Five-Year Financial Plan

Fiscal Years
2023-2024-2025-2026-2027

FY 2023 Version

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. 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, and to communicate how FDA plans to utilize user fee resources to execute the MDUFA V commitments and statutory requirements.

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 committed to publish a MDUFA five-year financial plan no later than the second quarter of fiscal year (FY) 2023. FDA also committed to publish updates to the five-year plan no later than the second quarter of each subsequent fiscal year. The purpose of this document is to meet these commitments.

C. Updates to the Five-Year Plan

All estimates in the plan are subject to review and reassessment each fiscal year as the actual amounts for appropriations, obligations, and collections for the previous 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. FDA similarly plays a significant role in the nation's counterterrorism capability.

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 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

The expanding scope and funding levels of the Agency's user fee programs, the reporting of the Agency's performance commitments associated with these fees, and the need for FDA to convey how these fees are executed calls for strong financial governance. This governance includes an understanding of the design of these

programs, clear financial plans, data-driven decisions on resource allocation, consistency and transparency about assumptions, reliable financial forecasting, and accountability for resources spent.

Agency-level executive oversight of FDA's user fee programs is the responsibility of the FDA Executive Committee, which is Chaired by the Commissioner and comprises Center Directors, Deputy Commissioners, Chief Counsel, and other senior executives. The Executive Committee 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, oversee the development of 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.

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.

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
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, a type of premarket application 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, 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, a request for 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.
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 demonstration of 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.

Fee Type	Definition
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.
Annual 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 annual adjustments that must be made for inflation. The fee amounts are to be published in the Federal Register each year 60 days before the start of each fiscal year.[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.

F. Forward View

MDUFA was reauthorized by Congress based on the recommendations developed through a consultative process involving FDA and:

a. the Committee on Energy and Commerce of the House of Representatives;

b. the Committee on Health, Education, Labor, and Pensions of the Senate;

c. scientific and academic experts;

d. health care professionals;

e. representatives of patient and consumer advocacy groups; and

f. the regulated industry

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

as required by statute. Information including meeting minutes and MDUFA V commitments is available here: Medical Device User Fee Amendments 2022 (MDUFA V) | FDA.

FDA expects that many of the recent external factors impacting the program are likely to continue in the coming years. This includes potential impact from the COVID-19 pandemic, and continued competition for the necessary scientific and technical talent needed to deliver MDUFA performance commitments and related public health priorities.

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 will continue, 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, and the Accreditation Scheme for Conformity Assessment (ASCA) regarding testing standards, which will transition from a pilot to a program. and the advancement of international harmonization of regulatory standards and practices as they relate to the premarket review process.

FDA also will implement several new commitments under MDUFA V. FDA will establish 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. 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 the FDA meets specified performance goals in FY 2023, FY 2024, and FY 2025; it will trigger add-on payments to supplement FDA's resources to support enhanced performance goals in FY 2025, FY 2026, and FY 2027.

To achieve the new commitments set forth in the MDUFA V agreement, the FDA plans to add 273 positions funded from MDUFA V fees and 118 TAP Pilot positions funded from the MDUFA carryover balance through FY 2026 and funded through MDUFA V fees in FY 2027. In addition, if the enhanced performance goals are met, FDA plans to increase the number of positions, which would be funded by additional MDUFA fee collections.

FDA will continue striving to improve the Agency's 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 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.

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

MDUFA V has three new potential adjustments that may impact collections by increasing or decreasing establishment registration base fees only.

- The performance improvement adjustment provides new authority for FDA to increase fee revenue above the statutory annual total revenue amount to support performance improvement 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 Presubmissions.

- The hiring adjustment provides for the reduction of base establishment registration fees in FYs 2025, 2026, and 2027 if specific hiring goal thresholds for FYs 2023, 2024, and 2025 are not met.

- 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.

