FY 2021

FINANCIAL REPORT
TO CONGRESS

for the

Medical Device User Fee Amendments of 2017

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Executive Summary

The Medical Device User Fee Amendments of 2017 (MDUFA) requires the Food and Drug Administration (FDA) to report annually on the financial aspects of MDUFA implementation. This is the fourth report under the fourth authorization of MDUFA (MDUFA IV) and covers fiscal year (FY) 2021.

MDUFA specifies that the following three legal conditions must be satisfied each year for FDA to collect and spend MDUFA user fees:

1. Within FDA's Salaries and Expenses Appropriation, the amount appropriated for devices and radiological health, excluding fees, each fiscal year must be more than 1 percent less than $320,825,000, multiplied by an adjustment factor specified in the statute.

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

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

Section 704(g)(10) of the Federal Food, Drug, and Cosmetic Act also contains a provision that FDA must spend at least as much on medical device establishment inspections as it spent in FY 2002, increased by 5 percent each fiscal year. If FDA does not satisfy this condition for 2 consecutive years, FDA is prohibited from allowing accredited third parties to conduct certain medical device establishment inspections.

FDA met the three legal conditions in FY 2021, and this report explains how these legal conditions were satisfied. The statements and tables in the report provide data on medical device user fee collections, expenditures, and carryover, as well as comparative data from prior years. FDA also fulfilled the provision regarding spending on medical device inspections, which enables FDA to continue with the third-party inspection program.

In FY 2021, FDA had net collections of $269 million in medical device user fees, spent $250 million in user fees for the device review process, and carried $323 million forward for future fiscal years.

MDUFA IV user fees and non-user fee appropriations in FY 2021 supported 1,620 full-time equivalents, including salaries and operational expenses, to support the review of device applications. Detailed program accomplishments can be found in the FY 2021 MDUFA Performance Report.

Report Overview

A. Scope

This financial report addresses the implementation and use of medical device user fees by the Food and Drug Administration (FDA or Agency) during the period of October 1, 2020, through September 30, 2021. It presents the legal conditions that FDA must satisfy to collect and spend medical device user fees each year and documents how FDA determined that it met those requirements. It also presents information on the spending level for medical device inspections that must be satisfied for FDA to continue the third-party inspection program and documents how FDA determined that it met that requirement. In addition, this report presents summary statements of fiscal year (FY) 2021 fee collections, carryover, obligations of user fees, and total costs of the process for the review of device applications from both Medical Device User Fee Amendments (MDUFA) fees and non-user fee appropriations.

B. Report Requirements

In accordance with section 738A(a)(4) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), for FY 2018 through FY 2022, FDA will publish an annual financial report on the implementation of the authority for user fees during each fiscal year and the use by FDA of the fees collected for such fiscal year. The purpose of this report is to meet these requirements.

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

Management Discussion

C. Agency Background

FDA is responsible for protecting the public's health by helping to ensure the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation. FDA also has responsibility for regulating the manufacturing, marketing, and distribution of tobacco products and advancing the public's health. FDA not only helps speed innovations that make medical products more effective and safe 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 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	Regulates medical devices related to licensed blood and cellular products.
ORA	Protects consumers and enhances the public's health by maximizing compliance of FDA-regulated products and minimizing the risk associated with those products.
HQ	Provides FDA-wide program direction and administrative services to ensure FDA's consumer and patient safety programs are effectively and efficiently managed.

User Fee Governance

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

FDA leverages the User Fee Financial Management Committee (UFFMC) for user fee governance. The UFFMC consists of senior financial, business operations, and program experts across the Agency that evaluate user fee resource needs, develop financial allocation plans, and forecast resource requirements – both programmatic and administrative – to support user fee financial decisions. The UFFMC is responsible for providing oversight and support of appropriate standards and policies to ensure FDA's compliance with sound financial management practices, as well as FDA's compliance with statutory provisions that authorize FDA to collect and spend user fees. The UFFMC receives policy guidance and strategic direction directly from FDA's Executive Committee relative to how the Agency will forecast and react to industry trends, plan and manage its research agenda in support of the user fee programs, and forecast its user fee workload. The UFFMC advises the Executive Committee and other Center- and Office-level bodies on a variety of financial and performance-related topics.

D. User Fee Background and Structure

The FD&C Act, as amended by MDUFA, authorizes FDA to collect fees from industry to supplement non-user fee appropriations that the Agency spends on the process for the review of device applications. The FDA Reauthorization Act of 2017 includes the third reauthorization of MDUFA, also known as MDUFA IV, which extends the program from October 1, 2017, through September 30, 2022. This 5-year reauthorization ensures continued funding for FDA from FY 2018 through FY 2022 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 2022. Fees for other application types and for periodic reports are fixed by statute as a percentage of the PMA fee for each year.

MDUFA IV 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 IV's fee structure.

Exhibit 2: MDUFA IV 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.
	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.
	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.
	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.
	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.
	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.
	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.
	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).

Fee Type		Definition
	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 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, typically at the beginning of August.[A]

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

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

E. Legal Conditions

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

[A] See https://www.federalregister.gov/documents/2020/08/03/2020-16793/medical-device-user-fee-rates-for-fiscal-year-2021.

Exhibit 3: MDUFA Legal Conditions

Legal Condition #	Details	
1	Description	Within FDA's Salaries and Expenses Appropriation, the amount appropriated for devices and radiological health, excluding fees, each fiscal year must be more than 1 percent less than $320,825,000, multiplied by an adjustment factor specified in the statute.
	Condition Was Met	In FY 2021, the final appropriation for the Device and Radiological Health line of FDA's Salaries and Expenses Appropriation (excluding user fees) was $408,108,000. Therefore, the first legal condition was satisfied.
2	Description	The fee amounts FDA may collect for each fiscal year must be specified in that year's user fee appropriation acts.
	Condition Was Met	The Consolidated Appropriations Act, 2021 (Public Law 116-260), which the President signed on December 27, 2020, made appropriations through September 30, 2021, for the salaries and expenses account of FDA. This act specified that $236,059,000 shall be derived from medical device user fees and that medical device user fees collected in excess of this amount are also appropriated for FDA. Therefore, the second legal condition was satisfied.
3	Description	The third condition requires a minimum spending from appropriations, excluding user fees, on the MDUFA program. The minimum spending from appropriations is the amount that FDA spent on the MDUFA program in FY 2009, multiplied by the adjustment factor.
	Condition Was Met	That specified minimum level for FY 2021 is $237,987,861 (rounded to the nearest thousand dollars). In FY 2021, FDA spent $269,569,602 from appropriations (exclusive of user fees) on the process for the review of device applications. Because FDA spent more than the specified minimum amount from appropriations in FY 2021, the third legal condition was satisfied.

