FY 2017 MDUFA
FINANCIAL REPORT

REQUIRED BY THE

MEDICAL DEVICE USER FEE AMENDMENTS OF 2012

FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

EXECUTIVE SUMMARY

The Medical Device User Fee Amendments of 2012 (MDUFA) require the Food and Drug Administration (FDA) to report annually from fiscal year 2013 to fiscal year 2017 on the financial aspects of MDUFA implementation. As required under the statute, this report covers activities for fiscal year (FY) 2017, the final year of MDUFA III.

MDUFA specifies that the following three legal conditions must be satisfied each fiscal year in order 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 $280,587,000, multiplied by an adjustment factor specified in the statute.

2. The fee amounts FDA can collect must be specified in appropriation acts.

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

MDUFA also contains a provision that FDA must spend at least as much on medical device 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 device establishment inspections.

FDA met the three legal conditions in FY 2017, and this report explains how these legal conditions were satisfied. FDA also fulfilled the provision regarding spending on medical device inspections, which enables FDA to continue with the third-party accreditation program. The statements and tables in the report provide data on FY 2017 medical device user fee collections, obligations, and carryover balances, as well as comparative data from prior years.

In FY 2017, FDA had net collections of $139.6 million in medical device user fees, spent $133.9 million in user fees for the review process, and carried a user fee balance of $109.4 million forward for future fiscal years. Of the total carryover balance, there are existing claims on roughly $58.2 million, leaving $51.2 million available for allocation.

In FY 2017, MDUFA user fees and non-user fee appropriations supported 1,646 full-time equivalents, including salary and operational expenses to support the staff responsible for the process for the review of device applications. Detailed program accomplishments can be found in the FY 2017 MDUFA Performance Report.

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1: BACKGROUND

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Medical Device User Fee Amendments (MDUFA) (Title II of the Food and Drug Administration Safety and Innovation Act (FDASIA), Public Law 112-144), authorizes the Food and Drug Administration (FDA or the Agency) to collect fees from the medical device industry to augment non-user fee appropriations spent on FDA's medical device review process. As amended, MDUFA authorization was extended for an additional 5 years, through fiscal year (FY) 2017. This reauthorization is referred to as "MDUFA III." FDA spends fee revenues and non-user fee appropriations to hire, support, and maintain personnel for the review of medical device applications to ensure that safe and effective devices reach the American public more quickly.

Under MDUFA III, 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); modular PMAs; 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. In addition, under MDUFA III, 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 2017. Fees for other application types and for periodic reports are fixed by statute as a percentage of the PMA fee for each year.

MDUFA requires FDA to submit a financial report to Congress within 120 days of the end of each fiscal year. This financial report addresses the implementation and use of medical device user fees by FDA during the period of October 1, 2016, through September 30, 2017. The report presents the legal conditions that must be satisfied annually for FDA to collect and spend medical device user fees. It also presents information on the spending level for medical device inspections that must be satisfied for FDA to continue the third-party accreditation program. In addition, this report presents statements of FY 2017 user fee collections, carryover balances, obligations, and total costs of the process for the review of device applications from both fees and non-user fee appropriations.

2: LEGAL CONDITIONS

MDUFA imposes three legal conditions that must be satisfied in each fiscal year for FDA to collect and spend medical device user fees. A summary of how each of these legal conditions was satisfied in FY 2017 is described below.

Legal Condition 1 – The Device and Radiological Health line of FDA's Salaries and Expenses Appropriation (excluding user fees) each fiscal year may not be more than 1 percent less than $280,587,000 (rounded to the nearest thousand dollars), multiplied by an adjustment factor, or $291,788,000 (rounded to the nearest thousand dollars) for FY 2017. In FY 2017, the final appropriation for the Device and Radiological Health line of FDA's Salaries and Expenses Appropriation (excluding user fees) was $329,681,000. Therefore, the first legal condition was satisfied.

Legal Condition 2 – The amount of user fees collected for each fiscal year must be specified in that year's appropriation acts. The President signed the Consolidated Appropriations Act, 2017 (Public Law 115-31), on May 5, 2017. It specified that $126,083,000 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.

Legal Condition 3 – User fees may be collected and used only in the fiscal years when FDA spends a specified minimum amount of appropriated funds for the review of medical device applications. This specified minimum is the amount FDA spent on the review of medical device applications from appropriations (exclusive of user fees) in FY 2009, multiplied by an adjustment factor. That specified minimum level for FY 2017 is $234,818,000 (rounded to the nearest thousand dollars). In FY 2017, FDA obligated $256,368,118 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 2017, the third legal condition was satisfied.

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 2017 is $40,383,000 (rounded to the nearest thousand dollars). In FY 2017, FDA obligated $43,356,000 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.

References

Detailed explanations and calculations of how each of these legal conditions were satisfied in FY 2017 are described in section 4.1 - Appendix A.

3: FINANCIAL INFORMATION

3.1 – USER FEE COLLECTIONS

Introduction

MDUFA specifies that user fees shall be collected for medical device application submissions and annual user fees shall be collected for establishment registration and periodic reporting. 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. Under MDUFA, fees collected and appropriated, but not spent by the end of a fiscal year, continue to remain available for FDA to spend in future years.

User fee collections are reported in the year the fee was originally due --referred to as the cohort year. For example, a fee originally due in FY 2016, even if it is received in FY 2017, is attributed to FY 2016 collections. 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-year numbers.

Unearned Fees[1] are fees received for applications that had not been submitted to FDA as of September 30, 2017, or for FY 2017 establishment fees received without identification of the remitter.

The receivables for FY 2016 and FY 2017 are from uncollected establishment and periodic reporting fees. After 90 days of attempting to collect the delinquent debt, FDA turns these receivables over to the Program Support Center (PSC), Department of Health and Human Services, for further attempts at collection. After 120 days of the debt being outstanding, PSC will turn the debt over to the United States Treasury for further collection efforts.

[1] "Unearned Fees" are fees received for applications that had not been submitted to FDA as of September 30, 2017, or for FY 2017 establishment fees received without identification of the remitter. The unearned fees are included above in the "Total Fees Collected" amounts.

Data

Table 1 provides totals of user fees collected during the past 2 fiscal years and reflects the amount of open receivables.

