



THE SECRETARY OF HEALTH AND HUMAN SERVICES  
WASHINGTON, D.C. 20201

May 27, 2011

The Honorable Joseph R. Biden, Jr.  
President  
United States Senate  
Washington, DC 20510

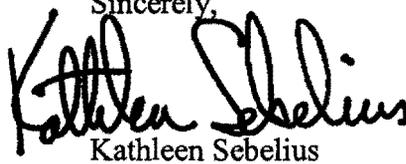
Dear Mr. President:

The Medical Device User Fee and Modernization Act (MDUFMA) of 2002, as amended, requires the Food and Drug Administration (FDA) to report annually on the financial aspects of its implementation of the MDUFMA. Please find enclosed the Fiscal Year (FY) 2010 report which documents how FDA has met each of the necessary conditions specified in MDUFMA allowing FDA to continue collection of device user fees.

In addition to presenting the user fee collections and related expenses for FY 2010, this report also details the amounts carried forward at the end of the year, which remain available for use in enhancing the process for the review of device applications. In FY 2010, FDA had net collections in medical device user fees of \$63.5 million. Approximately 55 percent of appropriated fee collections are spent on personnel compensation and benefits for staff. The remaining 45 percent was spent for other operational expenses, including operating support for personnel engaged in the process for the review of device applications and infrastructure for the device review process.

Availability of these fee collections enables FDA to strengthen its device review process and meet the performance goals established for this program.

Sincerely,

  
Kathleen Sebelius

Enclosure

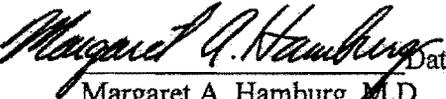
# FY 2010 MDUFMA FINANCIAL REPORT

REQUIRED BY THE

## MEDICAL DEVICE USER FEE AND MODERNIZATION ACT OF 2002

As Amended

FOOD AND DRUG ADMINISTRATION  
DEPARTMENT OF HEALTH AND HUMAN SERVICES

 Date: MAY 24 2011  
Margaret A. Hamburg, M.D.  
Commissioner of Food and Drugs

## EXECUTIVE SUMMARY

The Medical Device User Fee and Modernization Act (MDUFMA) of 2002, as amended, requires the Food and Drug Administration (FDA) to report annually on the financial aspects of its implementation of MDUFMA. This is the annual financial report to Congress that covers activities for fiscal year (FY) 2010.

MDUFMA, as amended, specifies that three conditions must be satisfied in order for FDA to collect and spend MDUFMA fees each year:

1. Within FDA's salaries and expenses appropriation, the amount appropriated for devices and radiological health, excluding fees, each year must be at least \$205,720,000, multiplied by an adjustment factor specified in MDUFMA.
2. The fee amounts that FDA can collect must be specified in the appropriation Acts.
3. FDA must spend at least as much from appropriated funds, exclusive of user fees, for the review of medical device applications as it spent in FY 2002, multiplied by the adjustment factor specified in MDUFMA.

MDUFMA also contains a provision that FDA must spend at least as much on medical device inspections as it spent in FY 2002, increased by five percent in each fiscal year.

This report explains how FDA met the statutory conditions in FY 2010, and also provides information on user fee collections, expenditures, and carryover balances. In FY 2010, FDA net collections totaled \$63.5 million from fees. FDA obligated \$57.1 million from MDUFMA collections to support FDA's medical device review program. FDA carried forward into FY 2011 a balance of \$44.2 million—about \$6.5 million more than the carryover balance brought forward into FY 2010. (It was expected that carryover balances would grow through 2010, and be drawn down in the final two years of the program (2011-2012).) About 55 percent of the total expenses for the medical device review program in FY 2010 were for employee pay and benefit costs. The remaining 45 percent was spent on operating and infrastructure costs necessary to support the medical device review program.

MDUFMA fees, along with the increased appropriations from Congress, enabled FDA to dedicate 400 more full-time equivalents (FTEs) to the medical device review program in FY 2010 than the 829 FTE used in FY 2002—the year before MDUFMA was enacted. An additional 77 contractor staff-years were also dedicated to the device review program in FY 2010 compared with FY 2002. These resources have enabled FDA to achieve most of the performance goals associated with the enactment of MDUFMA and strengthen FDA's medical device review program.