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

Section 704(g)(10) of the FD&C Act also provides that FDA's obligations for medical device establishment inspections must be equal to or greater than the amount spent in FY 2002, increased by 5 percent each fiscal year. If this condition is not met for 2 consecutive years, FDA is not allowed to use accredited third parties to conduct certain medical device establishment inspections in future years.

That specified minimum level for FY 2021 is $49,086,008. In FY 2021, FDA obligated $47,584,759 from appropriations (exclusive of user fees) for medical device inspections. Therefore, FDA's spending on medical device establishment inspections did not meet the specified minimum level. As a result of the ongoing public health emergency, FDA began FY 2021 with ongoing travel restrictions and other uncertainties that were continuing to impact the Agency's oversight operations. FDA is continuing to complete its mission-critical work, prioritize higher-tiered inspectional needs (e.g., for-cause inspections), and carry out surveillance inspections using risk-based approaches for evaluating the public health impact. As described in the FY 2020 MDUFA Financial Report, FDA's spending on medical device establishment inspections exceeded the specified minimum level for FY 2020. Therefore, FDA may continue to permit accredited third parties to conduct certain medical device establishment inspections in future years. However, in accordance with section 704(g)(10) of the FD&C Act, if the medical device establishment inspection spending trigger is not met for 2 consecutive fiscal years, third-party inspections cannot be conducted in the next fiscal year.

Financial Information

This section provides an overview of the program financials for MDUFA for FY 2020 and FY 2021. These financials include user fee revenues, obligations, carryover, non-user fee appropriations, and full-time equivalents (FTEs).

F. User Fee Financials

Table 1 represents a summary of the MDUFA User Fee financial position for FY 2020 and FY 2021. The financial notes referenced in this table can be found in **Appendix D**.

Table 1: Medical Device Collections, Obligations, and Carryover for Fiscal Years 2020 and 2021

Budgetary Resources	Notes	FY 2020	FY 2021
Target Revenue	Note 1	**$220,142,000**	**$236,059,000**
Total Carryover, Beginning of Year		$206,320,319	$299,060,981
Net Collections[B]		$295,402,430	$268,753,004
Recoveries	Note 2	$1,803,465	$3,748,055
Total Budgetary Resources		**$503,526,214**	**$571,562,040**

Obligations	Notes	FY 2020	FY 2021
Total Payroll and Operating	Note 3	$170,074,845	$212,859,689
Total Rent	Note 4	$11,388,136	$12,768,317
Total Shared Services[C]	Note 5	$23,002,253	$24,271,738
Total Obligations		**$204,465,234**	**$249,899,743**

Carryover	Notes	FY 2020	FY 2021
Total Carryover, End of Year [D, E]		**$299,060,981**	**$322,958,046**

Target Revenue has been rounded to the nearest thousand dollars.

Budgetary Resources: The budgetary resources component of **Table 1** illustrates the sum of the total user fee funding (i.e., the existing total carryover and additional user fee collections). The target revenue is the inflation-adjusted total revenue amount calculated when fees for the fiscal year are set. Net collections are the actual amount collected including refunds during the fiscal year.

MDUFA specifies how the fees must be calculated each fiscal year, including annual adjustments to the base fees and the total revenue that must be made for inflation. After the applicable inflation adjustment to fees is done, FDA may increase the base fee amounts on a uniform proportionate basis if

[B] For FY 2021, this included $11.19M of unearned revenue. See **Note 7**.
[C] This includes payroll and operating for the Working Capital Fund's FTE.
[D] For FY 2021, this included $47.2M of unearned revenue and $26.7M of unappropriated amounts. See **Table 6**, **Note 7**, and **Note 8**.
[E] For FY 2021, there was a one-time Journal Voucher adjustment required to correct a historical misalignment of Budgetary Resource and Cash Account Balances.

necessary to achieve the inflation-adjusted total revenue amount. See section 738(c)(2)(D)(ii) of the FD&C Act. If necessary after this adjustment, FDA may further increase the base establishment registration fees to generate the inflation-adjusted total revenue amount (see section 738(c)(3) of the FD&C Act). If submissions or registrations are higher than estimated, collections may exceed the inflation-adjusted total revenue amount in a given fiscal year. FDA has applied the adjustments to calculate the target revenue for annual fee setting. See **Table 2**.

Obligations: The obligations component of **Table 1** shows the expenditure of MDUFA fee funds broken out into major expense categories.

MDUFA fees may be expended only for costs to support the "process for the review of device applications," as specified in the statute. See sections 737(9) and 737(10) of the FD&C Act.

Carryover: MDUFA fees that are collected, earned, appropriated, and not obligated at the end of a fiscal year remain available to FDA for use in future fiscal years. In this report, such fee funds, plus certain user fee funds that FDA has collected that are considered unappropriated or otherwise subject to restrictions, are referred to as the "total carryover" or the "MDUFA carryover." Maintaining an appropriate level of carryover enables FDA to mitigate financial risks to the program, including, for example, the risk of under-collecting fee amounts and the risk of a lapse in appropriations so that FDA can continue performing activities related to the process for the review of device applications under such financial constraints.

G. User Fee Revenue

Table 2 outlines the target revenue amounts for FY 2020 and FY 2021. The financial notes referenced in this table can be found in **Appendix D**.

Table 2: Medical Device Revenue and Collections Statement for Fiscal Years 2020 and 2021

Target Revenue	Notes	FY 2020	FY 2021
Total Revenue Amount		$200,132,014	$211,748,789
Inflation Adjustment	Note 6	$20,010,199	$24,310,455
Target Revenue Total		**$220,142,000**	**$236,059,000**

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

The process for setting the annual target revenue is defined in the statute. The initial amount for FY 2021 (i.e., the "total revenue amount") is specified in the statute. Each year's total revenue amount is to be adjusted for inflation. Please refer to the respective Notes referenced in the table above for more details.