TABLE 1: MEDICAL DEVICE USER FEE COLLECTIONS AND RECEIVABLES BY FEE SOURCE AS OF SEPTEMBER 30, 2017

Fees Collected	FY 2016	FY 2017	Notes
Application Fees	$49,387,513	$51,018,345	
Registration Fees	$100,201,228	$92,221,423	
Total Collections	**$149,588,741**	**$143,239,768**	A
Unearned Fees			
Application Fees	$3,055,590	$6,809,611	
Registration Fees	$472,935	$716,969	
Total Unearned	**$3,528,525**	**$7,526,580**	
Fees Receivable			
Application Fees	$712,412	$684,025	
Registration Fees	$13,771	$30,177	
Total Receivables	**$726,183**	**$714,202**	

Numbers have been rounded to the nearest dollar

Notes

A. Because of refunds and transfers, the total fee collections for cohort year 2016 decreased by $3,023,568 compared to the collections reported in the FY 2016 financial report. Additionally, all but $3,528,525 of the unearned fee revenue reported in FY 2016 has now been either refunded or credited to the cohort year in which the application was actually received.

References

The balances carried over from year to year are described in section 3.3 - Carryover Balances.

Trending of historical fees paid and rates are provided in section 4.2 - Appendix B.

3.2 – USER FEE OBLIGATIONS

Introduction

MDUFA fees may be expended only for costs necessary to support the "process for the review of device applications," as defined in MDUFA. For ease of reading, the "process for the review of device applications" is referred to as the "MDUFA program" in this report.

Fluctuations in object class obligations are due to variations in programmatic operations from year-to-year. As a result, increases or decreases in specific categories do not necessarily indicate growth or reductions in the overall MDUFA program.

Data

Table 2 provides a breakout of user fee obligations by expense category during the past 2 fiscal years.

TABLE 2: MEDICAL DEVICE USER FEE OBLIGATIONS BY OBJECT CLASS EXPENSE CATEGORY AS OF SEPTEMBER 30, 2016 AND 2017

Object Class Expense Category	FY 2016	FY 2017
Personnel Compensation Benefits		
Full-time permanent	$55,274,174	$53,338,788
Other than full-time permanent	$10,634,204	$10,452,708
Other personnel compensation	$4,014,025	$4,538,971
Military personnel	$2,785,182	$2,295,845
Special personal services payments	$37,489	$33,768
Civilian personnel benefits	$21,346,988	$21,335,676
Military personnel benefits	$1,568,027	$1,231,713
Benefits former personnel	$2,972	$0
Total Personnel Compensation and Benefits	**$95,663,061**	**$93,227,469**
Non-Pay Costs		
Travel & transportation of persons	$1,481,478	$1,296,108
Transportation of things	$200	$125
Rent payments to the General Services Administration (GSA)	$7,978,000	$6,106,000
Rent payments to others	$0	$218
Communications, utilities, & miscellaneous	$254,150	$430,513
Printing & reproduction	$24	$114,011
Other contractual services:		
Consulting services	$5,852,268	$1,619,379
Other services	$18,861,110	$12,705,119
Purchases of goods & services from government accounts	$6,997,353	$11,685,655
Operations & maintenance of facilities	$1,174,831	$287,539
Research & development contracts	$0	$0
Operations & maintenance of equipment	$739,344	$4,626,690
Subsistence & support of persons	$0	$0
Supplies & materials	$170,734	$446,801
Equipment	$401,214	$786,915
Land & structure	$0	$0
Grants, subsidies, & contributions	$0	$400,000
Insurance claims & indemnities	$0	$0
Interest account	$0	$0
Refunds	$0	$17,025

Receivables – collected	$5,018	$103,058
Total Non-Pay Costs	**$43,915,724**	**$40,625,157**
Total Obligations	**$139,578,785**	**$133,852,626**

Numbers have been rounded to the nearest dollar

References

Allowable and excluded costs are described in section 4.3 - Appendix C.

3.3 – CARRYOVER BALANCES

Introduction

At the end of a fiscal year, MDUFA fees collected and appropriated, but not obligated (referred to as "carryover balances"), remain available, with certain exceptions, to FDA in future fiscal years. The operations in FY 2017 resulted in a net increase of the carryover balance of $6,291,108, resulting in a year-end carryover balance of $109,444,020. Not all of this is available to FDA, as there are anticipated claims on this balance as described in section 3.5, Table 5.

Data

Table 3 captures FDA's carryover balances at the beginning and end of the 5-year authorization for MDUFA I, MDUFA II, and for each fiscal year in MDUFA III.

Table 3 also reflects the amount of fees collected net of any refunds or other adjustments that occurred during each fiscal year, for all cohort years combined, and the amount obligated during the fiscal year. The numbers do not include any accounts receivable. Therefore, the numbers for FY 2016 and FY 2017 are different from the numbers in Table 1 in section 3.1 – User Fee Collections, which reflect the total net collections for the cohort years only.

Obligations in Table 3 include any recoveries and deobligations from prior years, which may cause differences from Tables 2 and 7. In FY 2017, FDA recovered $495,543 in MDUFA deobligations.

TABLE 3: MEDICAL DEVICE USER FEE COLLECTIONS, OBLIGATIONS, AND CARRYOVER BALANCES BY FISCAL YEAR

Program	Fiscal Years	Beginning Carryover	Net Collection	Obligations	Year-End Carryover
MDUFA I	2003-2007	$0	$144,018,382	$133,155,510	$10,862,872
MDUFA II	2008-2012	$10,862,872	$312,851,252	$270,497,394	$53,216,730
MDUFA III	2013	$53,216,730	$104,927,586	$91,729,400	$66,414,916
	2014	$66,414,916	$122,672,633	$106,941,722	$82,145,827
	2015	$82,145,827	$141,006,826	$130,517,244	$92,635,409
	2016	$92,635,409	$150,051,730	$139,534,228	$103,152,912
	2017	$103,152,912	$139,648,191	$133,357,083	$109,444,020

Numbers have been rounded to the nearest dollar

3.4 – COLLECTIONS REALIZED

Introduction

The following information depicts collections realized by cohort year (the same as Total Collections in Table 1 section 3.1 – User Fee Collections), collection amounts specified in the appropriation acts, and the offset amount taken when fees were set for FY 2017.

