual amounts for the prior fiscal years.

Table 1a: Medical Device User Fee Budgetary Resources for Fiscal Year 2023 through Fiscal Year 2027

Budgetary Resources	FY2023 Actual	FY2024 Actual	FY2025 Estimate	FY2025 Actual	FY2026 Estimate	FY2027 Estimate
Total Carryover, Beginning of Year	**$252,026,792**	**$248,753,175**	**$226,235,374**	**$226,240,393**	**$239,538,744**	**$228,873,557**

Budgetary Resources	FY2023 Actual	FY2024 Actual	FY2025 Estimate	FY2025 Actual	FY2026 Estimate	FY2027 Estimate
Total Revenue in statute:	$312,606,000	$335,750,000	$350,746,400	$350,746,400	$366,486,300	$418,343,000
Inflation Adjustment	1.038935	1.079318	1.122491	1.122491	1.167391	1.214087
Inflation-adjusted total revenue (rounded to the nearest thousand dollar)	$324,777,000	$362,381,000	$393,710,000	$393,710,000	$427,833,000	$507,905,000
Performance Improvement Adjustment	N/A	N/A	$17,282,545	$17,282,545	$50,332,880	$52,346,211
Hiring Adjustment	N/A	N/A	$0	$0	$0	$0
Operating Reserve Adjustment	$0	$0	$0	$0	$0	$0
Inflation-adjusted total revenue +/- Adjustments	**$324,777,000**	**$362,381,000**	**$410,992,545**	**$410,992,545**	**$478,165,880**	**$560,251,211**
Net Collections	$311,810,191	$346,163,806	$410,992,545	$420,108,584	$478,165,880	$560,251,211
Recoveries	$1,373,080	$2,340,334	$1,778,000	$3,675,474	$2,463,000	$2,463,000
Total Budgetary Resources	**$565,210,063**	**$597,257,315**	**$639,005,919**	**$650,024,451**	**$720,167,624**	**$791,587,768**

Estimates of performance improvement adjustments that depend upon data available prior to the date specified in statute have not been provided.

Table 1b: Medical Device User Fee Obligations for Fiscal Year 2023 through Fiscal Year 2027

Obligations	FY2023 Actual	FY2024 Actual	FY2025 Estimate	FY2025 Actual	FY2026 Estimate	FY2027 Estimate
Total Payroll and Operating	$264,760,276	$309,447,933	$377,202,641	$342,035,399	$416,019,626	$483,311,748
TAP (Non Add-funded thru carryover)	*$5,621,581*	*$13,419,088*	*$32,267,116*	$13,894,812	*$11,000,000*	*$0*
Third Party (Non Add-funded thru carryover)	*$1,600,000*	*$1,600,000*	*$1,600,000*	$1,600,000	*$1,600,000*	*$1,600,000*
Total Rent	$11,665,308	$6,959,098	$7,716,457	$7,652,065	$8,203,853	$8,785,704
Total Shared Services	$40,031,304	$54,614,910	$60,457,156	$60,798,243	$67,070,588	$69,753,412
Total Obligations	**$316,456,888**	**$371,021,941**	**$445,376,254**	**$410,485,707**	**$491,294,067**	**$561,850,864**

Table 1c: Medical Device User Fee Carryover for Fiscal Year 2023 through Fiscal Year 2027

Carryover	FY2023 Actual	FY2024 Actual	FY2025 Estimate	FY2025 Actuals	FY2026 Estimate	FY2027 Estimate
Total Carryover, End of Year	**$248,753,175**	**$226,235,374**	**$193,629,665**	**$239,538,744**	**$228,873,557**	**$229,736,904**
Unearned Revenue	($62,498,454)	($65,193,572)	($65,193,572)	($70,957,814)	($70,957,814)	($70,957,814)
Unappropriated Amounts	($26,680,243)	($26,680,243)	($26,680,243)	($26,680,243)	($26,680,243)	($26,680,243)
Total Appropriated	**$159,574,478**	**$134,361,559**	**$101,755,850**	**$141,900,687**	**$131,235,500**	**$132,098,847**