MDUFA specifies that user fees shall be collected for certain medical device application submissions (which include periodic reports) and that annual user fees shall be collected for establishment registrations. In addition, the statute directs FDA to set the fee rate for each application type and for periodic reports as a percentage of the standard fee for a PMA. These base fee amounts for each application type are adjusted for inflation and then, if necessary, further increased and rounded to the nearest thousand dollars to generate the target revenue total. User fee collections are recognized and reported in the year that the fee was originally due (referred to as the "cohort year"). Totals reported for each fiscal year are net of any refunds for the cohort year. To ensure the quality of the information provided in this financial report, FDA annually updates the prior year's numbers.

Cohort Year

The year in which user fee collections are originally due and reported. For example, a fee originally due in FY 2021 but received in FY 2022 is attributed to FY 2021's collections.

Under MDUFA, fees collected, earned, and appropriated but not spent by the end of the fiscal year continue to remain available for FDA to spend in future years, as they are classified as "no-year funding." The funds carried over from year to year are described in **Section I – User Fee Carryover**. Unearned fees are fees received by September 30, 2021, either for applications that had not been submitted to FDA as of September 30, 2021, or for establishment fees received without identification of the remitter.

Decrease in Collections

The primary factor in the decrease in collections from FY 2020 to FY 2021 was the decrease in the number of registration fees received by the Agency.

User fee collections were composed of collections from medical device application submissions and annual establishment registration user fees under MDUFA IV. **Table 3** outlines MDUFA collections by fee source and cohort year. Unearned fees are a subset of total collections. Fees receivable is the balance of money due that has not yet been collected as of September 30, 2021.

Table 3: Medical Device User Fee Collections by Fee Source for Cohort Years 2020 and 2021

Fees Collected	Cohort Year 2020			Cohort Year 2021		
	Estimated†	Actual	% Dif.	Estimated†	Actual	% Dif.
Application Fees	$80,749,538	$74,531,229	-8%	$84,527,617	$81,896,418	-3%
Registration Fees	$140,853,636	$222,431,704	58%	$152,315,344	$191,515,007	26%
Total Collections	**$221,603,174**	**$296,962,933**	**34%**	**$236,842,961**	**$273,411,425**	**15%**

Unearned Fees	Actual 2020	Actual 2021
Application Fees	$3,403,451	$7,070,390
Registration Fees	$3,167,680	$4,120,490
Total Unearned Fees	**$6,571,131**	**$11,190,880**

Fees Receivable	Actual 2020	Actual 2021
Application Fees	$1,833,301	$2,175,169
Registration Fees	$163,372	$372,208
Total Receivables	**$1,996,673**	**$2,547,377**

Numbers have been rounded to the nearest dollar.
†Estimated values were taken from the Medical Device User Fee Rates for FY 2020 and FY 2021.

H. Total MDUFA Program Costs

The MDUFA program is supported by both user fees and non-user fee appropriations. MDUFA fees may be expended only for costs necessary to support the "process for the review of device applications," as specified in the statute. For more information on the allowable and excluded costs. See **Appendix A**. In addition, FDA calculates the total MDUFA program costs based on what is allowable under "the process for the review of device applications."

For historical context, **Table 4** provides the total amounts (from user fees and non-user fee appropriations) spent by FDA and by each FDA organization on the MDUFA program for the past 5 fiscal years. As illustrated by the table, costs have increased over time, but the percentage spent by each FDA organization has remained steady.

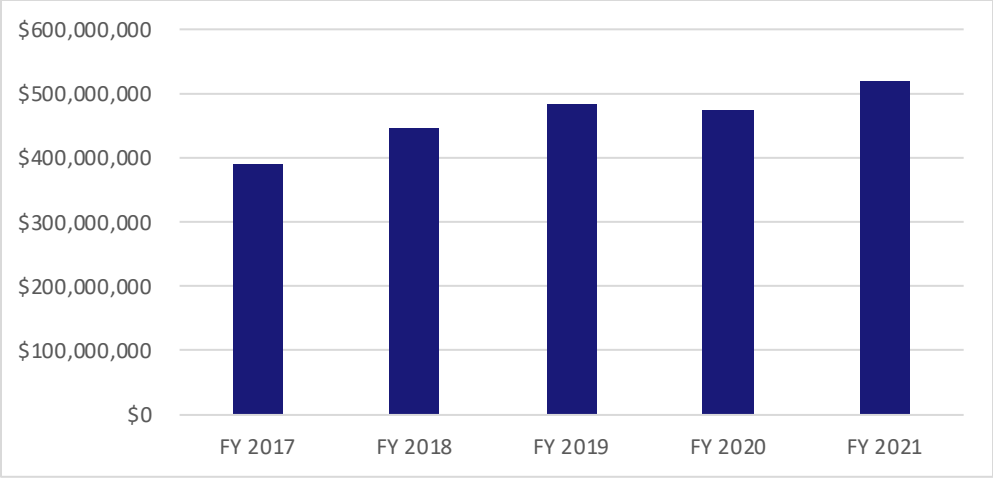
Table 4: MDUFA Program – Historical Trend of Total Costs by Organization as of September 30 Fiscal Year

Costs		FY 2017	FY 2018	FY 2019	FY 2020	FY 2021
Total Spent		**$390,220,744**	**$445,840,984**	**$483,338,372**	**$471,643,425**	**$519,469,345**
CBER	Spent	$36,983,291	$47,516,423	$49,038,852	$52,009,143	$42,036,545
	Percent	9%	11%	10%	11%	8%
CDRH	Spent	$303,699,059	$345,841,190	$385,201,127	$377,702,623	$431,620,290
	Percent	78%	78%	80%	80%	83%
ORA	Spent	$16,209,003	$13,842,148	$10,829,248	$11,036,341	$10,093,225
	Percent	4%	3%	2%	2%	2%
HQ	Spent	$33,329,390	$38,641,223	$38,269,145	$30,895,317	$35,719,285
	Percent	9%	9%	8%	7%	7%

Numbers have been rounded to the nearest dollar.