Data

Previous cohort year collections realized in FY 2017 have been updated from last year's report. The update reflects net collections for each cohort year through September 30, 2017. Cohort year fees collected after September 30, 2017, will be reported in the FY 2018 Financial Report. Other variances between Table 3 and Table 4 are a result of unapplied collections at the end of the fiscal year. These collections will either be applied or refunded during FY 2018.

TABLE 4: MEDICAL DEVICE USER FEES COLLECTED, COLLECTION AMOUNTS SPECIFIED IN APPROPRIATION ACTS, AND EXCESS AMOUNTS AS OF SEPTEMBER 30, 2017

Fiscal Year	Collection Amount Specified in Appropriation Acts	Collections Realized	Amount in Excess of Collection Amount Specified in Appropriation Acts
2003	$25,125,000	$21,620,549	$0
2004	$31,654,000	$26,281,779	$0
2005	$33,938,000	$31,814,416	$0
2006	$40,300,000	$35,047,878	$0
2007	$43,726,000	$28,715,714	$0
Total MDUFA I			**$0**
2008	$48,431,000	$48,777,342	$346,342
2009	$52,547,000	$58,664,523	$6,117,523
2010	$57,014,000	$65,665,291	$8,651,291
2011	$61,860,000	$71,536,566	$9,676,566
2012	$57,605,000	$67,215,833	$9,610,833
Total MDUFA II			**$34,402,556**
2013	$97,722,000	$104,178,226	$6,456,226
2014	$114,833,000	$124,471,307	$9,638,307
2015	$128,282,000	$138,592,059	$10,310,059
2016	$137,677,000	$149,588,741	$11,911,741
2017	$126,083,000	$143,239,768	$17,156,768
Total MDUFA III			**$55,473,100**
Offset When Fees Were Set for FY 2017			**$14,678,151**

Numbers have been rounded to the nearest dollar

References

For more detail on collection amounts specified in appropriation acts, refer to section 2 – Legal Conditions.

3.5 – Reserves and Balance Available for Allocation

Introduction

MDUFA's carryover balance in FY 2017 is $109,444,020. There are anticipated claims on this balance that are described below. After subtracting these claims, FDA's total remaining carryover balance is $51,208,747.

Data

Table 5 provides a summary of carryover balances as of September 30, 2017, and anticipated claims on those balances.

Table 5: Summary Statement of Medical Device User Fee Carryover Balance as of September 30, 2017

Status of Carryover Funds	Amount	Notes
Total Carryover Balance	$109,444,020	
Unearned Fee Revenue, FY 2008 through FY 2017	($28,798,773)	A
Collections That Were Not Appropriated	($19,936,500)	B
1-Month Reserve for Next Fiscal Year	($9,500,000)	C
Remaining Carryover Balance	**$51,208,747**	

Numbers have been rounded to the nearest dollar

Notes

A. 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, 2017, was $7,089,716 from MDUFA II and $21,709,057 from MDUFA III.

B. The $10,424,670 collected in excess of appropriations during the FY 2008 to FY 2011 period is deemed unavailable for obligation. Additionally, the $9,511,830 in excess collections that was offset when setting fees for FY 2012 is deemed unavailable for obligation.

C. MDUFA requires FDA to have at least 1 month of operating funds from fees consequently there is $9,500,000 in reserve for the first month of the next fiscal year.

3.6 – TOTAL MDUFA PROGRAM COSTS

Introduction

There are four organizational components that support the MDUFA program: the Center for Devices and Radiological Health (CDRH), the Center for Biologics Evaluation and Research (CBER), the Office of Regulatory Affairs (ORA), and FDA Headquarters (HQ). The MDUFA program is supported by both user fees and non-user fee appropriations.

Data

Table 6 shows the full cost (non-user fee appropriations and user fees) of the MDUFA program during the past 10 fiscal years by FDA organizational components (CDRH, CBER, ORA, and HQ). The percentages spent in the various FDA components have remained essentially stable over time.

TABLE 6: MDUFA PROGRAM – HISTORICAL TREND OF TOTAL COSTS BY ORGANIZATION AS OF SEPTEMBER 30 OF EACH FISCAL YEAR

Fiscal Year	Total Spent	Spent by CDRH	CDRH %	Spent by CBER	CBER %	Spent by ORA	ORA %	Spent by HQ	HQ %
2008	$235,199,599	$179,941,933	77%	$26,815,222	11%	$11,835,564	5%	$16,606,880	7%
2009	$270,848,437	$212,217,413	78%	$29,121,473	11%	$10,747,226	4%	$18,762,325	7%
2010	$292,707,540	$224,106,088	77%	$30,132,907	10%	$13,893,434	5%	$24,575,111	8%
2011	$299,864,531	$231,004,393	77%	$33,715,375	11%	$14,464,887	5%	$20,679,876	7%
2012	$320,136,649	$244,845,422	76%	$33,818,790	11%	$15,550,580	5%	$25,921,857	8%
2013	$324,367,624	$249,456,182	77%	$32,558,370	10%	$12,891,793	4%	$29,461,279	9%
2014	$360,203,389	$277,908,584	77%	$37,020,557	10%	$14,339,241	4%	$30,935,007	9%
2015	$377,839,866	$295,387,061	78%	$39,812,108	11%	$13,312,237	4%	$29,328,460	8%
2016	$382,410,783	$301,765,033	79%	$35,685,878	9%	$13,640,088	4%	$31,319,784	8%
2017	$390,220,744	$303,699,059	78%	$36,983,291	9%	$16,209,003	4%	$33,329,390	9%

Numbers have been rounded to the nearest dollar

Table 7 provides the total amount spent on the MDUFA program for the last 10 years, and the dollar amount and percentages derived from fees and non-user-fee appropriations.