Efforts to Enhance Financial Management

MDUFA Five-Year Financial Plan

FDA committed to publish a MDUFA five-year financial plan no later than the end of the 2nd quarter of FY 2023. This document satisfies that requirement. This initial financial plan includes the MDUFA V annual hiring targets. No later than the end of the 2nd quarter of each subsequent fiscal year, FDA will publish updates to the five-year plan as of the end of the prior fiscal year. The annual updates will 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; and

- 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 will retain 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 will include assessment of positions (filled/vacant) and MDUFA process FTEs, including the subset funded by user fees, for each applicable FDA Center and Office.

The report will include the contractor's findings from the assessment and recommendations for improved methodologies to represent MDUFA FTE resources, including the subset funded by user fees. The assessment will be published on FDA's website by March 31, 2025.

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 of the FY 2023 through 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 1 represents a summary of the forecasted MDUFA financial position, as it relates to user fee resources (collections and carryover). This table also provides an overview of planned obligations for which the user fee resources would be used and the projected End of Year carryover balance. Annual updates to this plan will provide actual amounts for the prior fiscal years. The financial notes referenced in this table can be found in **Appendix B**.

Table 1: Medical Device User Fee Collections, Obligations, and Carryover for Fiscal Year 2023 through Fiscal Year 2027

Budgetary Resources	Notes	FY 2023 Estimate	FY 2024 Estimate	FY 2025 Estimate	FY 2026 Estimate	FY 2027 Estimate
Total Carryover, Beginning of Year		$252,026,792	$234,889,631	$212,767,508	$179,934,109	$135,808,363
Total Revenue in statute:		$312,606,000	$335,750,000	$350,746,400	$366,486,300	$418,343,000
Inflation Adjustment	Note 1	1.038935	1.056103	1.073556	1.091296	1.109330
Inflation-adjusted total revenue (rounded to the nearest thousand dollar)		$324,777,000	$354,587,000	$376,546,000	$399,945,000	$464,080,000
Performance Improvement Adjustments		*n/a*	*n/a*	*TBD*	*TBD*	*TBD*
Hiring Adjustment		*n/a*	*n/a*	*TBD*	*TBD*	*TBD*
Operating Reserve Adjustment		*$0*	*TBD*	*TBD*	*TBD*	*TBD*
Inflation-adjusted total revenue +/- Adjustments		$324,777,000	$354,587,000	$376,546,000	$399,945,000	$464,080,000
Net Collections		$324,777,000	$354,587,000	$376,546,000	$399,945,000	$464,080,000
Recoveries	Note 3	$1,619,483	$1,619,483	$1,619,483	$1,619,483	$1,619,483
Total Budgetary Resources		**$578,423,275**	**$591,096,114**	**$590,932,991**	**$581,498,592**	**$601,507,846**

Obligations	Notes	FY 2023 Estimate	FY 2024 Estimate	FY 2025 Estimate	FY 2026 Estimate	FY 2027 Estimate
Total Payroll and Operating	Note 4	$290,662,705	$328,502,389	$359,458,516	$390,817,935	$410,569,575
TAP – "Non Add-funded thru carryover"		*$15,799,019*	*$21,504,820*	*$32,267,116*	*$43,545,978*	*$0*
Third Party – "Non Add- funded thru carryover"		*$1,600,000*	*$1,600,000*	*$1,600,000*	*$1,600,000*	*$1,600,000*
Total Rent	Note 5	$13,961,214	$8,649,092	$8,735,583	$8,822,939	$8,911,168
Total Shared Services	Note 6	$38,909,725	$41,177,125	$42,804,783	$46,049,355	$46,810,321
Total Obligations		**$343,533,644**	**$378,328,606**	**$410,998,883**	**$445,690,229**	**$466,291,064**

