FY 2018 MDUFA
FINANCIAL REPORT

REQUIRED BY THE

MEDICAL DEVICE USER FEE AMENDMENTS

FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Executive Summary

The Medical Device User Fee Amendments of 2017 (MDUFA) requires the Food and Drug Administration (FDA or the Agency) to report annually on the financial aspects of MDUFA implementation. This is the first report under the fourth authorization of MDUFA (MDUFA IV) and covers fiscal year (FY) 2018.

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 for the review of device applications as it spent in FY 2009, multiplied by an adjustment factor specified in the statute.

MDUFA 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 2018, 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 balances, 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 2018, FDA had net collections of $198.84 million in medical device user fees, spent $165.38 million in user fees for the device review process, and carried a cumulative balance of $144.24 million forward for future fiscal years. There are existing claims on roughly $74.43 million, leaving $69.81 million available for allocation.

MDUFA user fees and non-user fee appropriations in FY 2018 supported 1,711 full-time equivalents (667 from MDUFA user fees), including salaries and operational expenses, to support the review of device applications. Detailed program accomplishments can be found in the FY 2018 MDUFA Performance Report.

Report Overview

A. Scope

This financial report addresses the implementation and use of medical device user fees by FDA during the period of October 1, 2017, through September 30, 2018. 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 FY 2018 fee collections, carryover balances, obligations of user fees, and total costs of the process for the review of medical device applications from both MDUFA fees and non-user fee appropriations.

B. Report Requirements

In accordance with Federal Food, Drug, and Cosmetic Act (FD&C Act) section 738A(a)(4), FDA will publish an annual financial report on the implementation of the authority for user fees during such 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. Organization Background

FDA is responsible for protecting public health by ensuring 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 helps to speed innovations that make medical products more effective, safer, and helps the public get 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 public health by assuring 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 public health by maximizing compliance of FDA-regulated products and minimizing 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 Agency performance commitments associated with these fees, and the need for FDA to convey how these fees are executed calls for strong financial governance. This includes an understanding of the design of these programs, clear financial plans, data-driven decisions on resource allocation, consistency and transparency about assumptions, reliable financial forecasting, and accountability for resources spent.

FDA's current user fee governance process leverages the User Fee Financial Management Committee (UFMC) that 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 UFMC is responsible for providing oversight support and support of appropriate standards and policies to ensure FDA compliance with sound financial management practices, as well as compliance with statutory provisions that authorize FDA to collect and spend user fees.

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 medical device applications. The FDA Reauthorization Act of 2017 (FDARA) 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); De Novo classification requests; biologics license applications (BLAs); certain supplements to all of these applications; 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 the MDUFA IV 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). 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 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) 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 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 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). 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 (a predicate device).
	513(g) request for classification information	A request made under section 513(g) 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 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.

MDUFA user fees are not a fee-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.

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 2018, the final appropriation for the Device and Radiological Health line of FDA's Salaries and Expenses Appropriation (excluding user fees) was $332,743,000. 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 President signed the Consolidated Appropriations Act, 2018 (Public Law 115-141), on March 23, 2018. It specified that $193,291,000 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 2018 is $223,546,000 (rounded to the nearest thousand dollars). In FY 2018, FDA spent $280,465,569 from appropriations (exclusive of user fees) for the review of medical device applications. Because FDA spent more than the specified minimum amount from appropriations in FY 2018, 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**.

MDUFA also provides that FDA 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 2018 is $42,402,000 (rounded to the nearest thousand dollars). In FY 2018, FDA obligated $46,898,436 from appropriations (exclusive of user fees) for medical device inspections. Because spending on medical device establishment inspections exceeded the specified

minimum level for each of the most recent 2 fiscal years, FDA may continue to permit accredited third parties to conduct certain medical device establishment inspections in future years.

Financial Information

This section provides an overview of the program financials for MDUFA for fiscal years 2017 and 2018. These financials include user fee revenue, obligations, carryover, non-user fee appropriations, and FTEs.

F. User Fee Financials

Table 1 represents a summary of the MDUFA User Fee financial position for FY 2017 and FY 2018. The financial notes referenced in this table can be found in **Appendix D**.