TABLE 7: MDUFA PROGRAM – HISTORICAL TREND OF TOTAL COSTS BY FUNDING SOURCE AS OF SEPTEMBER 30 OF EACH FISCAL YEAR

Fiscal Year	Total Spent	Spent from Appropriations	Appropriations Percent	Spent from MDUFA Fees	MDUFA Fee Percent
2008	$235,199,599	$198,776,699	85%	$36,422,900	15%
2009	$270,848,437	$223,545,693	83%	$47,302,744	17%
2010	$292,707,540	$235,520,440	80%	$57,187,100	20%
2011	$299,864,531	$240,608,031	80%	$59,256,500	20%
2012	$320,136,649	$249,808,499	78%	$70,328,150	22%
2013	$324,367,624	$232,638,224	72%	$91,729,400	28%
2014	$360,203,389	$253,261,667	70%	$106,941,722	30%
2015	$377,839,866	$247,322,622	65%	$130,517,244	35%
2016	$382,410,783	$242,831,997	64%	$139,578,785	36%
2017	$390,220,744	$256,368,118	66%	$133,852,626	34%

Numbers have been rounded to the nearest dollar.

References

An expense category breakout of the FY 2016 and FY 2017 dollar amounts spent from MDUFA fees is provided in Table 2 of section 3.2 – User Fee Obligations.

The development of the costs associated with the MDUFA program is described in more detail in section 4.4 – Appendix D.

3.7 – FULL-TIME EQUIVALENT

Introduction

Full-time equivalent (FTE) is a measure of a paid staff year devoted to the MDUFA program. In this table, an FTE does not represent an accounting of individual people, but rather an estimate of labor hours expended on MDUFA program activities on an FTE basis.

FDA dedicated 829 FTEs to the MDUFA program in FY 2002 before MDUFA was enacted. In FY 2017, MDUFA fees and non-user fee appropriations paid for 1,646 FTEs—817 (99 percent) more FTEs than in FY 2002 before MDUFA was enacted. The program will continue to see increases in FTEs over the next year in order to meet the performance goals agreed to in MDUFA IV.[2]

Data

Table 8 presents total FTE levels that support the MDUFA program by FDA organizational components (CDRH, CBER, ORA, and HQ) for the last 10 years, paid from both user fees and non-user fee appropriations. Staff in the consolidated shared services organization (facilities, procurement, information technology (IT) services, etc.) is included in the FTE levels for the various components.

TABLE 8: HISTORICAL TREND OF TOTAL FTES UTILIZED BY ORGANIZATION AS OF SEPTEMBER 30 OF EACH FISCAL YEAR

Fiscal Year	CDRH	CBER	ORA	HQ	Total
2008	843	109	66	77	1,095
2009	853	109	60	87	1,109
2010	949	120	72	89	1,230
2011	1,008	120	72	82	1,282
2012	1,093	128	71	90	1,382
2013	1,133	129	63	99	1,424
2014	1,170	125	66	112	1,473
2015	1,293	131	60	108	1,592
2016	1,315	124	62	115	1,616
2017	1,330	130	70	116	1,646

Numbers have been rounded to the nearest full FTE.

References

The development of the costs associated with the MDUFA program is described in more detail in section 4.4 – Appendix D.

[2] Details on the performance goals agreed to in MDUFA IV are available in the MDUFA IV commitment letter at: https://www.fda.gov/downloads/ForIndustry/UserFees/MedicalDeviceUserFee/UCM535548.pdf

4: APPENDICES

4.1 – APPENDIX A: 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 provides detailed descriptions of these conditions and explanations of how FDA met these conditions in FY 2017. A summary of the legal conditions was provided in section 2 – Legal Conditions.

Adjustment Factor

In order to compare and determine whether the legal conditions are satisfied, FDA must calculate and incorporate an adjustment factor (defined in section 737(10) 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 2011.

The Consumer Price Index (CPI) for October 2015—the October of the fiscal year preceding FY 2017—was 237.838. The CPI in October 2011 was 226.421. Dividing the CPI from October 2015 by the CPI from October 2011 yields an adjustment factor of 1.050424 (rounded to the sixth decimal point) for FY 2017.

Legal Condition 1

The first legal condition is found in section 738(h)(1)(A) of the FD&C Act. It states:

> 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 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 $280,587,000 multiplied by the adjustment factor applicable to such fiscal year.

This provision specifies a minimum that must be appropriated each year for the Device and Radiological Health line of FDA's appropriation, exclusive of user fees. The minimum amount for FY 2017 is 1 percent less than $280,587,000 multiplied by the adjustment factor of 1.050424, or $291,788,000 (rounded to the nearest thousand dollars) for FY 2017. In FY 2017, the Device and Radiological Health line of FDA's appropriation, exclusive of user fees, was $329,681,000. Since this amount is greater than $291,788,000, the first legal condition was met.

Legal Condition 2

The second legal condition is described in section 738(i)(2)(A)(i) of the FD&C Act. It states that fees:

> 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….

The President signed the Consolidated Appropriations Act, 2017 (Public Law 115-31), on May 5, 2017. It specified that $126,083,000 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 met.

Legal Condition 3

The third legal condition is defined in section 738(i)(2)(A)(ii) of the FD&C Act. It states that fees:

> [S]hall only 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 the Department of Health and Human Services 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.

The third condition requires a minimum spending from appropriations, excluding user fees, on the process of medical device review. The minimum spending from appropriations is the amount that FDA spent on the MDUFA program in FY 2009, multiplied by the adjustment factor. FDA must spend at or above this minimum spending level from appropriations.

In FY 2009, the amount spent from appropriations for the MDUFA program was $223,545,692. After applying the adjustment factor of 1.050424, the minimum appropriation spending level for the MDUFA program for FY 2017, excluding user fees, is $234,818,000 (rounded to the nearest thousand dollars).

In FY 2017, FDA obligated $256,368,118 from appropriations, exclusive of user fees, for the MDUFA program, which exceeds the specified minimum appropriation spending level. Therefore, the third legal condition was met.

In addition, MDUFA includes a provision that FDA's fiscal year obligations for medical device establishment inspections must be equal to or greater than its obligations for this purpose in FY 2002, with a 5 percent increase for 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 device establishment inspections. This condition is cited in section 704(g)(10) of the FD&C Act.

Table 9 shows the required statutory minimum to be obligated for device establishment inspections (FY 2002 base level of $19,425,000 increased by 5 percent in each subsequent fiscal year, rounded to the nearest thousand dollars) and FDA obligations for medical device establishment inspections from the past 10 years.