Carryover	FY2023 Actual	FY2024 Actual	FY2025 Estimate	FY2025 Actuals	FY2026 Estimate	FY2027 Estimate
Future Year Refunds Allowance, Set Aside	($2,000,000)	($2,373,000)	($2,413,000)	($2,413,000)	($2,282,000)	($2,282,000)
One-Month Reserve	($30,198,417)	($32,809,167)	($37,150,571)	($39,847,157)	($46,687,601)	($46,687,601)
Subtotal	**$127,376,061**	**$99,179,392**	**$62,192,279**	**$99,640,530**	**$82,265,899**	**$83,129,246**
Carryover set-aside for MV commit ments (TAP&Third Party) End of Year	($110,778,419)	($95,759,331)	($61,892,215)	($80,264,519)	$0	$0
Carryover Net of Unavailable and Set Aside, End of Year	**$16,597,642**	**$3,420,061**	**$300,064**	**$19,376,011**	**$82,265,899**	**$83,129,246**

The terms in **Tables 1a – 1c** are defined below.

Budgetary Resources:

- Total Carryover, Beginning of Year is the total amount of unobligated fee funds at the end of the preceding fiscal year and includes amounts restricted for spending such as unappropriated and unearned revenue amounts. Inflation Adjusted Total Revenue is the total revenue amount specified in the statute for each year of MDUFA V adjusted to maintain the purchasing power of fee funds in consideration of inflation. The inflation 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 it is compounded yearly.

- Inflation Adjusted Total Revenue +/- Adjustments 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.

- Net Collections are the actual amounts collected during the fiscal year (net of refunds) and are estimated to be equal to the inflation adjusted total revenue plus or minus the new statutory adjustments as applicable (i.e., performance improvement, hiring, and operating reserve).

- Recoveries are the 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. For the purpose of this plan update,

recoveries are estimated to be $2,463,000 annually. This amount is calculated using a three-year average of recoveries from FY 2023 through FY 2025 and rounded to the nearest thousand.

- Total Budgetary Resources is the total user fee funding (i.e., the existing total carryover, user fee collections, and recoveries).

Obligations:

- Obligations are the actual expenditures of MDUFA fees for FY 2023, FY 2024, and FY 2025 and planned annual expenditures for FY 2026 and FY 2027 of MDUFA fees. Obligations are discussed in more detail in **Section I**.

- TAP (Non Add-funded thru carryover) and Third Party (Non Add-funded thru carryover) are a subset of Total Payroll and Operating Obligations and represent those obligations towards the TAP Pilot and Third Party review program that FDA funded in FY 2023, FY 2024, and FY 2025 and plans to fund from the MDUFA carryover in FY 2026. FDA intends to fund the FY 2027 TAP Pilot obligations from new user fee collections, not carryover fees.

Carryover:

- Total Carryover, End of Year 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 precluding from obligating.

- Unappropriated Amount is the amount that FDA collected in user fees in excess of the amount specified in appropriations acts prior to FY 2013. See **Appendix C** for details.

- Unearned Revenue are fees received by September 30, of a particular fiscal year, either for applications that had not been submitted to FDA as of September 30, of that same fiscal year, 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. Beginning in FY 2023, FDA has implemented new protocols in their User Fee System that will send automated reminders to payors who have yet to submit their application to minimize the growth of unearned revenue.

- Future Year Refunds Allowance, Set Aside is a small amount FDA maintains to provide for any refunds as a matter of prudent operations. For that purpose, a total of $2,282,000 in fee funds available for obligation is being set aside annually for each future fiscal year. This amount is

calculated using a three-year average of refunds of earned MDUFA fees for FY 2023 through FY 2025 and rounded to the nearest thousand.

- One-Month Reserve is the amount FDA sets aside annually to maintain unobligated carryover of not less than one month of operating reserves for the first month of the next fiscal year.

- Carryover Set-Aside for MV Commitments (TAP & Third Party) is the amount of carryover that will be excluded from the designated amount within the operating reserves and not subject to the operating reserve adjustment per MDUFA V. 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 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.

H. User Fee Revenue

Fee Setting

FDA assumes, for planning purposes, that net collections will equal the inflation adjusted total revenue amount plus or minus any applicable MDUFA V adjustments. Net collections may differ from the inflation adjusted total revenue amount plus or minus the adjustments if the actual number of fee-paying units differs from the number of fee-paying units estimated when fees are set each year.

Annual updates to this plan will include (1) the actual collections amounts from the preceding fiscal years; (2) the total revenue amount with the actual (applicable) inflation adjustment for the current fiscal year; and (3) the amount(s) of any applicable MDUFA V adjustments for the current fiscal year.