Table 1: Medical Device Collections, Obligations, and Carryover for Fiscal Years 2017 and 2018

Budgetary Resources	Notes	FY 2017	FY 2018
Target Revenue	Note 1	**$126,083,000**	**$193,291,000**
Total Carryover, Beginning of Year		$103,152,912	$109,444,021
Net Collections		$139,648,191	$198,839,963
Recoveries	Note 2	$495,543	$1,327,551
Total Budgetary Resources		**$243,296,646**	**$309,611,535**

Obligations	Notes	FY 2017	FY 2018
Total Payroll and Operating	Note 3	$99,945,099	$120,836,388
Total Rent	Note 4	$10,280,000	$16,900,938
Total Shared Services	Note 5	$23,627,527	$27,638,089
Total Obligations		**$133,852,626**	**$165,375,415**

Carryover	Notes	FY 2017	FY 2018
Total Carryover, End of Year		**$109,444,020**	**$144,236,120**

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

Budgetary Resources: The budgetary resources component of **Table 1** illustrates the sum of available user fee funding (i.e., the existing available carryover balance and additional user fee collections) that will be used to fund obligations. 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 during the fiscal year.

MDUFA IV specifies how the fees must be calculated each fiscal year, including annual adjustments to base fees and total revenue that must be made for inflation. After the applicable inflation adjustment to fees is done, FDA may increase, if necessary to achieve the inflation-adjusted total revenue amount, the base fee amounts on a uniform proportionate basis (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)). If submissions or registrations are higher than estimated, collections may exceed the inflation-adjusted total revenue amount in a given 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 defined in MDUFA IV.

Carryover: MDUFA fees are available until expended, with certain exceptions. This means that the fees that are collected, appropriated, and not obligated at the end of a fiscal year remain available to FDA for use in future fiscal years. The unobligated fee funds at the end of each fiscal year are referred to as the "carryover balance." Maintaining an appropriate level of carryover enables FDA to mitigate financial risks to the program, including, for example, the risk of under-collecting of fee amounts and the risk of a lapse in appropriations, so FDA can continue performing medical device application reviews under the financial constraints.

G. User Fee Revenue

Table 2 outlines the target revenue amounts for FY 2017 and 2018. The financial notes referenced in this table can be found in **Appendix D**.

Table 2: Medical Device Revenue and Collections Statement for Fiscal Year 2017 and 2018

Target Revenue	Notes	FY 2017	FY 2018
Total Revenue Amount		$130,184,348	$183,280,756
Inflation Adjustment	Note 6	$10,577,218	$10,010,428
Offset Amount	Note 7	($14,678,151)	N/A
Target Revenue Total		**$126,083,000**	**$193,291,184**

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 of the annual target revenue is defined in statute. The initial amount for FY 2018, i.e., the "total revenue amount," is specified in 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 medical device application submissions (which includes periodic reporting) and annual user fees shall be collected for establishment registration. The statute also directs FDA to set the fee rate for each application type and for periodic reports as a percentage of the standard fee for a PMA. These base fee amounts for each application type are adjusted for inflation and then, if necessary, further increased to generate the inflation-adjusted total revenue amount. 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 prior years' numbers.

Cohort Year
The year in which user fee collections are originally due and reported. For example, a fee originally due in FY 2017, but received in FY 2018, is attributed to FY 2017 collections.

Under MDUFA, fees collected 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 balance carried over from year to year is described in **Section I – User Fee Carryover**. A 1-month reserve exists to manage the carryover balance over time.

Increase in Collections
The primary factors in the increase in collections were the greater-than-expected number of registration fees received by the Agency and the increase in the target total revenue amount from MDUFA III to MDUFA IV.

Unearned Fees are fees received prior to September 30, 2018, for applications that had not been submitted to FDA as of September 30, 2018, or for establishment fees received without identification of the remitter.

User fee collections were comprised of collections from medical device application submissions and annual registration user fees under MDUFA IV. **Table 3** outlines MDUFA collections by fee source and cohort year (CY). Unearned fees are a subset of total collections.