TABLE 9: OBLIGATIONS FOR THE INSPECTION OF MEDICAL DEVICE ESTABLISHMENTS (ROUNDED TO THE NEAREST THOUSAND) AS OF SEPTEMBER 30 OF EACH FISCAL YEAR

Fiscal Year	Minimum 2002 – Obligations Increased by 5% Per Year	Actual Obligations	Excess or Shortfall	Notes
2008	$26,031,000	$32,989,000	$6,958,000	
2009	$27,333,000	$35,927,000	$8,594,000	
2010	$28,700,000	$41,596,000	$12,896,000	
2011	$30,135,000	$43,261,000	$13,126,000	
2012	$31,641,000	$43,620,000	$11,979,000	
2013	$33,223,000	$40,304,000	$7,081,000	
2014	$34,885,000	$43,990,000	$9,105,000	
2015	$36,629,000	$43,262,000	$6,633,000	
2016	$38,460,000	$43,634,000	$5,174,000	
2017	$40,383,000	$43,356,000	$2,973,000	A

Notes

A. FDA has spent more than the statutory minimum for device inspections for each of the past 2 fiscal years, and therefore may continue to allow accredited third parties to conduct certain device establishment inspections in future years.

4.2 – APPENDIX B: FEES, WAIVERS, AND REDUCTIONS

MDUFA Fee History

MDUFA III established fee rates for "premarket applications" (which include PMAs, BLAs, and product development protocols) fees and for annual establishment registration fees. The rates for all other fees are statutorily set as a percent of the full PMA fee. The premarket report fee and the efficacy supplement fee are equal to the PMA fee. The panel track supplement fee is 75 percent of the PMA fee. The 180-day supplement fee is 15 percent of the PMA fee. The real-time supplement fee is 7 percent of the PMA fee. The 30-day notice fee is 1.6 percent of the PMA fee. The premarket notification submission (510(k)) fee is 2 percent of the PMA fee. The request for classification information (513(g)) fee is 1.35 percent of the PMA fee, and the fee for periodic reporting concerning class III devices is 3.5 percent of the PMA fee. Qualified small businesses (an entity that reported $100,000,000 or less in gross receipts or sales in its most recent federal income tax return) pay 25 percent of the specified fee, except for 510(k)s, 30-day notices, and requests for classification for which they pay 50 percent of the specified rate. There is no small business rate for annual establishment registrations.[3]

[3] FDA published FY 2017 medical device user fee rates in the *Federal Register* on July 29, 2016 (81 FR 49987) https://www.gpo.gov/fdsys/pkg/FR-2016-07-29/pdf/2016-17903.pdf

Table 10 exhibits the rates for all fee types from FY 2008 through FY 2017.

TABLE 10: TRENDS IN MEDICAL DEVICE USER FEE RATES FOR STANDARD AND SMALL BUSINESS FEES FROM FISCAL YEARS 2008 TO 2017

	Full Fee Application	Panel Track Supplement	180-Day Supplement	Real-Time Supplement	510(k)	30-Day Notice	513(g) Request for Classification Information	Annual Fee for Class III Periodic Report	Annual Establishment Registration
FY 2008	$185,000	$138,750	$27,750	$12,950	$3,404	$2,960	$2,498	$6,475	$1,706
Small Business	*$46,250*	*$34,688*	*$6,938*	*$3,237*	*$1,702*	*$1,480*	*$1,249*	*$1,619*	*$1,706*
FY 2009	$200,725	$150,544	$30,109	$14,051	$3,693	$3,212	$2,710	$7,025	$1,851
Small Business	*$50,181*	*$37,636*	*$7,527*	*$3,513*	*$1,847*	*$1,606*	*$1,355*	*$1,756*	*$1,851*
FY 2010	$217,787	$163,340	$32,668	$15,245	$4,007	$3,485	$2,940	$7,623	$2,008
Small Business	*$54,447*	*$40,835*	*$8,167*	*$3,811*	*$2,004*	*$1,742*	*$1,470*	*$1,906*	*$2,008*
FY 2011	$236,298	$177,224	$35,445	$16,541	$4,348	$3,781	$3,190	$8,270	$2,179
Small Business	*$59,075*	*$44,306*	*$8,861*	*$4,135*	*$2,174*	*$1,890*	*$1,595*	*$2,068*	*$2,179*
FY 2012	$220,050	$165,038	$33,008	$15,404	$4,049	$3,521	$2,971	$7,702	$2,029
Small Business	*$55,013*	*$41,259*	*$8,252*	*$3,851*	*$2,024*	*$1,760*	*$1,485*	*$1,925*	*$2,029*
FY 2013	$248,000	$186,000	$37,200	$17,360	$4,960	$3,968	$3,348	$8,680	$2,575
Small Business	*$62,000*	*$46,500*	*$9,300*	*$4,340*	*$2,480*	*$1,984*	*$1,674*	*$2,170*	*$2,575*
FY 2014	$258,520	$193,890	$38,778	$18,096	$5,170	$4,136	$3,490	$9,048	$3,313
Small Business	*$64,630*	*$48,473*	*$9,695*	*$4,524*	*$2,585*	*$2,068*	*$1,745*	*$2,262*	*$3,313*
FY 2015	$250,895	$188,171	$37,634	$17,563	$5,018	$4,014	$3,387	$8,781	$3,646
Small Business	*$62,724*	*$47,043*	*$9,409*	*$4,391*	*$2,509*	*$2,007*	*$1,694*	*$2,195*	*$3,646*
FY 2016	$261,388	$196,041	$39,208	$18,297	$5,228	$4,182	$3,529	$9,149	$3,845
Small Business	*$65,347*	*$49,010*	*$9,802*	*$4,574*	*$2,614*	*$2,091*	*$1,765*	*$2,287*	*$3,845*
FY 2017	$234,459	$175,871	$35,174	$16,415	$4,690	$3,752	$3,166	$8,207	$3,382
Small Business	*$58,624*	*$43,968*	*$8,794*	*$4,104*	*$2,345*	*$1,876*	*$1,583*	*$2,052*	*$3,382*

Table 11 summarizes the number of applications received by FDA, from FY 2015 through FY 2017, where fees were paid in full before September 30, 2017.