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

Exhibit 4: Historical MDUFA Program Obligations for Fiscal Year



As demonstrated by this exhibit, the MDUFA program's costs in FY 2021 increased from FY 2020 and previous year's levels. This increase was primarily due to an increase in the MDUFA process work and in FDA's hiring to support those activities. In FY 2021, the MDUFA program obligated funds to support the hiring of FTEs and the meeting of MDUFA IV's commitments, such as improving the premarket process, developing infrastructure, and enhancing scientific and regulatory review. Specifically, resources were used to support the following key areas:

- Digital health
- Independent assessments
- Infrastructure
    - Quality management
    - Scientific and regulatory review capacity (recruitment and retention)
    - Information technology (IT) infrastructure for submission management
    - Training
    - Time reporting
- Patient engagement and the science of patient input
- Real-world evidence
- Standards
- Third-party review

Details of these areas can be found in the 2021 MDUFA Performance Report to Congress.

Focusing specifically on the user fee component of total MDUFA program costs, **Table 5** provides a comparison breakout of user fee obligations by expense category during the past 2 fiscal years. The financial notes can be found in **Appendix D**.

Table 5: Medical Device User Fee Obligations by Expense Category for Fiscal Years 2020 and 2021

User Fee Obligations	Notes	FY 2020	FY 2021
Payroll & Operating	Note 3		
CDRH		$149,591,477	$191,912,710
CBER		$11,006,994	$10,844,490
ORA		$2,124,606	$1,626,083
HQ		$7,351,768	$8,476,406
Total Rent	Note 4	$11,388,136	$12,768,317
Total Shared Services[D]	Note 5	$23,002,253	$24,271,738
Total Obligations		**$204,465,234**	**$249,899,743**

Numbers have been rounded to the nearest dollar.

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

- **Payroll and Operating:** These obligations provide for payroll and operating costs that support the allowable activities for which MDUFA fees may be expended, as set forth in the statute. Such payroll and operating activities include, for example, core regulatory review functions, pre-approval inspections, guidance and policy development activities, scientific activities, and management and administrative functions that support the MDUFA program.

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

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

I. User Fee Carryover

MDUFA fees collected, earned, appropriated, and not obligated at the end of the fiscal year remain available to support the MDUFA program in future fiscal years. Such fee funds, plus certain user fee funds that FDA has collected that are considered unappropriated or otherwise subject to restrictions, are referred to in this report as the "total carryover" or "MDUFA carryover."

Maintaining an appropriate level of carryover enables FDA to mitigate financial risks to the program, including, for example, the risk of under-collecting fee amounts and the risk of a lapse in appropriations.

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

Table 6 provides MDUFA carryover at the end of FY 2020 and FY 2021. The financial notes can be found in **Appendix D**.

Table 6: MDUFA Carryover by Fiscal Year

Carryover	Notes	FY 2020	FY 2021
Total Carryover, End of Year		**$299,060,981**	**$322,958,046**
Unappropriated Amounts	Note 8	($26,680,243)	($26,680,243)
Unearned Fee Revenue	Note 7	($41,136,132)	($47,151,094)
Future Year Refunds Allowance, Set Aside		$0	($1,452,407)
One-Month Reserve	Note 9	($19,671,583)	($20,289,417)
Carryover Net of Unavailable and Set Aside, End of Year		**$211,573,023**	**$227,384,886**

Numbers have been rounded to the nearest dollar.

These terms are defined below:

- **Total Carryover, End of Year**: This is the total amount of unobligated fee funds at the end of the fiscal year.
- **Unappropriated Amounts:** FDA's MDUFA carryover includes $26,680,243 in fee collections that are considered unappropriated and therefore currently unavailable for obligation. This amount is the cumulative total of fee collections that exceeded the annual level of MDUFA fees appropriated for a given year, prior to a technical fix that was added to the appropriations language to ensure that all fee collections would be considered appropriated. See **Note 8** for additional details.
- **Unearned Fee Revenue:** Unearned fees are fees received by September 30, 2021, for applications that had not been submitted to FDA as of September 30, 2021, or for establishment fees received without identification of the remitter.
- **Future Year Refunds Allowance, Set Aside:** FDA maintains a small amount to provide for any refunds as a matter of prudent operations. For that purpose, a total of $1,452,407 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 2019 – 2021.
- **One-Month Reserve:** FDA may use unobligated carryover from fees collected in previous fiscal years to ensure that sufficient fee revenues are available in that fiscal year, so long as FDA maintains unobligated carryover of not less than 1 month of operating reserves for the first month of the next fiscal year.
- **Carryover Net of Unavailable and Set Aside, End of Year:** This is the total carryover less any carryover funds subject to set asides, or subject to any restrictions that currently preclude FDA from obligating the carryover funds.

The operations in FY 2021 resulted in a net increase of the total carryover of $23,897,065 from $299,060,981 at the end of FY 2020 to $322,958,046 at the end of FY 2021. While excess collections in FY 2021 decreased relative to FY 2020 levels, the FY 2021 excess collections continue to be attributed to an increase in the number of new establishment registrations, which has led to the higher collection amounts. The increase is due to the registration of new establishments with FDA that are engaged in the manufacture, preparation, propagation, compounding, or processing of COVID-19-related devices.

FDA has plans to allocate carryover funds toward meeting MDUFA IV commitments. This includes retaining highly qualified staff and supporting the premarket review process.

Table 7 reflects the historical amount of fees collected and the amount obligated during the previous and current reauthorization periods.