Table 3: Medical Device User Fee Collections by Fee Source for Cohort Years 2017 and 2018

Fees Collected	CY 2017			CY 2018		
	Estimated†	Actual	% Dif.	Estimated	Actual	% Dif.
Application Fees	$43,928,578	$49,134,521	12%	$75,810,626	$73,068,260	-4%
Registration Fees	$82,145,398	$91,699,709	12%	$117,468,096	$128,219,756	9%
Total Collections	**$126,073,976**	**$140,834,230**	**12%**	**$193,278,722**	**$201,288,015**	**4%**

Unearned Fees	Actual 2017	Actual 2018
Application Fees	$3,520,789	$12,189,250
Registration Fees	$324,672	$850,798
Total Unearned Fees	**$3,845,461**	**$13,040,048**

Fees Receivable	Actual 2017	Actual 2018
Application Fees	$560,600	$1,216,143
Registration Fees	$29,377	$22,305
Total Receivables	**$589,977**	**$1,238,448**

Numbers have been rounded to the nearest dollar.

†Estimated values were taken from the Medical Device User Fee Rates for FY 2018.

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 defined in MDUFA. For more information on the allowable and excluded costs, see **Appendix A.** In addition, FDA calculates 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 amount (from user fees and non-user fee appropriations) spent by FDA and by each FDA organization on the MDUFA program for the past 5 years. As illustrated by the table, costs have increased over time, but the percentage spent by each FDA organization has remained steady.

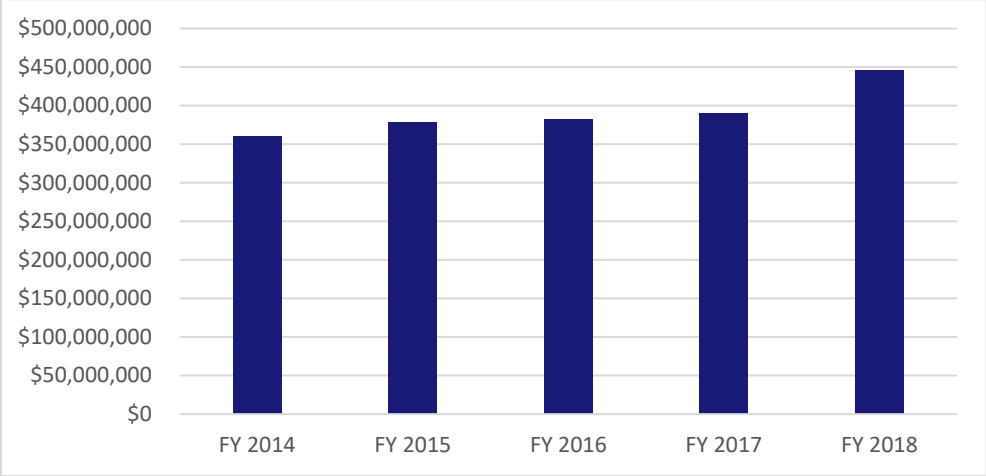
Table 4: MDUFA Program – Historical Trend of Total Costs by Organization as of September 30 of Each Fiscal Year

Costs		FY 2014	FY 2015	FY 2016	FY 2017	FY 2018
Total Spent		$360,203,389	$377,839,866	$382,410,783	$390,220,743	$445,840,984
CBER	Spent	$37,020,557	$39,812,108	$35,685,878	$36,983,291	$47,516,423
	Percent	10%	11%	9%	9%	11%
CDRH	Spent	$277,908,584	$295,387,061	$301,765,033	$303,699,059	$345,841,190
	Percent	77%	78%	79%	78%	78%
ORA	Spent	$14,339,241	$13,312,237	$13,640,088	$16,209,003	$13,842,148
	Percent	4%	4%	4%	4%	3%
HQ	Spent	$30,935,007	$29,328,460	$31,319,784	$33,329,390	$38,641,223
	Percent	9%	8%	8%	9%	9%

Numbers have been rounded to the nearest dollar.

Exhibit 4 below provides an illustration of historical MDUFA obligations.