The process for setting fees is defined in the statute, including annual adjustments to the base fees and the total revenue amount that must be made for inflation, adjustments to base fees to reach the inflation-adjusted total revenue amount, and any applicable performance improvement, hiring, or operating reserve adjustments to establishment registration fees.

The total revenue amounts for FY 2023 through FY 2027 are specified in statute as follows:

- $312,606,000 for FY 2023

- $335,750,000 for FY 2024

- $350,746,400 for FY 2025

- $366,486,300 for FY 2026
- $418,343,000 for FY 2027

These amounts are adjusted to maintain the purchasing power of fee funds in consideration of inflation. The adjustment is a composite measure that weights by 40% operating expenses, based on changes in the Consumer Price Index (CPI), and weights by 60% payroll-related expenses, based on changes in FDA's average personnel compensation and benefits amounts.

The actual (applicable) inflation adjustment utilized for fee setting for FY 2026 was 1.167391. The estimated applicable inflation adjustment for FY 2027 is 1.214087. See **Table 1a**.

Next, the applicable inflation adjustment to base fees is performed. FDA may then increase the base fee amounts on a uniform proportionate basis if necessary to achieve the inflation-adjusted total revenue amount. If necessary, after this adjustment, FDA may further increase the base establishment registration fees to generate the inflation-adjusted total revenue amount.

MDUFA V has three new potential adjustments that may impact collections by increasing or decreasing establishment registration base fees only. The operating reserve adjustment is potentially applicable in each of the five years of MDUFA V. The performance improvement and hiring adjustments are potentially applicable in FYs 2025, 2026, and 2027.

FDA may increase fee revenue above the statutory annual inflation-adjusted total revenue amount to support performance improvements in FY 2025, FY 2026, and FY 2027 if the Agency meets certain performance goals in FYs 2023, 2024, and 2025 in four premarket submission areas: PMAs, 510(k)s, De Novos, and Pre-submissions (section 738(c)(4) of the FD&C Act). If applicable, this provision further increases base establishment registration fee amounts to achieve an increase in total fee collections equal to the applicable performance improvement adjustment, which is set forth in the statute. The maximum amounts of the performance improvement adjustments available (prior to the inflation adjustment) are:

- $15,396,600 for FY 2025
- $44,135,500 for FY 2026
- $56,244,000 for FY 2027

FDA is to measure whether it meets the performance goals based on data available as of dates specified in the statute. FDA met the FY 2024 Pre-submission Written Feedback goal and the FY23 De Novo Decision goal, which

determined the performance improvement adjustment amount for FY 2026. The amount of this adjustment for FY 2026 is $50,332,880.

Beginning with FY 2025, the hiring adjustment provides for the reduction of base establishment registration fees in FYs 2025, 2026, and 2027 if specified hiring goal thresholds for FYs 2023, 2024, and 2025 are not met as described in statute (section 738(c)(5) of the FD&C Act). The hiring adjustment would serve to decrease the base establishment registration fee amounts as necessary to achieve a reduction in total fee collections equal to the hiring adjustment amount. The calculation for the hiring adjustment is the product of the number of hires by which the hiring goal specific for the fiscal year before the prior fiscal year was not met, multiplied by $72,877, then multiplied by the applicable inflation adjustment for the fiscal year for which the hiring goal was not met.

FDA met the specified hiring goal threshold for FY 2025. Accordingly, there is no hiring adjustment for FY 2027.

For FYs 2023 to 2027, the operating reserve adjustment requires FDA to decrease base establishment registration fees if the amount of operating reserves of carryover user fees exceeds the "designated amount," and such reduction is necessary to provide for not more than such designated amount of operating reserves in the following fiscal year (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 to 2026, a total of $118,000,000 is excluded from the designated amount as it is intended to support the MDUFA V commitments for the TAP Pilot and Third Party Review program. Any residual amount of the excluded $118,000,000 that is left unspent at the end of FY 2026 will be considered part of the designated amount 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. As shown in **Table 1b**, FDA spent a total of $37,735,481 by the end of FY25 on the TAP pilot and Third Party Review Program, leaving $80,264,519 remaining to be excluded from the designated amount.

No operating reserve adjustment was necessary for FY 2026 fee setting because the operating reserve did not exceed the designated amount.

Annual updates to this plan will update the inflation adjusted total revenue amount for the current fiscal year, the amount of any applicable MDUFA V adjustments for the current fiscal year, and the actual collections amount from the preceding fiscal years.