TABLE 11: TRENDS IN MEDICAL DEVICE APPLICATIONS ASSOCIATED WITH USER FEES COLLECTED FROM FY 2015 TO FY 2017

Application Type	FY 2015	FY 2016	FY 2017
Full Fee Applications	42	37	40
Small Business	*7*	*10*	*7*
Panel Track Supplement	22	17	27
Small Business	*3*	*1*	*2*
180-Day Supplements	143	116	184
Small Business	*15*	*16*	*36*
Real-Time Supplements	204	179	195
Small Business	*28*	*27*	*20*
510(k)s	2,768	2,599	3,141
Small Business	*1,037*	*1,005*	*1,125*
30-Day Notice	920	929	1,080
Small Business	*71*	*76*	*82*
513(g) Request for Classification Information	75	68	98
Small Business	*33*	*46*	*41*
Annual Fee for Periodic Reporting	554	582	429
Small Business	*73*	*75*	*37*
Establishment Registration	25,363	26,046	27,268

The quantity of application fees received by FDA should not be used as a surrogate for medical device review workload. Many applications submitted to FDA are not charged fees by FDA, and therefore are not counted in Table 11, for the following reasons:

- first applications (PMAs and BLAs) submitted by small businesses (defined for these purposes as an entity that reported $30,000,000 or less in gross receipts or sales in its most recent federal income tax return);
- applications bundled under one fee because of similar medical device review issues;

- applications solely for pediatric indications;
- applications for original investigational device exemptions (IDEs) and IDE supplements;
- PMA supplements other than real-time and 180-day supplements;
- annual report submissions that must be examined;
- applications for Humanitarian Device Exemption (HDEs) submitted under section 520(m) of the FD&C Act;
- applications submitted under section 351 of the Public Health Service (PHS) Act for a product licensed for further manufacturing use only;
- applications submitted by a state or federal government entity for devices that are not intended for commercial distribution; and
- 510(k)s submitted to certified third-party reviewers, rather than to FDA.

MDUFA Waiver and Reduction History

MDUFA directs FDA to waive the first premarket application fee from a qualified small business and to reduce fees for subsequent applications from qualified small businesses in all categories except the annual establishment registration fee. In addition, MDUFA exempts applications submitted solely for pediatric indications from fees.

Table 12 summarizes the waivers and reductions granted by FDA for MDUFA fees payable in FY 2017, as well as the total value of each. Please note that the waivers and reductions listed below are for cohort year FY 2017 only.

TABLE 12: FY 2017 SMALL BUSINESS FEE WAIVERS AND REDUCTIONS GRANTED AS OF SEPTEMBER 30, 2017

Category	Number	Amount Reduced Per Fee	Total Value
Full Fees Waived	11	$234,495	$2,579,445
Full Fees Reduced	7	$175,871	$1,231,097
Panel Track Supplements Reduced	2	$131,903	$263,806
180-Day Supplements Reduced	36	$26,380	$949,680
Real-Time Supplements Reduced	20	$12,311	$246,220
510(k)s Fees Reduced	1,125	$2,345	$2,638,125
30-Day Notice Fees Reduced	82	$1,876	$153,832
513(g)s Fees Reduced	41	$1,583	$64,903
Annual Periodic Report Fees Reduced	37	$6,155	$227,735
Total	**1,361**		**$8,354,843**

Numbers have been rounded to the nearest dollar

In FY 2017, FDA waived 11 fees for first-time submissions of PMAs or BLAs, and waived or reduced 1,361 fees.

FDA collected $139,648,191 in fee revenue during FY 2017. Had there been no small-business waivers or reductions, FDA would have collected an additional $8,354,843 (i.e., an additional 6 percent of collections).

FDA received 5 HDE applications and 120 supplements in FY 2017 (which includes 77 30-day notices). None of these are subject to MDUFA fees. FDA does not know if any of these would have been submitted had they been subject to a fee, therefore the extent to which this exemption resulted in any loss of revenue is unknown.

CBER received two exemption requests in FY 2017 for applications submitted under section 351 of the PHS Act for a product licensed for further manufacturing use only.

FDA granted exemptions for state or federal government entities for products that were not intended for commercial distribution to 21 510(k)s and 1 Real-Time Supplement in FY 2017. The total value of these exemptions was $114,905.

FDA granted an exemption for pediatric indications in FY 2017 to 13 510(k)s, 1 30-Day Notice, and 1 Real-Time Supplement. The total value of these exemptions was $81,137.

FDA received 87 510(k) submissions subject to third-party review in FY 2017 compared to 80 in FY 2016, 85 in FY 2015, 84 in FY 2014, and 128 in FY 2013. FDA exempted fees for these 87 submissions. The total value of these exemptions in FY 2017 was $408,030, assuming that 26 percent (the same percent of total FY 2017 510(k)s submitted that paid the small business rate) of the third-party submissions would have paid the reduced small business fee.

Table 13 summarizes total waivers, reductions, and exemptions granted from FY 2008 to FY 2017 and the corresponding dollar values.

TABLE 13: TRENDS IN SMALL BUSINESS FEE WAIVERS AND REDUCTIONS GRANTED AS OF SEPTEMBER 30, 2017

Waivers, Reductions, and Exemptions	Value of Each Type of Fee Waiver, Reduction, and Exemption				Total Value of All Fee Waivers, Reductions, and Exemptions
	Small Business	Govt. Sponsored Application Not for Commercial Distribution	Pediatric Indications	510(k)s Subject to Third-Party Review	
FY 2008	$5,755,408	$34,558	$305,028	$1,225,760	$7,320,754
FY 2009	$7,738,614	$0	$259,709	$963,894	$8,962,217
FY 2010	$8,370,548	$0	$505,002	$831,015	$9,706,565
FY 2011	$7,126,657	$0	$8,696	$691,767	$7,827,120
FY 2012	$8,519,907	$688,493	$248,045	$708,575	$10,165,020
FY 2013	$10,060,368	$54,560	$4,960	$548,080	$10,667,968
FY 2014	$7,351,997	$56,870	$5,170	$378,968	$7,793,005
FY 2015	$6,131,015	$1,896,764	$920,788	$426,530	$9,375,097
FY 2016	$9,783,498	$98,286	$391,037	$418,240	$10,691,061
FY 2017	$8,354,843	$114,905	$81,137	$408,030	$8,958,915
Total	**$91,928,264**	**$2,979,246**	**$3,888,861**	**$9,371,066**	**$108,167,437**

Numbers have been rounded to the nearest dollar

4.3 – APPENDIX C: ALLOWABLE AND EXCLUDED COSTS FOR THE MDUFA PROGRAM

Introduction

The FD&C Act, as amended, defines the process for the review of device applications and the costs that may be included in that process. Fees may only be spent for activities that are included in this definition, although fee-generating activities are only a small subset of the activities that are included in this definition. Using the statutory definition and the methodologies described in Appendix D, the Agency identified those activities that were applicable to the MDUFA program.