Carryover	Notes	FY 2023 Estimate	FY 2024 Estimate	FY 2025 Estimate	FY 2026 Estimate	FY 2027 Estimate
Total Carryover, End of Year		$234,889,631	$212,767,508	$179,934,109	$135,808,363	$135,216,782
Unearned Fee Revenue	Note 7	($53,933,164)	($53,933,164)	($53,933,164)	($53,933,164)	($53,933,164)
Unappropriated Amounts	Note 8	($26,680,243)	($26,680,243)	($26,680,243)	($26,680,243)	($26,680,243)
Total Appropriated		**$154,276,224**	**$132,154,101**	**$99,320,702**	**$55,194,956**	**$54,603,375**
Future Year Refunds Allowance, Set Aside		($2,000,000)	($2,000,000)	($2,000,000)	($2,000,000)	($2,000,000)
One-Month Reserve	Note 9	($29,548,917)	($31,378,833)	($33,328,750)	($38,673,333)	($38,673,333)
Subtotal		**$122,727,308**	**$98,775,268**	**$63,991,952**	**$14,521,623**	**$13,930,042**
Carryover set-aside for MV commitments *(TAP & Third Party),* End of Year		($100,600,981)	($77,496,161)	($43,629,045)	$0	$0
Carryover Net of Unavailable and Set Aside, End of Year		**$22,126,327**	**$21,279,107**	**$20,362,907**	**$14,521,623**	**$13,930,042**

Total Revenue has been rounded to the nearest thousand dollars. All other numbers have been rounded to the nearest dollar.

The terms in **Table 1** 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.

- The MDUFA V adjustments for "Performance Improvement", "Hiring", and "Operating Reserve", if triggered by meeting certain conditions, allow FDA to set fees so as to either increase or decrease collections above or below the "inflation adjusted total revenue" amount.

- "Inflation Adjusted Total Revenue" is the total revenue amount specified in the statute for each year of MDUFA V as adjusted for inflation. Additional details on inflation are included in **Note 1.**

- "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. Additional details on the total revenue methodology are included in **Note 2.**

- "Net Collections" are the actual amounts collected during the fiscal year 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 estimated to be $1,619,483 annually for the purposes of this plan. Additional details on recoveries are included in **Note 3**.

- "Total Budgetary Resources" illustrates the sum of the total user fee funding (i.e., the existing total carryover and additional user fee collections) forecast for FY 2023 through FY 2027.

Obligations

- The "Obligations" component of **Table 1** shows the planned annual expenditures for FY 2023 through FY 2027 of MDUFA fees. Obligations are discussed in more detail in **Section I**.

- The "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 estimated obligations towards the TAP Pilot and Third Party review program that FDA plans to fund from the MDUFA carryover in FY 2023 through 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": 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 8** for additional details.

- "Unearned Fee Revenue": Unearned fees are fees received by September 30, of a particular fiscal year, for applications that had not been submitted to FDA as of September 30, of that same fiscal year, or for establishment fees received without identification of the remitter. See **Note 7** for additional details.

- "Future Year Refunds Allowance, Set Aside": FDA maintains a small amount to provide for any refunds as a matter of prudent operations. For that purpose, a total of $2,000,000 in fee funds available for obligation is being set aside annually. This amount is calculated using a three-year average of refunds of earned MDUFA fees for FY 2020 through FY 2022.

- "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. Additional details on the one-moth reserve are included in **Note 9.**

- "Carryover set-aside for MV Commitments (TAP & Third Party)": Per MDUFA V statute, 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.

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

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 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 for inflation 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 inflation adjustment utilized in FY 2023 was 1.038935%. The estimated inflation adjustments utilized for the out-years are 1.056103% in FY 2024, 1.073556% in FY 2025, 1.091296 in FY 2026, and 1.109330 in FY 2027. The estimated inflation adjustments will be updated with actual inflation adjustments each year.

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 Presubmissions (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 are:

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

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.

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.

No operating reserve adjustment was necessary in FY 2023 because the operating reserve did not exceed the designated amount. As shown in **Table 1**, FDA estimates spending $17,399,019 of the $118,000,000 excluded from the designated amount to fund the TAP Pilot and Third Party Review programs in FY 2023, leaving $100,600,981 remaining to be excluded from the designated amount at the end of FY 2023.