Table 7: Historical Medical Device User Fee Collections, Obligations, and Carryover by Reauthorization Period

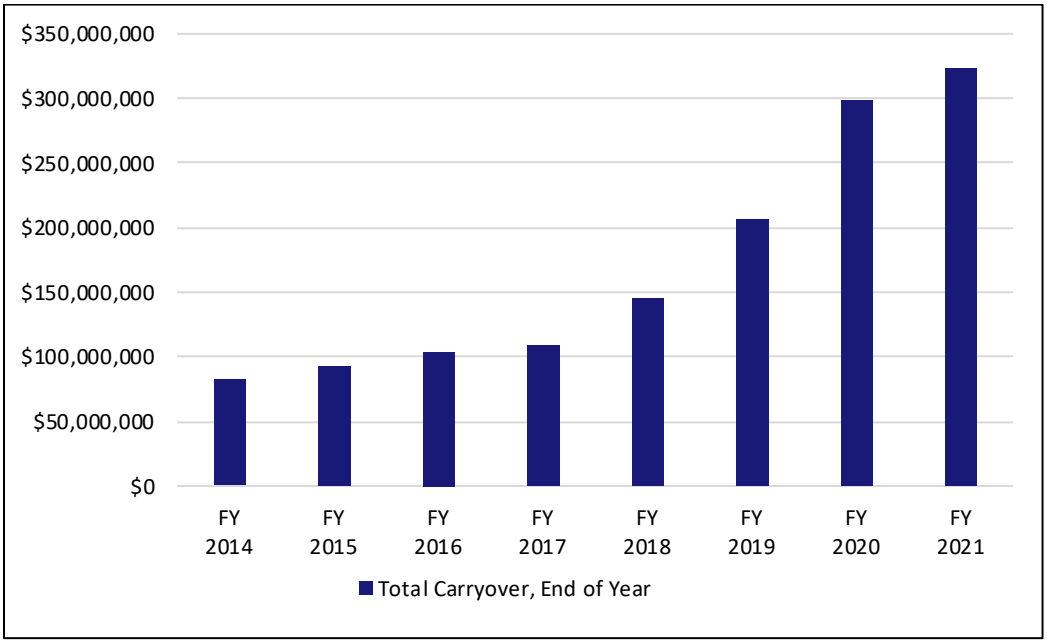
Carryover	Notes	MDUFA I	MDUFA II	MDUFA III	MDUFA IV			
		FYs 03 07	FYs 08 12	FYs 13 17	FY18	FY19	FY20	FY21
Total Carryover, Beginning of Year		**$0**	**$10,862,872**	**$53,216,730**	**$109,444,020**	**$144,236,120**	**$206,320,319**	**$299,060,981**
Net Collections		$144,018,382	$312,851,252	$658,306,967	$198,839,963	$208,098,889	$295,402,430	$268,753,004
Recoveries	Note 2	$0	$0	$540,100	$1,327,551	$1,166,897	$1,803,465	$3,748,055
Total Obligations		($133,155,510)	($270,497,394)	($602,619,777)	($165,375,415)	($147,181,587)	($204,465,234)	($249,899,743)
Total Carryover, End of Year[F]		**$10,862,872**	**$53,216,730**	**$109,444,020**	**$144,236,120**	**$206,320,319**	**$299,060,981**	**$322,958,046**

Numbers have been rounded to the nearest dollar.

[F] For FY 2021, there was a one-time Journal Voucher adjustment required to correct a historical misalignment of Budgetary Resource and Cash Account Balances.

Exhibit 5 provides a historical perspective of carryover for the last five fiscal years. The MDUFA carryover has historically included a larger proportion of funds considered unavailable for obligation due to the high levels of unearned fee revenue (**Note 7**).

Exhibit 5: Historical Carryover by Fiscal Year



J. Non-User Fee Appropriations Spent on MDUFA Program

For FDA to obligate user fees collected under MDUFA, a certain amount of non-user fee appropriations must be spent on the process for the review of device applications during that fiscal year. This amount is often referred to as a "non-user fee budget authority spending trigger." The spending trigger was $233,862,549 for FY 2020 and $237,987,861 for FY 2021.

The non-user fee budget authority (BA) spending trigger amount is determined by multiplying the amount spent from appropriations exclusive of user fees on the medical device review process in FY 2009 ($223,545,692) times the adjustment factor applicable to the fiscal year. See **Note 10** for more details on the adjustment factor.

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

Table 8: Historical Trend of MDUFA Program Costs by Funding Source as of September 30 for Fiscal Year 2017 to 2021

Obligations		FY 2017	FY 2018	FY 2019	FY 2020	FY 2021
Total Obligated		**$390,220,744**	**$445,840,984**	**$483,338,372**	**$471,643,425**	**$519,469,345**
Non-User Fee Appropriations	Total	$256,368,118	$280,465,569	$336,156,785	$267,178,191	$269,569,602
	Percent	66%	63%	70%	57%	52%
User Fee Revenue	Total	$133,852,626	$165,375,415	$147,181,587	$204,465,234	$249,899,743
	Percent	34%	37%	30%	43%	48%

Numbers have been rounded to the nearest dollar.

K. Full-Time Equivalents

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

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

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

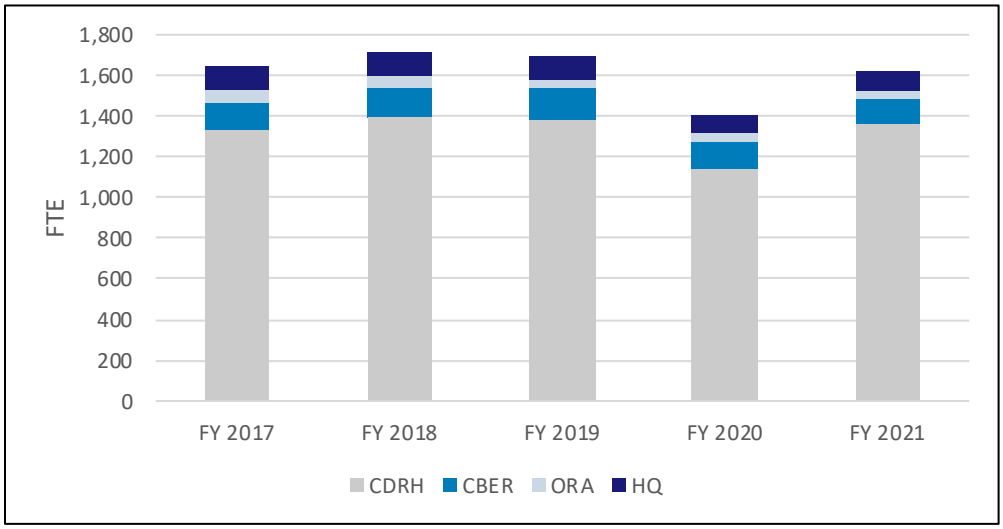
Table 9: Historical Trend of Medical Device User Fee Total Process FTEs Utilized by Organizations as of September 30 Fiscal Year 2016 to 2021

Organization	FY 2017	FY 2018	FY 2019	FY 2020	FY 2021
CDRH	1,330	1,386	1,381	1,136	1,365
CBER	130	155	153	137	124
ORA	70	56	43	40	40
HQ	116	114	115	86	90
Total	**1,646**	**1,711**	**1,692**	**1,399**	**1,620**

Numbers have been rounded to the nearest whole number

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

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



As demonstrated by this graph, MDUFA Process FTEs increased in FY 2021. This increase was primarily attributed to increased hiring, which provided more resources to support MDUFA process activities.