Projected Collections

As noted above, the net collections are the actual amount collected during the fiscal year, net of refunds, and are estimated to be equal to the inflation adjusted

total revenue plus or minus the new statutory adjustments as applicable. See **Table 1a**. The annual updates to this plan will provide the actual net collections amounts by cohort year for the preceding year(s) as well as updated planned amounts for the remaining fiscal years.

I. User Fee Obligations

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**.

Table 2 provides a breakout of planned user fee obligations by expense category for the five years represented in this plan; non-user fee funds supporting the MDUFA program are not included here. Annual updates to this plan will provide actual amounts for the preceding fiscal years, as well as updated planned amounts for the remaining fiscal years.

Table 2: Medical Device User Fee Obligations by Expense Category for Fiscal Year 2023 through Fiscal Year 2027

User Fee Obligations	FY2023 Actual	FY2024 Actual	FY2025 Estimate	FY2025 Actual	FY2026 Estimate	FY2027 Estimate
Total Budgetary Resources	**$565,210,063**	**$597,257,315**	**$639,005,919**	**$650,024,451**	**$720,167,624**	**$791,587,768**
Payroll & Operating						
CDRH	$238,396,261	$282,662,843	$346,823,026	$313,732,491	$383,989,394	$450,519,721
CBER	$14,263,635	$16,063,200	$18,058,572	$12,930,268	$18,977,733	$19,796,650
OII	$1,731,907	$1,820,440	$2,706,779	$2,488,637	$2,733,258	$2,831,541
HQ	$10,368,473	$8,901,450	$9,614,264	$12,884,003	$10,319,241	$10,163,836
Total Rent	$11,665,308	$6,959,098	$7,716,457	$7,652,065	$8,203,853	$8,785,704
Total Shared Services	$40,031,304	$54,614,910	$60,457,156	$60,798,243	$67,070,588	$69,753,412
Total Obligations	**$316,456,888**	**$371,021,941**	**$445,376,254**	**$410,485,707**	**$491,294,067**	**$561,850,864**

The terms in **Table 2** are defined below.

- Payroll and Operating are obligations to provide for payroll and operating costs 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.

- Rent is the amount the General Services Administration (GSA) charges to FDA for the federal buildings that FDA occupies, as well as amounts paid directly to non-federal sources for direct leases and services. This rent is

charged at different rates by GSA 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 MDUFA fees, and a portion is paid from non-user fee appropriations. 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. In FY 2024, total rent-related obligations of MDUFA fees decreased from FY 2023 as, under the statute), certain expenses previously eligible for MDUFA fee funding were no longer eligible and had shifted to non-user fee appropriations. The future yearly amounts, for the purposes of this plan, have been re-baselined based on FY 2024 GSA Rent actuals.

- Shared Services is the amount charged to the FDA for the shared services organizations, located within the Working Capital Fund, that provide support across the user fee programs, such as human resources and information technology (IT). **See Appendix B** for the full list of organizations.

J. Hiring

Enhancements to the medical device review program require that FDA recruit, hire and retain sufficient numbers and types of technical, scientific, and other program experts to support the process for the review of device applications. MDUFA V provides significant new resources to FDA to support these activities.

To help ensure that FDA accomplishes hiring in accordance with the assumptions underlying the agreement, FDA established annual hiring goals for each year of MDUFA V.

The hiring goals for FY 2023-2025 are:

- FY 2023: 144 hires
- FY 2024: 42 hires
- FY 2025: 24 hires if base establishment fees are not increased by the performance improvement amount associated with meeting the FY 2023 Pre-submission Written Feedback Goal; and 83 hires if they are.

The MDUFA V agreement provides for enhancements to the shared outcome total time to decision goals and to specified review performance goals, provided that specified goals were met in prior years. The agreement further provides that if those performance improvement adjustments are triggered, the Agency will

increase hiring beginning for FY 2025 to support the enhanced goals. As noted above, FDA met the FY 2023 Pre-submission Written Feedback goal, which triggered the performance improvement adjustment for FY 2025 and the statutory hiring goal of 83 hires for FY 2025. Hiring will be increased to support the enhanced goals. The MDUFA V statute sets forth the parameters to calculate potential add-on hires (the performance improvement hires) and applicable thresholds.