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 and are estimated to be equal to the inflation adjusted total revenue plus or minus the new statutory adjustments as applicable. See **Table 1**. 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. 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. The financial notes can be found in **Appendix B**.

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

User Fee Obligations	Notes	FY 2023 Estimate	FY 2024 Estimate	FY 2025 Estimate	FY 2026 Estimate	FY 2027 Estimate
Total Budgetary Resources		$578,423,275	$591,096,114	$590,932,991	$581,498,592	$601,507,846
Payroll & Operating						
CDRH		$262,237,626	$299,114,064	$329,200,054	$359,942,590	$379,100,196
CBER		$15,992,805	$17,038,413	$17,758,057	$18,158,969	$18,535,520
ORA		$2,295,080	$2,437,400	$2,479,852	$2,523,026	$2,566,940
HQ		$10,137,194	$9,912,512	$10,020,554	$10,193,349	$10,366,920
Total Rent	Note 5	$13,961,214	$8,649,092	$8,735,583	$8,822,939	$8,911,168
Total Shared Services	Note 6	$38,909,725	$41,177,125	$42,804,783	$46,049,355	$46,810,321
Total Obligations		**$343,533,644**	**$378,328,606**	**$410,998,883**	**$445,690,229**	**$466,291,064**

Numbers have been rounded to the nearest dollar.

Total obligations include payroll and operating, rent, and shared services costs. Non-user fee funds supporting the MDUFA program are not included here. 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 (see **Note 4**). 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.

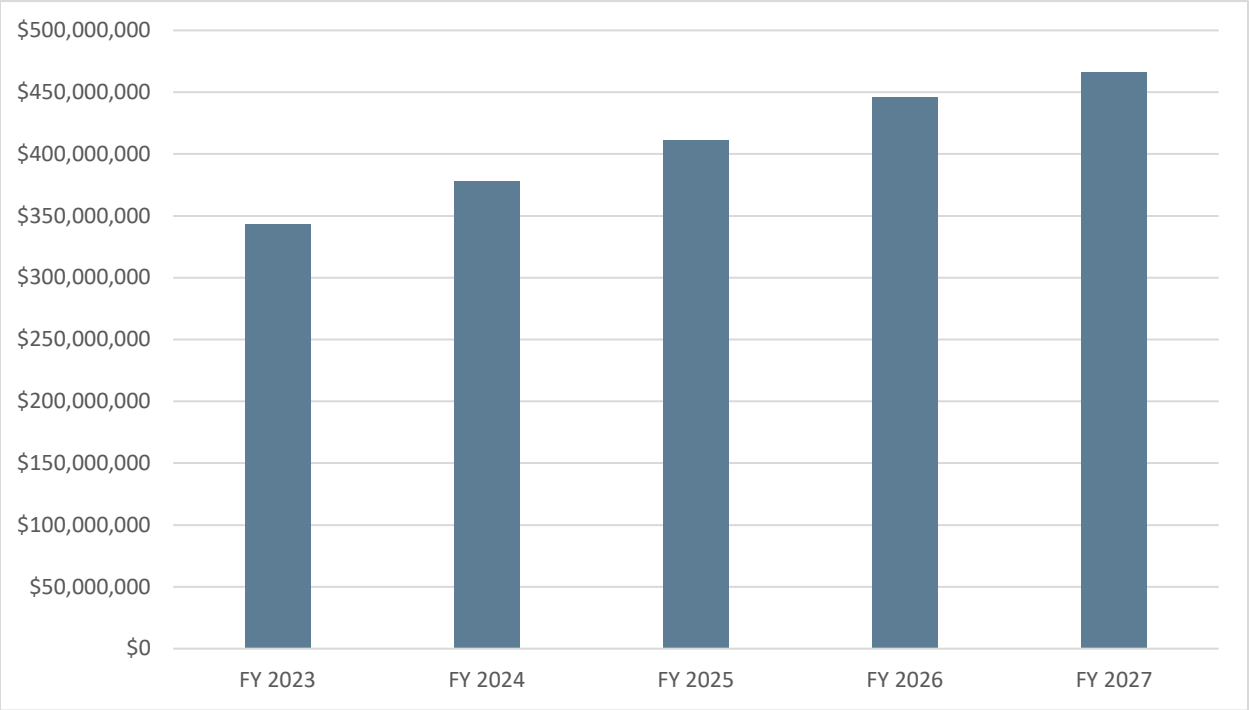
- **Rent:** This amount is paid to the General Services Administration (GSA) for the federal buildings that FDA occupies, as well as directly to non-federal sources for direct leases and services (see **Note 5**). Rental rates vary based on the type and location of the space provided. The future year amounts, for the purposes of this plan, are assumed to have an increase of 1% yearly.