Management Assurance

L. Internal Controls

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

1. Effective and efficient operations,
2. Reliable reporting, and
3. Compliance with applicable laws and regulations.

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

In alignment with FMFIA, OMB A-123, OMB A-11, the Green Book, and HHS guidelines, FDA established an Enterprise Risk Management (ERM) Program, with an ERM Council as the governance body responsible for providing overall oversight and accountability. The Council's purview includes deciding

on and managing the Agency's Enterprise Risk Profile and ensuring integration with FDA's FMFIA, budget formulation, and strategic planning activities. The ERM Council has senior executive representatives from each FDA Center and Office, and is chaired by the Chief Operating Officer, with a Center Director as Co-Chair and Chief Financial Officer (CFO) as President Pro Tempore. FDA's ERM Program supports the Council in managing the Agency's Enterprise Risk Profile, facilitates risk response planning, collaborates with Center and Office senior leaders and staff in conducting a range of analyses to manage risks, and provides communications and training opportunities that promote a risk-informed culture.

Additionally, FDA has an established Senior Assessment Team (SAT) to act as the governance body responsible for providing oversight and accountability for FDA's internal control over reporting, including overseeing the FMFIA and OMB A-123 assessments, and for fostering an environment that promotes strong internal control. The SAT is chaired by FDA's CFO and co-chaired by the Deputy CFO and Director of the Office of Financial Management, as well as a Program Co-Chair who is a Center Deputy Executive Officer appointed by the CFO. The SAT members are representatives from each FDA Center and Office.

FDA's internal control program includes integrated management controls covering the OMB A-123 appendices. Specifically, reporting controls are implemented in accordance with Appendix A, Management of Reporting and Data Integrity Risk; charge card controls are implemented in accordance with Appendix B, A Risk Management Framework for Government Charge Card Programs; controls over financial disbursements are implemented in accordance with Appendix C, Requirements for Payment Integrity Improvement; and financial system controls are implemented in accordance with Appendix D, Compliance with the Federal Financial Management Improvement Act of 1996. FDA's reimbursable activity cycle memo is specifically focused on the reporting controls related to the accounts receivable and payment processes associated with the user fee programs. This cycle memo describes the processes and controls performed by FDA to monitor the user fee cash receipts process and includes controls over reconciliation performance, aging, write-offs, and the interface between the User Fee System (UFS) and the Unified Financial Management System.

In FY 2021, FDA's annual assessment of internal controls included tests of 80 business, charge card, and IT controls across 18 transaction sub-cycles to identify recommendations to strengthen internal controls and compliance. This assessment included 27 IT controls related to the UFS. Annually, FDA conducts an improper payments risk assessment and performs improper payment testing. In March 2021, FDA completed this testing, which involved 100 payments related to user fee funding, including payments for vendors (64), purchase cards (16), grants (14), and travel (6). Any deficiencies identified during FDA's internal control testing are tracked under a Continuous Monitoring Program to facilitate timely remediation. UFS is compliant with HHS guidelines and with OMB Circular A-123 Appendix D, Compliance with the Federal Financial Management Improvement Act of 1996. FDA's Integrated Budget and Acquisition Planning System (IBAPS) not only is used to support FDA's budget formulation, budget execution, acquisition planning, and payroll planning but also meets FDA's and HHS's system requirements.

FDA has also implemented other internal control procedures, including the performance of Organizational Risk Reviews, which are reviews of targeted financial and non-financial management processes to identify potential recommendations to enhance internal controls. Also, FDA maintains a Continuous Monitoring Program to oversee the timely implementation of corrective action plans for any deficiencies identified through any of its control assessments.

As a component of HHS, FDA's financial data is presented in HHS's consolidated financial statements. The FY 2021 HHS audit found that FDA's financial statements fairly present, in all material respects, the consolidated financial position of HHS as of September 30, 2021, and 2020, and related notes are in accordance with generally accepted accounting principles in the United States. Further, FDA's FY 2021 Assurance Statement found no material weaknesses or financial system nonconformances.

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 assume what the Agency's total appropriation will be in any given year. As a result, FDA has some risk of missing important performance goals, or failing to meet the non-user fee BA 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 BA spending trigger requirements, and difficulties with hiring. To minimize this risk, FDA enhanced its planning and execution around the hiring of new staff and its contract actions in the fourth year of the reauthorization. Consequently, FDA reduced the percentage increase in carryover funds relative to previous years in MDUFA IV. By putting more emphasis on the initial planning of initiatives in the early years of the 5-year cycle, FDA experienced less variance than it has in the past in its planned allocations versus actual expenditures.

- **Uncertainty of Non-User Fee Appropriations Levels:** It is difficult to predict the amount of non-user fee appropriations that will be approved by Congress, which creates planning challenges as non-user fee fund levels are often uncertain for much of the fiscal year. With Continuing Resolutions (CR) becoming more prevalent, FDA has been required to spend at or slightly below levels from the prior authorized fiscal year during the CR period, thus limiting its ability to spend the non-user fee appropriations from the onset.

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

- **Under-Collecting and Over-Collecting Fees:** If FDA does not receive the estimated number of industry submissions, there may be an excess or deficit in targeted revenue. When FDA under-collects user fees, it leverages its carryover to maintain continuity in operations. When FDA over-collects, the carryover may increase without additional planned expenditures being identified to obligate those funds towards. The changes in the fee structure, minimization of clean-up billing, and the operating reserve are meant to mitigate these risks in MDUFA IV. In addition, 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.