MDUFA Program Costs

Included Activities

Section 737(8)(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:*

- 510(k)s -- Traditional/Supplements/Abbreviated/Specials (third-party and non-third-party);
- Evaluation of Automatic Class III Designations;
- Traditional and Priority Review PMAs (includes amendments, supplements, and annual reports);
- Modular PMAs (shell, modules, amendments, supplements, and annual reports);
- PDPs (including amendments, supplements, and annual reports);
- Premarket Reports (amendments, supplements, and annual reports);
- Reclassification Petitions;
- Class II Exemption Petitions;
- BLAs and BLA Supplements (applications subject to 351 of the PHS Act);
- Recruitment and use of outside experts during the review process;
- Obtaining advisory committee input (e.g., convened meetings, homework assignments);
- Resolution of product jurisdictional issues;
- Dispute resolution/appeals;
- IT support for review activities; and
- Recruitment of review staff.

Section 737(8)(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 issuance of deficiency letters, meetings with applicants to discuss such letters, and review of the responses.*

Section 737(8)(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 review of manufacturing information submitted in PMAs, pre-approval current good manufacturing practices (GMP) inspections, and resolution of any identified GMP issues.*

Section 737(8)(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:*

- conduct of bioresearch monitoring inspections (both "for cause" and pre-approval) of sponsors, institutional review boards, and clinical investigators;
- adverse event and complaint investigations related to ongoing clinical trials; and
- Good Laboratory Practice inspections (21 CFR Part 58).

Section 737(8)(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 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 review of the IDEs (original, amendments, and supplements) and INDs (amendments, supplements, and safety reports). Also included are pre-IDEs (review of the submission and any meetings or correspondence), significant/non-significant risk determinations, and Determination/Agreement meetings.*

Section 737(8)(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 development of device-specific, cross-cutting, special control, and program-related guidances as well as "Blue Book Memoranda" and Standard Operating Procedures.*

Section 737(8)(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(8)(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:

- informal consultation via phone, meetings, e-mail, and facsimile;
- meetings between FDA and applicants, such as pre-submission meetings, Determination/Agreement meetings, and meetings to discuss deficiencies in premarket applications;
- use of outside experts in the review of premarket applications;
- review of labeling prior to approval of a premarket application or supplement;
- FDA-sponsored conferences/workshops related to premarket submissions; and
- staff participation at non-FDA meetings related to such applications.

Section 737(8)(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 the review of requests for information submitted under section 513(g) and the "call" for PMAs for pre-amendment devices.*

Section 737(8)(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:*

- protocols for the post-market studies;
- modifications to such protocols;
- data collected under the protocol; and
- labeling changes (instructions for use, warnings, precautions, etc.), if needed as a result of the review of the data.

Section 737(8)(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:

- epidemiology studies; and
- post-marketing problem identification/resolution, including reports filed under the Medical Device Report regulation.

Training related to premarket and post-market approval activities*. This would include the following types of training:*

- scientific, clinical, and statistical training;

- managerial or other administrative training;
- policy/regulatory training;
- professional development (coursework, attendance at professional meetings, library resources);
- “Vendor Days;” and
- Site Visit Program for premarket reviewers.

User Fee Act implementation. *This would include activities such as:*

- guidance/regulation development;
- stakeholder outreach for educational and comment purposes;
- training of agency staff; and
- IT support for implementation.

All user-fee-related costs represented by the above activities are collectively referred to in this report as costs for the MDUFA program.

Section 737(9) 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:

A. officers and employees of FDA, FDA contractors, advisory committees, and costs related to such officers, employees, committees, and to contracts with such contractors;

B. management of information, and the acquisition, maintenance, and repair of computer resources;

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

D. collecting user fees and accounting for resources allocated for the review of premarket applications, premarket reports, supplements, and submissions.

Excluded Activities

- enforcement policy and regulation development;
- third-party inspection program;
- 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;
- 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 (MQSA), radiation safety authorities of the FD&C Act (sections 531 et seq.), and the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

4.4 – APPENDIX D: DEVELOPMENT OF COSTS FOR THE MDUFA PROGRAM

General Methodology

The costs associated with the MDUFA program are based on obligations attributed to CDRH, CBER, ORA, and HQ. These organizations correspond to the cost categories presented as follows:

Cost Category	FDA Organization
Costs for the Review of PMAs, PDPs, PMRs, Modular PMAs, Supplements, and 510(k)s	CDRH
Costs for the Review of BLAs, PMAs, Modular PMAs, Supplements, and 510(k)s	CBER
Field Inspection and Investigation Costs	ORA
Agency General and Administrative Costs	HQ

The costs for each component are shown in Table 6. They were derived using time-reporting systems in CDRH, CBER, and ORA, and were calculated for HQ as described in more detail in this appendix. Using the definitions of costs and activities included in the MDUFA program, as explained in the discussion in Appendix C, the cost categories within each organization listed above were identified as parts of the medical device review process.

Center Costs

Costs of the MDUFA program are tracked for each organizational component in CDRH and CBER, usually at the division level. Most FDA components involved in the MDUFA program perform a mixture of activities – some within the scope of the MDUFA program, and some not. FDA groups its organizational components into three categories:

- direct review and laboratory
- indirect review and support
- Center-wide costs

The allocation of costs for each category is discussed below.

Direct Review and Laboratory

Employees in all components of CDRH and CBER, other than those noted below as Center indirect review and support components, reported their time in activities that could be used to differentiate between time spent on the MDUFA program and all other time.

Both CDRH and CBER have existing time-reporting systems in place. These time-reporting systems were modified after the enactment of MDUFA, and over the years when necessary, so that time could be reported in categories that could be separated into allowable and excluded

activities with respect to the MDUFA program, as defined in MDUFA and as further defined in Appendix C.

The percent of time reported as having been expended on allowable device review process activities for each cost-center (usually an organization component at the Division level) is then applied to all costs incurred for that cost-center for the entire fiscal year.