  Section 738(g)(3) of the FD&C Act provides that "beginning on October 1, 2023, the authorities under section 737(10)(C) shall include only 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.

- **Shared Services:** FDA has several shared service organizations that provide support across the user fee programs, such as human resources and information technology (IT). Shared services at FDA are located within the Working Capital Fund (WCF). Yearly costs are determined by the Cost Allocation and Recovery framework discussed previously. **Note 6** provides a full list of what is contained in the WCF.

Exhibit 3 provides an illustration of projected MDUFA obligations from FY 2023 through FY 2027.

Exhibit 3: Forecasted User Fee Obligations by Fiscal Year



As demonstrated by this graph, MDUFA user fee obligations are projected to increase over the course of MDUFA V. The increase in MDUFA fee obligations can be attributed to FTE growth, increased FTE costs, and other operating investments such as the TAP Pilot.

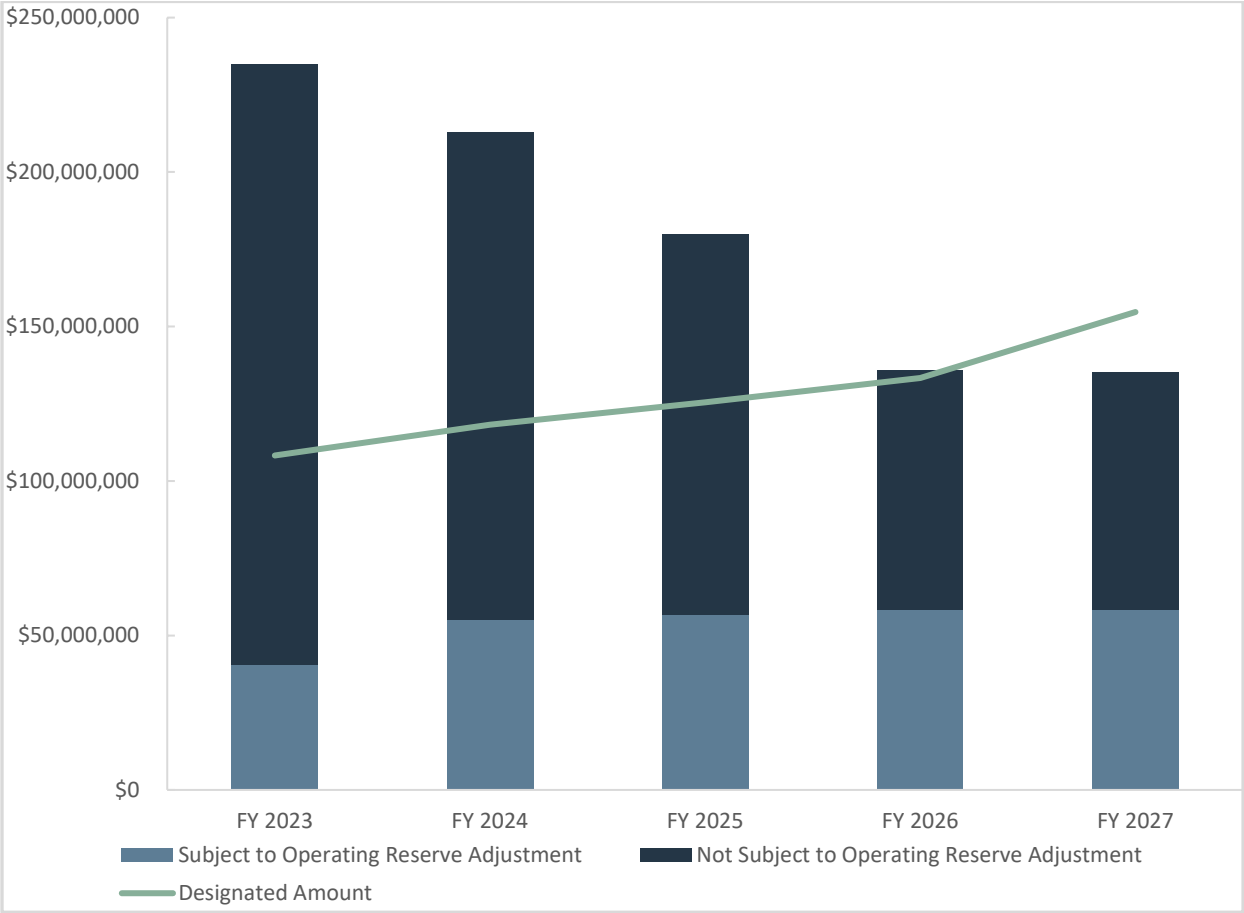
FDA expects to continue to build staff and operational capacity to manage review workload and deliver on performance and procedural goals.