Exhibit 4: Historic MDUFA Program Obligations by Fiscal Year



As demonstrated by this graph, program needs remained steady through MDUFA III, but experienced an increase in the first year of MDUFA IV (FY 2018). This is due to program enhancements that were agreed to in the MDUFA IV commitment letter.

In FY 2018, the MDUFA program obligated funds to support the hiring of FTE and the meeting of MDUFA IV 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:

- Quality Management
- Standards
- Digital Health
- Independent Assessment
- Real World Evidence

Details can be found in the MDUFA performance report.

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 2017 and 2018

User Fee Obligations	Notes	FY 2017	FY 2018
Payroll & Operating	Note 3		
CDRH		$83,491,635	$103,565,220
CBER		$9,006,033	$9,479,649
ORA		$1,699,859	$1,675,677
HQ		$5,747,572	$6,115,843
Total Rent	Note 4	$10,280,000	$16,900,938
Total Shared Services	Note 5	$23,627,527	$27,638,089
Total Obligations		**$133,852,626**	**$165,375,415**

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 is as follows:

- **Payroll and Operating:** These obligations provide for all payroll and operating costs that support the allowable activities for which MDUFA fees may be expended, as set forth in statute. This includes, 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 is paid to the General Services Administrations 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 service organizations that provide support across the user fee programs, such as human resources and IT.

I. User Fee Carryover

MDUFA fees collected, appropriated, and not obligated at the end of the fiscal year remain available to support the MDUFA program in future fiscal years. This balance is referred to as 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. FDA considers maintaining a carryover balance of 1 month as a reasonable range to mitigate these risks.

As noted above, the statute requires at least a 1-month operating reserve that can be maintained at the end of each fiscal year.

The carryover balance includes two categories:

- **Carryover Unavailable for Use** – This value represents carryover funds subject to claims or restrictions that precludes FDA from obligating the carryover funds.
- **Carryover Available for Use** – This value represents carryover funds that are not subject to any claims or restrictions and are therefore available for obligation.

The net change in carryover balance each year is equal to net collections minus net obligations. This is demonstrated best in **Table 1**.

Table 6 provides MDUFA carryover balances at the end of FY 2017 and FY 2018. The financial notes can be found in **Appendix D**.

Table 6: MDUFA Carryover by Fiscal Year

Carryover	Notes	FY 2017	FY 2018
Total Carryover, End of Year		**$109,444,020**	**$144,236,120**
Unearned Fee Revenue (FY 2008 – FY 2018)	Note 8	($28,798,773)	($37,160,260)
Unappropriated amounts	Note 9	($19,936,500)	($20,205,246)
One-Month Reserve	Note 10	($9,500,000)	($17,060,833)
Carryover Unavailable for Use, End of Year		**($58,235,273)**	**($74,426,339)**
Carryover Available for Use, End of Year		**$51,208,747**	**$69,809,781**

Numbers have been rounded to the nearest dollar.

To determine how much carryover is available for obligation at the end of a fiscal year, the following factors must be considered:

- **Total Carryover, End of Year** – This is the total amount of unobligated fee funds at the end of the fiscal year.
- **Carryover Unavailable for Use, End of Year** – As noted above, this value includes unobligated fee funds subject to any claims or restrictions on fees collected. This includes:
    - **Unearned Fee Revenue** – Unearned Fees are fees received prior to September 30, 2018, for applications that had not been submitted to FDA as of September 30, 2018, or for establishment fees received without identification of the remitter.
    - **Unappropriated amounts** – FDA's MDUFA carryover balance includes approximately $20,000,000 in fee collections that are considered unappropriated. This amount is the cumulative total of fee collections that exceeded the annual level of MDUFA funds appropriated for a given year, in fiscal years FY 2008 – FY 2011, plus an offset amount in FY 2012. Beginning in FY 2012, a technical fix was added to the appropriations language to ensure that all fee collections would be considered appropriated. In the absence of an appropriation for this $20,205,246, it is unclear whether or not FDA can obligate these funds. See **Note 9** for additional details.
    - **One-Month Reserve** – FDA may use unobligated carryover balances 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 balances of not less than 1 month of operating reserves for the first month of the next fiscal year.
- **Carryover Available for Use, End of Year** – As noted above, this is the total carryover less any carryover unavailable for use. These funds become the carryover available for use at the beginning of the next fiscal year.