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## BACKGROUND

MDUFMA authorized FDA to collect fees from the medical device industry to augment appropriated funds for the medical device review process from FY 2003 through FY 2007. MDUFMA also required increasing funding from appropriations each year. FDA used the additional funds from fees and appropriations to support the process for the review of medical device applications as defined in MDUFMA, so that safe and effective devices reached the American public more quickly.

The Medical Device User Fee Amendments of FY 2007 (Title II of the Food and Drug Administration Amendments Act (FDAAA) of 2007) amended MDUFMA and extended its authorization for an additional five years, through FY 2012. This reauthorization is referred to as MDUFMA II.

Under MDUFMA II, companies must pay application fees when submitting certain device applications to FDA. Fee-paying applications include premarket applications (PMAs); 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). In addition, under MDUFMA II, 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 fees for a PMA and for device establishment registration are specified in the statute for each year through FY 2012. Fees for other application types and for periodic reports are fixed in statute as a percent of the PMA fee for each year. Each year in August, FDA publishes all fee rates for the next fiscal year based on the percentages specified in the statute.

MDUFMA requires FDA to submit two reports to Congress each fiscal year: 1) a performance report is to be sent within 120 days after the end of each fiscal year; and 2) a financial report is also to be sent within 120 days after the end of each fiscal year. FDA is separately transmitting the FY 2010 MDUFMA Performance Report that discusses FDA's progress in meeting the goals referred to in MDUFMA. This report is FDA's FY 2010 MDUFMA Financial Report covering the period October 1, 2009 through September 30, 2010.

As required by MDUFMA, this report presents the statutory conditions or "triggers" that must be satisfied as a condition for FDA to be able to collect and spend the fees, and explains how they were met in FY 2010. This report describes the process for the review of medical device applications, as defined in MDUFMA, and provides the total costs of this process in FY 2010, including costs paid from both fee collections and appropriations. The report also presents the FY 2010 fee collections, obligations, and carryover balances.

**MEETING THE STATUTORY CONDITIONS FOR  
USER FEES IN FY 2010**

MDUFMA imposes three statutory conditions that FDA must satisfy before it can collect and spend user fees. FDA's calculations show that FDA met these conditions in FY 2010, as summarized below.

The **first condition** is a funding condition that affects FDA's fee collections in FY 2010. MDUFMA, as amended, specifies a minimum amount that must be appropriated for the Device and Radiological Health line of FDA's appropriation, exclusive of user fees, for each year. For FY 2010, that minimum amount is \$250,722,000 (rounded to the nearest whole thousand dollars). In FY 2010, the final appropriation for the Device and Radiological Health line of FDA's appropriation, exclusive of user fees, was \$315,377,000. Therefore, FDA met the first condition.

The **second condition** is that the amount of user fees collected by FDA in each fiscal year must be specifically stated in the Appropriations Acts. The President signed the FY 2010 Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriation Act, Public Law 111-80, on October 21, 2009. It states that the amount collectable from medical device user fees is \$57,014,000. Therefore, FDA met the second condition.

The **third condition** is that user fees may only be retained and spent in years when FDA also spends a specified minimum level of appropriated funds, exclusive of user fees, for the review of medical device applications. The minimum level is the appropriations that FDA spent on the process for the review of medical device applications in FY 2002, multiplied by an adjustment factor. That adjusted minimum level for FY 2010 is \$145,852,218. FDA obligated \$235,520,440 from appropriations, exclusive of user fees, in FY 2010 on the process for the review of device applications as defined in MDUFMA. Because FDA spent more than the specified minimum level, FDA met the third condition.

MDUFMA also contains a provision that FDA obligations for medical device establishment inspections must be equal to or greater than the amount spent in FY 2002, increased by five percent each fiscal year. If this condition is not met for two consecutive years, FDA is not allowed to use accredited third parties to conduct certain medical device establishment inspections in the future years. Because spending on medical device establishment inspections exceeded the specified minimum level for each of the most recent two fiscal years, FDA may continue to permit accredited third parties to conduct certain medical device establishment inspections in future years.