In 2013, CDRH updated the majority of its time reporting codes to better align with the new workload outlined in MDUFA III. The new codes reflect areas of interest to the medical device industry and other stakeholders. In addition to these updates, CDRH refined codes to better reflect the included activities for the MDUFA program. After this update, CDRH conducted its time reporting survey for a 2-week period during each quarter of the fiscal year. The costs of the medical device review program presented in this report are based on the updated time reporting codes.

A similar procedure is used in CBER to measure the direct review and laboratory components costs for the device review process. CBER's process for determining allowable and excluded costs for MDUFA direct review and laboratory costs is identical to how CBER determines costs for the process for the review of human drug applications. CBER uses the time-reporting system it has had in place for over 10 years prior to the enactment of MDUFA, and which was validated by studies done prior to, and after, the Prescription Drug User Fee Act (PDUFA) was enacted in 1992. That system collects time reports from all employees other than management and administrative support personnel for a 2-week period during each quarter of the fiscal year. This process was validated by Arthur Andersen, LLP under PDUFA for 1992 and 1993.

CBER's existing time-reporting system was also modified to ensure that activities against which time was reported could be clearly divided into activities that were either allowable or excluded in the MDUFA-defined process for device application review. The results from each 2-week period are extrapolated for the quarter being reported. The extrapolated results for each quarter are averaged to estimate the full year costs.

Indirect Review and Support

Indirect review and support components provide the infrastructure for the review process. In CDRH, these are the Office of the Center Director and the Office of Management and Operations. In CBER, these components include the Office of the Center Director, Office of Management, and the Office of Communications, Outreach, and Development.

In both CDRH and CBER, the allowable costs for these indirect review and support components were determined by multiplying the average percent of allowable costs for all direct review and laboratory components by the total costs of each of these indirect review and support components.

Center-Wide Costs

A number of Center-wide and Agency-wide expenses are paid from the central accounts of the Center or of FDA rather than from funds allocated to a specific Center or division or office within the Center. These costs include rent, telecommunications and utility costs, some computer equipment and support costs, and costs of the Office of Shared Services, which supports all FDA programs and activities. A percentage of these Center and FDA-wide costs are chargeable to the MDUFA program. That percentage is a specific amount that either is

supported by independent documentation or is the amount of time reported for allowable activities (direct and indirect) in the Center, as a percentage of total time reported for all Center direct and indirect activities.

As in prior years, resources expended in FY 2017 by the Office of Shared Services in supporting the MDUFA program are reported as if they were incurred in CDRH, CBER, ORA, or HQ.

Field Inspection and Investigation Costs

ORA incurs all field inspection, investigation, and laboratory analyses costs. ORA costs are incurred in both district offices (the "field") and HQ offices, which are tracked in the Field Accomplishment and Compliance Tracking System (FACTS). FACTS is a time and activity tracking system that captures time spent in a variety of categories, including pre-approval inspections of manufacturing facilities, investigations of clinical studies, and analytical testing of samples, which are all part of the MDUFA program.

Table 14 summarizes the calculation of ORA costs for the MDUFA program for FY 2016 and FY 2017, including costs paid from non-user fee appropriations and costs paid from fee revenues.

Total direct hours reported in FACTS are used to calculate the total number of FTEs required by ORA to perform these activities. In addition to the direct time, an allocation of support time is also included to represent the work done by ORA administrative and management personnel.

The Agency multiplies the total number of FTEs used in the MDUFA program by the average salary and benefits cost in ORA to arrive at ORA salary and benefit costs for work that is within the scope of the MDUFA program. The Agency then allocates ORA obligations for operations and other costs to the medical device review activities based upon the ratio of user-fee-related FTEs to total ORA FTEs.

TABLE 14: OFFICE OF REGULATORY AFFAIRS COSTS OF THE MDUFA PROGRAM AS OF SEPTEMBER 30, 2016 AND 2017

Cost Component	FY 2016	FY 2017
FTE Utilized	59	66
ORA Average Salary and Benefits	$124,404	$128,889
Total Salary and Benefits	$7,339,836	$8,455,118
Operating and Other Costs[4]	$6,300,252	$7,753,885
Total	**$13,640,088**	**$16,209,003**

Numbers have been rounded to the nearest dollar

[4] Other costs are central, GSA, rent, rent-related, and Shared Services costs that are applicable to the MDUFA program.

Agency General and Administrative Costs

The Agency general and administrative costs include all costs incurred in FDA's HQ that are attributable to the Office of the Commissioner and all other FDA headquarters components that are not Centers or ORA. For the purpose of these calculations, HQ is considered to comprise the following offices:

- Immediate Office of the Commissioner
- Office of the Counselor to the Commissioner
- Office of Policy, Planning, Legislation, and Analysis
- Office of External Affairs
- Office of the Executive Secretariat
- Office of the Chief Counsel
- Office of Minority Health
- Office of Women's Health
- Office of the Chief Scientist (excluding the National Center for Toxicological Research)
- Office of Operations
- Office of Foods and Veterinary Medicine (excluding the Center for Food Safety and Applied Nutrition and the Center for Veterinary Medicine)
- Office of Medical Products and Tobacco (excluding the Center for Drug Evaluation and Research, CBER, CDRH, and the Center for Tobacco Products)
- Office of Global Regulatory Operations and Policy (excluding ORA)
- Office of Laboratory Science and Safety

In summary, the HQ costs include all of FDA except for the six product-oriented Centers, ORA, and the National Center for Toxicological Research.

The HQ costs applicable to the MDUFA program were calculated using a method prescribed by the Division of Cost Determination Management, Office of Finance, Office of the Secretary, Department of Health and Human Services. The method uses the percentage derived by dividing total HQ costs by the total FDA salary expenses (excluding benefits) after subtracting the salary expense (excluding benefits) from HQ. That percentage is then multiplied by the total salaries (excluding benefits) applicable to the MDUFA program in CDRH, CBER, and ORA to derive the applicable Agency general and administrative costs.

Using this methodology, FDA dedicated $33,329,390 in general and administrative costs to the MDUFA program in FY 2017. The costs are total costs obligated from non-user fee appropriations and user fees and are approximately 9 percent of the total costs of the MDUFA program in FY 2017.