The operations in FY 2018 resulted in a net increase of the carryover balance available for use of $18,601,034, from $51,208,747 at the end of FY 2017 to $69,809,781 at the end of FY 2018.

FDA has plans to allocate carryover funds toward hiring FTE and meeting MDUFA IV commitments, such as improving the premarket process, enhancing scientific and regulatory review, and developing infrastructure. FDA also plans to issue contracts for the commitment related to IT Infrastructure for Submission Management.

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

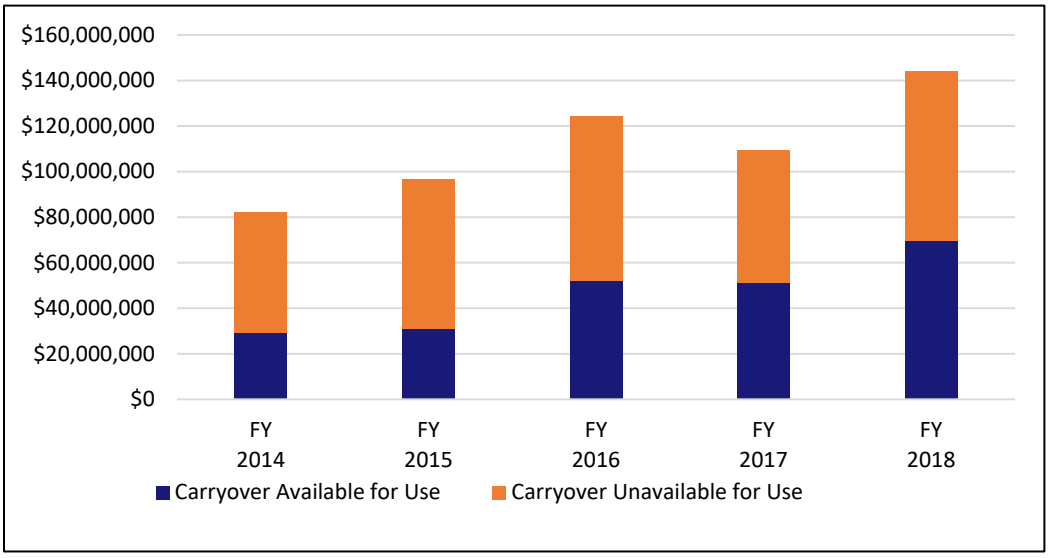
Table 7: Historic Medical Device User Fee Collections, Obligations, and Carryover Balances by Reauthorization Period

Carryover	Notes	MDUFA I	MDUFA II	MDUFA III	MDUFA IV
		FY 2003-2007	FY 2008-2012	FY 2013-2017	FY 2018
Total Carryover, Beginning of Year		**$0**	**$10,862,872**	**$53,216,730**	**$109,444,020**
Net Collections		$144,018,382	$312,851,252	$658,306,967	$198,839,963
Recoveries	Note 2	$0	$0	$540,100	$1,327,551
Total Obligations		($133,155,510)	($270,497,394)	($602,619,777)	($165,375,415)
Total Carryover, End of Year		**$10,862,872**	**$53,216,730**	**$109,444,020**	**$144,236,119**

Numbers have been rounded to the nearest dollar.

Exhibit 5 provides a historical perspective of carryover for the last 5 fiscal years. Carryover unavailable for use is historically larger in MDUFA than other user fee programs due to the high levels of unearned fee revenue (**Note 8**).

Exhibit 5: Historic 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 medical device applications during that fiscal year. This is often referred to as a "non-user fee budget authority (BA) spending trigger." The spending trigger was $234,817,760 for FY 2017 and $223,545,692 for FY 2018.

The non-user fee 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 11** for more details on the adjustment factor.