J. User Fee Carryover

Exhibit 4 shows the forecasted trend of carryover in MDUFA V.

The "Designated Amount" shown in **Exhibit 4** is equal to the sum of 13 weeks of operating reserves of carryover user fees plus one month of operating reserves described in section 738(c)(8)(A) of the FD&C Act (see section 738(c)(6)(B) of the FD&C Act).

Exhibit 4: Forecasted Carryover by Fiscal Year



The "not subject to operating reserve adjustment" consists of (1) the "Designated Amount" plus (2) the excluded amount, the latter of which is a total of $118 million for fiscal years 2023 through 2026. The carryover balance is projected to decrease over the course of MDUFA V as FDA spends down that $118 million set-aside to fund the TAP Pilot and Third Party review programs. As **Exhibit 4** exhibit shows, carryover funds subject to the operating reserve adjustment (light blue) are anticipated to consistently be less than the designated amount (green line), thus obviating the need for an operating reserve adjustment.

K. 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 minimum hiring goals for FY 2023-2025 are:

- FY 2023: 144 hires
- FY 2024: 42 hires
- FY 2025: 24 hires

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 to support the enhanced goals. The MDUFA V statute sets forth the parameters to calculate potential add-on hires.

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[2]

Organization	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
CBER	3	0	2	0	0
CDRH	141	42	22	63	0
ORA	0	0	0	0	0
HQ	0	0	0	0	0
Total FTE	**144**	**42**	**24**	**63**	**0**
Add on FTE	N/A	N/A	TBD	TBD	TBD

[2] Guaranteed Funding Scenario is shown in **Table 3**. This excludes the TAP Hires from Carryover

Management Assurance

L. Internal Controls

The Department of Health and Human Services (HHS) provides guidance to its operating divisions (OpDivs) to implement The Federal Managers' Financial Integrity Act of 1982 (FMFIA) through its FMFIA Guidelines, which is intended to strengthen internal controls and accounting systems. OpDivs, including FDA, are responsible for developing and maintaining internal control and compliance programs that include programmatic and operational controls, as well as reporting controls to support sound financial management. Additionally, FDA established an Enterprise Risk Management (ERM) Program, with an ERM Council as the governance body responsible for providing overall oversight and accountability. For further information regarding the Internal Controls and Enterprise Risk Management, please refer to the MDUFA User Fee Program's Financial Report.[3]

M. 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 estimate what the Agency's total appropriation will be in any given year. As a result, FDA has some risk of missing important performance goals, or failing to meet the non-user fee spending trigger for the fiscal year if 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. FDA intends to put more emphasis on the initial planning of initiatives in the early years of the five-year cycle, 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

[3] MDUFA Financial Reports | FDA

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 must maintain at least one month of an operating reserve so it can continue program operations in the event of a shutdown.