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

Strategic Challenges

FDA has committed to improving its hiring and retention of scientific staff, as described in the MDUFA IV commitment letter. As initiatives associated with these commitments span the course of MDUFA IV, FDA continues to strive to hire and retain experienced scientific staff. However, FDA has also encountered several challenges regarding interest, salaries, and expertise that have contributed to the difficulty in attracting and recruiting qualified staff. For example, competition with well-known tech innovation locations, the creation of new scientific and technical professional fields, and fewer candidates with a hybrid of specialties have resulted in hiring delays for the MDUFA program. In spite of these challenges, hiring is a key priority, and FDA remains focused on the recruitment and retention of skilled staff.

In addition, FDA will continue to prioritize COVID-19-related work in order to address the ongoing public health need for safe and effective medical devices. As the COVID-19 pandemic continues to evolve, the volume of new emergency use authorization submissions for COVID-19-related products should begin to lessen in non-in vitro diagnostic product (IVD) offices. This reduction will allow FDA to begin refocusing review resources to MDUFA-related activities, bringing review performance back to "pre-COVID" levels for non-IVD offices. The increased hiring in FY 2021 has and will continue to allow FDA to increase resources to support MDUFA activities, leading to an increase in MDUFA process costs. Details related to MDUFA performance can be found in the 2021 MDUFA Performance Report to Congress.

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. Traditional and priority review 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 meetings or 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; and 15. Recruitment of review staff.
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.	This includes activities such as 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.	This would include activities such as 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, and submissions.	For the types of applications identified above, this would include monitoring activities such as 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).

Included Activities	
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).	This would include 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, policy documents, or regulations to improve the process for the review of premarket applications, premarket reports, supplements, and premarket notification submissions.	This would include activities such as 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 would include national and international standards development and coordination related to the review of premarket applications.
Section 737(9)(H) - The provision of technical assistance to device manufacturers in connection with the submission of such applications, reports, supplements, or submissions.	This would include activities such as 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, 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.	This would include activities such as De Novo classification requests, the review of requests for information submitted under section 513(g), and the "call" for PMAs for pre-amendment 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 section 351 of the PHS Act.	This would include activities such as the review of 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, or premarket notification submissions.	This would include activities such as the following: 1. Epidemiology studies; and 2. Post-marketing problem identification/resolution, including reports filed under the Medical Device Report regulation.

Included Activities	
Training related to premarket and post-market activities related to the process for the review of device applications.	This would include the following types of training: 1. Scientific, clinical, and statistical training; 2. Managerial or other administrative training; 3. Policy/regulatory training; 4. Professional development (coursework, attendance at professional meetings, library resources); 5. "Vendor Days"; and 6. Site Visit Program for premarket reviewers.
Other user fee performance enhancements related to the process for the review of device applications.	1. Quality management; 2. Patient engagement and the science of patient input; 3. Emerging diagnostics; 4. Real-world evidence; 5. Digital health; 6. Total product life cycle; and 7. Independent assessment.
User Fee Act implementation.	This would include activities such as the following: 1. Guidance/regulation development; 2. Stakeholder outreach for educational and comment purposes; 3. Training of Agency staff; and 4. IT support for implementation.

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

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

The MDUFA program excludes costs related to the following:

Excluded Activities

1. Enforcement policy and regulation development;
2. Third-party inspection program;
3. Post-approval compliance actions and activities unrelated to PMA Conditions of Approval and investigations of safety and effectiveness issues for devices subject to FDA's regulation;
4. Post-approval activities relating to:
    - 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. User Fee Program History

The Medical Device User Fee and Modernization Act (MDUFMA) was a law passed by the United States Congress in 2002 that allowed FDA to collect fees from medical device manufacturers to fund the process for the review of device applications. The FD&C Act, as amended by subsequent user fee amendments, authorizes FDA to collect fees from industry to supplement non-user fee appropriations spent on FDA's human medical device review process. FDA spends MDUFA fee revenues and non-user fee appropriations to hire, support, and maintain personnel for the review of medical device applications to help ensure that safe, effective, and high-quality medical devices are available to the American public.

MDUFMA was reauthorized in 2007 with the Medical Device User Fee Amendments to the FDA Amendments Act (MDUFA II), in 2012 with the Medical Device User Fee Amendments to the Food and Drug Administration Safety and Innovation Act (MDUFA III), and in 2017 with the Medical Device User Fee Amendments to the FDA Reauthorization Act of 2017 (MDUFA IV)) with the support of industry, stakeholders, Congress, and the Administration. Over time, MDUFA has been a success, creating a predictable, streamlined review process and dramatically reducing the average time to new medical device approval and clearance. MDUFA IV continues to support medical device development oversight and marketing application review for the human medical device regulatory program.

C. Conditions for Assessment and Use of Fees

Introduction

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

Adjustment Factor

To determine whether the legal conditions are satisfied, FDA must calculate and incorporate an adjustment factor (defined in section 737(11) of the FD&C Act) in the assessments of the first and third conditions. The FD&C Act states:

> The term "adjustment factor" applicable to a fiscal year is the Consumer Price Index for all urban consumers (all items; United States city average) for October of the preceding fiscal year divided by such Index for October 2016.

The Consumer Price Index (CPI) for October 2019, the October of the fiscal year preceding FY 2021, was 257.346. The CPI in October 2016 was 241.729. Dividing the CPI of October 2019 by 241.729 yields an adjustment factor of 1.064605 for FY 2021.

Legal Conditions

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

Exhibit 7: Legal Conditions

Legal Condition #	FD&C Act Section	Details
1	738(g)(1)	With respect to the amount that, under the salaries and expenses account of the Food and Drug Administration, is appropriated for a fiscal year for devices and radiological products, fees may not be assessed under subsection (a) for the fiscal year, and the Secretary is not expected to meet any performance goals identified for the fiscal year, if—(A) the amount so appropriated for the fiscal year, excluding the amount of fees appropriated for the fiscal year, is more than 1 percent less than $320,825,000 multiplied by the adjustment factor applicable to such fiscal year; or (B) fees were not assessed under subsection (a) for the previous fiscal year.
2	738(h)(2)(A)(i)	The fees authorized by this section—(i) subject to subparagraph (C), shall be collected and available in each fiscal year in an amount not to exceed the amount specified in appropriation Acts, or otherwise made available for obligation, for such fiscal year.
3	738(h)(2)(A)(ii)	The fees authorized by this section— (ii) shall be available to defray increases in the costs of the resources allocated for the process for the review of device applications (including increases in such costs for an additional number of full-time equivalent positions in HHS to be engaged in such process) over such costs, excluding costs paid from fees collected under this section, for fiscal year 2009 multiplied by the adjustment factor.