Table 8 provides the total amount spent on the MDUFA program for the past 5 years, and the dollar amount and percentages derived from user fee and non-user fee appropriations. The percentages attributable to MDUFA fees have increased over time.

Table 8: Historical Trend of MDUFA Program Costs by Funding Source as of September 30 of Each Fiscal Year

Obligations		FY 2014	FY 2015	FY 2016	FY 2017	FY 2018
Total Obligated		$360,203,389	$377,839,866	$382,410,783	$390,220,744	$445,840,984
Non-User Fee Appropriations	Total	$253,261,667	$247,322,622	$242,831,997	$256,368,118	$280,465,569
	Percent	70%	65%	64%	66%	63%
User Fee Revenue	Total	$106,941,722	$130,517,244	$139,578,785	$133,852,626	$165,375,415
	Percent	30%	35%	36%	34%	37%

Numbers have been rounded to the nearest dollar.

K. Full Time Equivalents (FTEs)

FTEs, 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.

FTEs are distributed throughout the FDA component organizations based on the amount of work conducted to support MDUFA.

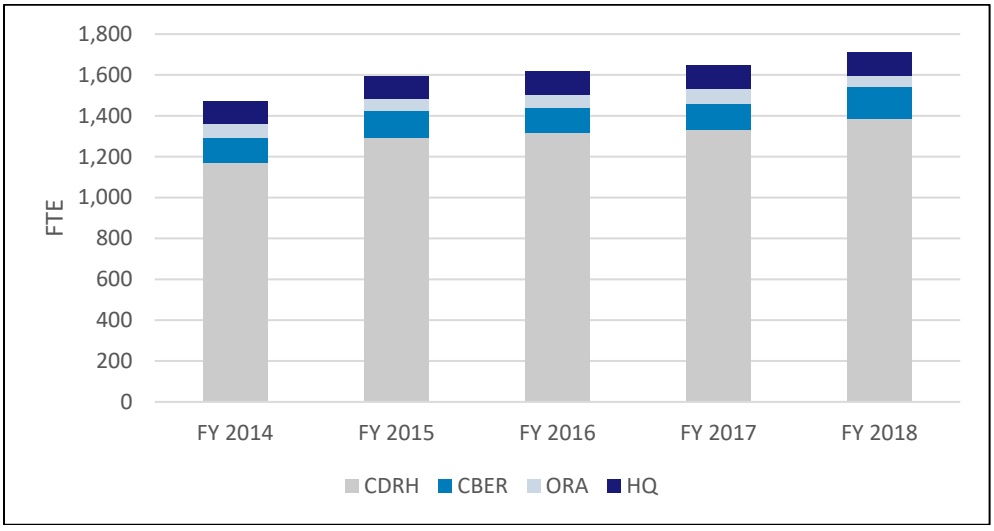
Table 9 presents total process FTE levels, paid from user fee and non-user fee appropriations, that support the medical device program. The data covers the past 5 years and is arranged by FDA organizational components (CBER, CDRH, ORA, and HQ). Staff in the consolidated shared services organizations (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 Organization as of September 30 of Each Fiscal Year

Organization	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018
CDRH	1,170	1,293	1,315	1,330	1,386
CBER	125	131	124	130	155
ORA	66	60	62	70	56
HQ	112	108	115	116	114
Total	**1,473**	**1,592**	**1,616**	**1,646**	**1,711**

Exhibit 6 provides the historical trend of FTE distribution and levels across FDA organizations for the past 5 years. There is a steady increase in FTEs, but the distribution has remained relatively the same.

Exhibit 6: Historic Medical Device User Fee Process FTE Levels by FDA Organization



Management Assurance

L. Internal Controls

The Federal Managers' Financial Integrity Act (FMFIA) of 1982 is intended to strengthen internal controls and accounting systems. The Office of Management and Budget's Circular No. A-123, *Management's Responsibility for Internal Control and Enterprise Risk Management* (OMB A-123), implements the requirements of the FMFIA. The FMFIA requires that management establish and maintain effective internal control to achieve the objectives of:

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

The U.S. 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 a cost-effective internal control and compliance program that includes programmatic and operational controls, as well as controls over financial reporting, and supports sound financial management. The Government Accountability Office (GAO) *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 to the President and Congress on the effectiveness of the internal controls and any identified material weaknesses in those controls. FDA's FY 2018 Assurance Statement that was submitted to HHS, found no material weaknesses or financial system nonconformances.