Finally, the MDUFA V agreement provides that for purposes of determining whether the hiring goal is met for FY 2023, FDA will include "pre-hires" that are made in FY 2022 for MDUFA V positions. In FY 2022, FDA had 10 MDUFA V Pre-Hires. In addition, for subsequent fiscal years, if FDA exceeds the hiring goal, the additional hires made above the goal will be counted towards the following fiscal year goal.

Table 3 illustrates FDA's hiring goals from FY 2023 through FY 2027. Beginning in FY 2024, **Table 3** will be updated with actual hires, at the Office level, for the preceding fiscal year.

Table 3: Target Hires by Organization for MDUFA V

Organization	FY2023 Actuals	FY2024 Actuals	FY2025 Target	FY2025 Actuals	FY2026 Target	FY2027 Target
CBER	0	3	2	1	0	0
CDRH	141	42	22	21	63	0
HQ	0	0	0	0	0	0
Other FDA	0	0	0	0	0	0
Add on Hires	*N/A*	N/A	*59*	*57*	*5*	*TBD*
Total Hires	**141**	**45**	**83**	**79**	**68**	**N/A**

The hiring targets for FY 2026 - 2027 have not been adjusted for any anticipated performance improvement adjustment that depends upon data available prior to the date specified in statute.

FY 2025 Actuals	Number of new MDUFA V hires by Office Target	Number of new MDUFA V hires by Office Actual
OCD	2	2
OCE	0	0
OM	1	1
OP	0	0
OPEQ	71	69
OSEL	3	3
OST	4	3
Total CDRH Hires	**81**	**78**
OBRR	2	1

OTP	0	0
OCBQ	0	0
Total CBER Hires	**2**	1
Total MDUFA V Hires	**83**	**79**

FDA made 79 MDUFA V hires in FY25, including 78 external hires and one internal hire.

Additional Reporting Requirements

Under MDUFA V, FDA committed to reporting on the following items annually starting with the FY 2024 update of the MDUFA Five-Year Financial Plan:

The changes in the personnel compensation and benefits costs for the process for the review of medical device applications that exceed the amounts provided by the personnel compensation and benefits portion of the inflation adjustment.

Table 4. Change in PC&B Costs Compared to Amount Provided by PC&B Portion of Inflation Adjustment

	FY 2024	FY 2025
Statutory Total Revenue		$350,746,400
Applicable Inflation Adjustment	1.079318	
PC&B (Payroll Adjustment) Factor		.023123
PC&B (Payroll Adjustment) Compounded		.024957
PC&B Inflation		**$8,753,602**
FDA Total MDUFA Process FTEs		2,048
FDA Avg. MDUFA Process PC&B per FTE	*$212,278*	*$222,344*
FDA PC&B Change from Previous Year		*$10,066*
Impact of PC&B increase		**$20,615,078**

The personnel compensation and benefits (PC&B) portion of the FY 2025 compounded inflation adjustment provided $8.8M to FDA compared to the PC&B increase in costs FDA incurred in FY 2025 of $20.6M. The PC&B increase in costs exceeded the PC&B portion of the inflation adjustment by $11.8M. However, the impact of CURES hiring authority for new and existing hires on these numbers was anticipated and revenue was included in the negotiated MDUFA V, which assists in mitigating the impact of the PC&B increase.

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:

Exhibit 3: Included Activities

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; 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 request; 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. Real-World Evidence 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[1]; 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:

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: 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.

[1] Section 905(b) of the FDA Reauthorization Act of 2017 amended the FD&C Act to provide under section 738(g)(3) that, beginning on October 1, 2023, the authorities under section 737(10)(C) shall include only leasing and necessary scientific equipment. The referenced authorities previously listed expenses for "leasing, maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, scientific equipment, and other necessary materials and supplies."

B. Shared Services Organizations

FDA has several shared service programs, supported by the WCF, that provide support for activities across the Agency. The shared service programs in FY 2026 include:

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

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

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

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

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

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

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

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

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

Office of Security and Passport Operations: Develops and implements the Agency-wide security policies and programs by providing leadership and guidance to managers and staff on all aspects of security. Delivers efficient passport and visa services and administers vital security functions that contribute to the

Agency's mission of protecting public health by enhancing the safety and security of all personnel, facilities, and information.

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

C. 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 5** outlines the excess user fees by fiscal year.

Table 5: 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 (Excluding Unearned Revenue)	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	**N/A**	**N/A**	**$26,680,243**

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