D. Financial Notes

Note 1. Target Revenue Methodology

The estimated user fee collections are based on the target revenue (i.e., inflation adjusted total revenue amount).

Note 2. Recoveries

Recoveries account for funds returned to the Agency in the form of de-obligations of prior year obligations. For example, recoveries could include funding from a contract that ended in a prior year and was not expended.

Note 3. Payroll and Operating Costs

Payroll and operating costs associated with the MDUFA program are based on obligations attributed to CDRH, CBER, ORA, and HQ. These costs relate to how much of the MDUFA revenue is going toward payroll and operating expenses.

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

Note 4. Rent Costs

GSA charges rent to FDA for the federal buildings that FDA occupies. This rent is charged at different rates depending on the type and location of the space provided. Since rent is an essential support cost for the process for the review of device applications, a portion of those charges is paid from non-user fee appropriations and a portion is paid from MDUFA fees. Also included in this account are recurring

costs that FDA pays directly to non-federal sources under the delegation of direct lease and service authority. These services include the rental of space and all recurring services for building operations such as overtime utilities, janitorial services, guards, and ground maintenance. The amount of rent and rent-related costs each FDA Center pays is directly related to the square footage occupied by that Center.

Note 5. Shared Services Costs

FDA contains several shared services organizations that provide support across the user fee programs. The shared services organizations include the following:

- **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.
- **Employee Resource & Information Center**: Provides support to all FDA employees requesting administrative, IT, facilities, human resources, and other employee services.
- **Office of Acquisitions and Grants Services**: Manages contracts, grants, and other agreements.
- **Office of Equal Employment Opportunity**: Promotes an inclusive work environment that ensures equal employment opportunities and fosters a culture that values diversity and empowers individuals.
- **Office of Facilities, Engineering, and Mission Support Services**: Provides FDA's employees with office and laboratory facilities.
- **Office of Financial Management:** Provides financial managerial services and policy guidance.
- **Office of Digital Transformation**: Provides the information, communication, and knowledge infrastructure and services that enhance, transform, and sustain the ability of FDA to protect and promote the public's health.
- **Division of Budget Execution and Control:** Initiates, monitors, and analyzes FDA's budget resources. The Agency's budget is composed of several appropriation accounts, including Salaries and Expenses, Revolving Fund for Color Certification and other Services, Cooperative Research and Development Agreement, Contingency Fund, Building and Facilities, and Royalties.
- **Office of External Affairs – History:** Provides research, documentation, and preservation of significant FDA historical resources and serves as historian for the Agency.
- **Office of Security Operations:** Develops and implements the Agency-wide security policies and programs by providing leadership and guidance to managers and staff on all aspects of security. Administers vital security functions that contribute to the Agency's mission of protecting the public's health by enhancing the safety and security of all personnel, facilities, and information.
- **Office of Laboratory Safety:** Reinforces FDA's expectations for safety and laboratory security, enhances communications among FDA's safety staff, and provides program support.
- **Office of Ethics and Integrity:** Protects the integrity of FDA's programs and operations by promoting an ethical culture and ensuring compliance with applicable federal ethics laws.
- **Office of Enterprise Management Services:** Provides strategic and tactical enterprise-wide services through the development and implementation of administrative policies, programs, and initiatives.
- **Program Alignment Team:** Provides advice and guidance on reorganizations and delegations of authority.
- **Office of Human Capital Management:** Provides human resources 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 resources solutions that enable FDA to hire a talented and qualified workforce.

Note 6. 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.

The applicable inflation adjustment utilized in FY 2021 was 1.114808 percent.

Note 7. Unearned Fee Revenues

Unearned fees are fees received by September 30, 2021, either for applications that had not been submitted to FDA as of September 30, 2021, or for establishment registration fees received without identification of the remitter. FDA is unable to obligate unearned revenue until applications or establishment registrations pertaining to these funds are submitted to FDA. The total unearned revenue as of September 30, 2021, was $47,151,094. **Table 10** outlines the total collections excluding unearned fee revenues for the last 2 cohort years.

Table 10: Medical Device User Fees Collected, Excluding Unearned Fee Revenue, for Cohort Years 2020 and 2021

Fees Collected	Cohort Year 2020	Cohort Year 2021
Target Revenue	**$220,142,000**	**$236,059,000**
Collections	$296,962,933	$273,411,425
Unearned Fee Revenue	($6,571,131)	($11,190,880)
Total Collections	**$290,391,803**	**$262,220,545**

Numbers have been rounded to the nearest dollar.

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

Table 11: Medical Device User Fees Collected, Collection Amounts Specified in Appropriations Acts, and Excess Amounts (Excluding Unearned Revenue) as of September 30, 2021

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[G]	$65,324,184	$57,605,000	$7,719,184
Total			**$26,680,243**

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 1 month of operating reserves for the first month of the next fiscal year.

Note 10. Minimum Non-User Fee Appropriations and Spending Adjustment Factor

FDA must calculate and incorporate an adjustment factor (defined in section 737(11) of the FD&C Act) to calculate both the non-user fee appropriations trigger in section 738(g)(1)(A) and the non-user fee BA spending trigger in section 738(h)(2)(A)(ii). The FD&C Act states, "the term 'adjustment factor' applicable to a fiscal year is the Consumer Price Index for all urban consumers (all items; United States city average) for October of the preceding fiscal year divided by such Index for October 2016."

[G] The amount of user fee collections (excluding unearned revenues) in excess of the amount specified in the relevant appropriations act for FY 2012 also should have been included in the total of unappropriated amounts in prior MDUFA Financial Reports.