FDA has established a Senior Assessment Team (SAT) as the governance body responsible for providing oversight and accountability for FDA's internal control over financial reporting, including overseeing the FMFIA and A-123 assessments, and to foster an environment that promotes strong internal control. The SAT is chaired by the FDA Chief Financial Officer (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.

In accordance with FMFIA, OMB A-123, the Green Book, and the HHS Guidelines, FDA has a robust internal control program, including integrated controls throughout processes, and conducts an annual assessment of its internal control activities. In addition, FDA has an Enterprise Risk Management (ERM) program, which began in earnest in FY 2016 and is integrated with FDA's FMFIA efforts. Under the ERM program, FDA has refreshed the enterprise risk profile and facilitated risk response planning for five priority enterprise risks. To accomplish this, Centers and Offices are engaged through senior leadership interviews, as well as working groups and problem-solving sessions. Further, FDA has established an ERM Community of Practice, and continues to align and integrate core ERM methodologies with those of internal controls. FDA's ERM program has facilitated cross-Center and Office collaboration to identify and manage risks. It is governed by the ERM Council, which is chaired by the Chief Operating Officer and the CDER Deputy Director for Operations.

FDA's internal control program includes an evaluation of controls over reporting, charge card compliance, improper payments, and financial systems compliance. One of the cycle memos included in the assessment scope includes internal controls over reporting for the reimbursable activity process, specifically focused on the Accounts Receivable and Payment process associated with the User Fee

programs. This includes controls over reconciliation performance, aging, write-offs, the interface between the User Fee System and the Unified Financial Management System. As an FDA-owned system, FDA's User Fee System is compliant with HHS requirements and requirements of the Federal Financial Management Improvement Act (FFMIA) of 1996. In addition, FDA's Integrated Budget and Acquisition Planning System (IBAPS) meets FDA and HHS system requirements.

FDA is also a participant in the annual audit of the consolidated financial statements of HHS, including the consolidated balance sheets, the related consolidated statement of net cost and changes in net position, the combined statement of budgetary resources, and the related notes to the financial statements. The FY 2018 audit found that the financial statements present fairly, in all material respects, the consolidated financial position of HHS as of September 30, 2018 and 2017, and its consolidated balance sheets, statement of net cost, changes in net position, combined statement of budgetary resources, and related notes are in accordance with U.S. generally accepted accounting principles.

FDA has also implemented other internal control procedures including a Continuous Monitoring Program to oversee the timely implementation of any Corrective Action Plans (CAPs) for deficiencies identified through any of its control assessments. This Continuous Monitoring Program allows for management oversight of targeted remediation efforts and strengthening of internal controls. In addition, FDA offers annual internal control training sessions, which cover the importance of internal controls, timely deficiency remediation, and roles and responsibilities.

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 in order to 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 of user fee revenue, non-user fee BA spending trigger requirements, and difficulties with hiring, especially in the first year of a reauthorization period as new and expanded initiatives are being implemented. To minimize this risk, FDA is enhancing its planning and execution around the hiring of new staff and contract actions in this first year of the reauthorization. By putting more emphasis on the initial planning of initiatives in the first year of the 5-year cycle, FDA predicts that there will be less variance while comparing planned allocations to actual expenditures than FDA has experienced in the past.

- **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 balance 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 UFMC and other FDA senior leaders determine how to mitigate any instances when user fee revenue is off forecasted estimates.

In addition to these mitigation strategies, FDA implemented the 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 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, the benefits expected from these initiatives will not be immediate, and thus, FDA may experience delays in hiring staff for the MDUFA program.