- **Undercollecting and Overcollecting Fees:** If FDA does not receive the estimated number of industry submissions, there may be an excess or deficit in total revenue. When FDA undercollects 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. 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" amends section 738(a)(3)(B) of the FD&C Act, by adding a new provision for small businesses reporting $1,000,000 or less of gross receipts or sales, which would authorize FDA to grant a waiver of the registration fee (excluding first time registering establishments), beginning on October 1, 2024, to establishments proving "financial hardship". FDA will estimate the volume of establishments who may qualify for the fee waiver to prepare FY25 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.

- **Section 736(f)(3) (amended by section 905(b) of FDARA):** FDA cannot use user fees on certain previously allowable expenses. Section 738(g)(3) of the FD&C Act provides that "beginning on October 1, 2023, the authorities under section 737(10)(C) shall include only 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. This change will have an impact on the finances of the program. FDA is monitoring the impacts to the program's funding.

In addition to these mitigation strategies, FDA continues to implement the Integrated Budget and Acquisition Planning System (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.

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.

Included 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, where 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.

Included Activities	
Section 737(9)(F) – The development of guidance, 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, submissions, or requests 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.

Included Activities	
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. 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:

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[4]; and 4. Collecting user fees and accounting for resources allocated for the review of premarket applications, premarket reports, supplements, and submissions.

[4] As of October 1, 2023, this will include only "leasing and necessary scientific equipment."

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

Note 1. Inflation Adjustment

The 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 it is compounded yearly.

Note 2. Total Revenue Methodology

The estimated user fee net collections are based on the inflation adjusted total revenue amount plus or minus adjustments (i.e., performance improvement, hiring and operating reserve adjustments).

Note 3. Recoveries

Recoveries are estimated to be $1,619,483 annually for the purposes of this plan. 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 4. 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 5. 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. The amount of rent each FDA Center pays is directly related to the square footage occupied by that Center.

Also included in this account are recurring costs that FDA pays to non-federal sources under the delegation of direct lease and service authority. These services include 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 Center pays is directly related to the square footage occupied by that Center.

Section 905(b) of the FDA Reauthorization Act of 2017 (FDARA) provided that the statutory definitions pertaining to allowable costs for the user fee programs would change on 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 6. Shared Services Costs

FDA has several shared service organizations, located within the WCF, that provide support across the user fee programs. The shared service organizations in FY 2023 include:

- **FDA Central**: Provides for Center-wide and Agency-wide services such as telecommunications, training, printing, mail and document management, IT systems, employee health units, and other support and miscellaneous services.
- **Office of Digital Transformation**: Provides the vision and leadership in IT, data, and cybersecurity needed to advance FDA's mission and strategic priorities.
- **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.
- **Division of Budget Execution and Control:** Initiates, monitors, and analyzes FDA budget resources.
- **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 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 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 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 the FDA to hire a talented and qualified workforce.
- **Office of Planning, Evaluation, and Risk Management:** Partners with FDA leaders to achieve organizational excellence by improving program performance, governance, operational efficiency, and risk management.

Note 7. Unearned Fee Revenue

Unearned fees 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 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. The total unearned revenue as of September 30, 2022, was $53,933,164.

Note 8. 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 4** outlines the excess user fees by fiscal year.

Table 4: Medical Device User Fees Collected, Collection Amounts Specified in Appropriations Acts, and Excess Amounts (Excluding Unearned Revenue) as of September 30, 2022

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	$4,415,601
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	**$26,680,242**

Numbers have been rounded to the nearest dollar.

Note 9. 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 one month of operating reserves for the first month of the next fiscal year.

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