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) of the FD&C Act defines in general terms 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 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: 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: 1. The review of manufacturing information submitted in PMAs 2. Pre-approval 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: 1. Conduct of bioresearch monitoring inspections (both "for cause" and pre-approval) 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 Public Health Service 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: 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: 1. Development of device-specific, cross-cutting, special control, and program-related guidances 2. "Blue Book Memoranda" and 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: 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 postmarket 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: 1. Protocols for the 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: 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 & the Science of Patient Input 3. Emerging Diagnostics 4. Real World Evidence 5. Digital Health 6. Total Product Life Cycle 7. Independent Assessment
User Fee Act implementation	This would include activities such as: 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, 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 regulation; 4. Post-approval activities relating to: o Promotion and advertising; o International coordination/Mutual Recognition Agreement work; o International standards development; o Liaison/outreach and manufacturing assistance; o Device tracking; o Inspections unrelated to the review of covered applications; o Export/import activities unrelated to the conduct of a clinical trial; o Research related to future products; and o All activities conducted under the Mammography Quality Standards Act (MQSA), radiation safety authorities of the FD&C Act (sections 531 et seq.), and the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

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 which 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 2016, the October of the fiscal year preceding FY 2018, was 241.729. Dividing the CPI of October 2016 by itself yields an adjustment factor of 1 for FY 2018.

Legal Conditions

Exhibit 7 below 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 deobligations 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. Pay and Operating Costs

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

Note 4. Rent Costs

The General Services Administration (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 medical 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 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 number of employees that must be housed.

Note 5. Shared Service Costs

FDA contains several shared service organizations that provide support across the user fee programs. The shared service organizations 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.
- **Employee Resource & Information Center (ERIC)**: Provides support to all FDA users requesting administrative, IT, facilities, human resources, and other employee services.
- **Employee Safety & Environmental Management (ESEM)**: Provides safety, health, and environmental compliance for all FDA employees.
- **Office of Acquisitions and Grants Services (OAGS)**: Manages contracts, grants, and other agreements.
- **Office of External Affairs (OEA) – History**: Provides the development, coordination, and dissemination of FDA communications and outreach to the news media and various stakeholders.
- **Office of Equal Employment Opportunity (OEEO)**: 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 (OFEMS)**: Provides FDA employees with office and laboratory facilities.
- **Office of Financial Management (OFM):** Provides financial managerial services and policy guidance.
- **Office of Human Resources (OHR)**: Supports workforce relations, client services, executive resources, accountability programs, policy and program development, and systems data and management.
- **Office of Information Management and Technology (OIMT)**: Provides the information, communication, and knowledge infrastructure and services that enhance, transform, and sustain the ability of FDA to protect and promote the public health.

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 2018 was 1.054618%.

Note 7. Offset Amount

Under MDUFA IV, the fifth-year fee offset provision was eliminated because the negotiated fee setting structure allows FDA to collect and use inflation adjusted base fee amounts each year without any reduction in fees due to increased submission or registration volume.

Note 8. Unearned Fee Revenue

FDA is unable to obligate or offset unearned revenue until applications are submitted to FDA pertaining to these funds. Total unearned revenue as of September 30, 2018, was $37,160,260.

Note 9. Unappropriated Amounts

This is the amount that FDA collected in user fees in excess of the amount specified in appropriations acts prior to FY 2012. **Table 10** outlines the excess user fees by fiscal year.

Table 10: Medical Device User Fees Collected, Collection Amounts Specified in Appropriations Acts, and Excess Amounts as of September 30, 2018

Fiscal Year	Collections Realized (Excluding Unearned Revenue)	Collection Amount Specified in Appropriation Acts	Amount in Excess of Collection Amount Specified in Appropriation Acts
2009	$57,554,216	$52,547,000	$5,007,216
2010	$63,932,631	$57,014,000	$8,651,291
2011	$70,139,400	$61,860,000	$9,676,566
Total			**$20,205,246**

Numbers have been rounded to the nearest dollar.

Note 10. One-Month Reserve

According to statute, FDA may use unobligated carryover balances 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 balances of not less than 1 month of operating reserves for the first month of the next fiscal year.

Note 11. 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) in order to calculate both the non-user fee appropriations trigger in section 738(g)(1)(A) and the 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.”