Additional details on the calculations that show that FDA satisfied these statutory conditions are provided in Appendix A.

## USER FEE COLLECTIONS

MDUFMA directs FDA to receive fees from medical device applications as well as annual establishment registration fees and periodic report fees through FY 2012. The statute directs FDA to set the fee rate for each application type and for periodic reports as a percentage of the standard fee for a PMA. For FY 2010, MDUFMA II specifies that the standard fee for a PMA is \$217,787 and that the device establishment fee is \$2,008. FDA then sets the other fees based on the percentages specified in the statute.<sup>1</sup>

Under MDUFMA, medical device user fees continue to remain available to FDA for use in future years for the medical device review process if they are not obligated at the end of the fiscal year. Cash balances carried to the next fiscal year are provided in table 3 on page 5, in the section CARRYOVER BALANCES. Table 1 shows the amount of user fees FDA has collected over the most recent two fiscal years.

**TABLE 1  
STATEMENT OF MEDICAL DEVICE FEE COLLECTIONS  
AS OF SEPTEMBER 30, 2010**

	FY 2009	FY 2010
Total Fees Collected	\$59,731,482	\$66,949,587
Unearned Fees <sup>1</sup>	\$3,379,163	\$3,794,403
Fees Receivable	\$1,564,873	\$204,011

<sup>1</sup>Unearned Fees are fees collected for applications that had not been received by FDA as of September 30, 2010 or for FY 2010 establishment fees received without identification of the remitter. They are included above in the 'Total Fees Collected' amounts.

Note that user fees collected (the first line in table 1) are initially credited to the year the fee is received. However, the revenues may be reassigned to the year the application is received, if that is different. This is referred to as the cohort year. Last year's report showed \$62,011,733 of fees collected in FY 2009, of which \$5,610,279 was shown as "unearned income" since the application for which the fee was paid had not been received by the end of FY 2009. The FY 2009 total fees collected line is decreased to \$59,731,482 in this report, and all but \$3,379,163 of the unearned income reported last year has now been either refunded or credited to the year the application was actually received.

The total fees collected line for FY 2010, when seen in next year's FY 2011 report, will also be different than the figure shown here—reflecting both the refund or reassignment of unearned income, and the refunds that will be made over the next 12 months. Totals reported for each year are net of any refunds for that year, as of September 30, but do not take into account any refunds that may be made after September 30. Information on the number of each type of fee received in FY 2010 is contained in Appendix B.

A summary of FY 2010 waivers, reductions, and exemptions is provided in Appendix C.

<sup>1</sup> FDA published FY 2010 medical device user fee rates in a Federal Register Notice on July 29, 2009. The specific fees for FY 2010 are found in Appendix B, on page B-1.

## OBLIGATION OF USER FEE COLLECTIONS

The user fees collected are expended only for costs necessary to support the process for the review of medical device applications, as defined in MDUFMA. The allowable and excludable costs for the process for the review of medical device applications are defined in Appendix D. As shown in the table 2, FDA obligated \$57,187,100 from medical device user fees in FY 2010. Table 2 provides a breakout of user fee obligations by expense category.

**TABLE 2**  
**FY 2010 MEDICAL DEVICE USER FEE OBLIGATIONS BY EXPENSE CATEGORY**  
**AS OF SEPTEMBER 30, 2010**

<b>Expense Category</b>	<b>FY 2009</b>	<b>FY 2010</b>
Personnel Compensation and Benefits	\$31,601,700	\$40,825,395
Travel and Transportation	\$411,743	\$418,913
GSA Rent	\$2,056,920	\$2,446,935
Communications	\$221,797	\$256,820
Contract Services	\$10,094,444	\$12,145,166
Equipment and Supplies	\$2,792,848	\$982,624
Other <sup>1</sup>	\$123,292	\$111,247
<b>Total Obligations</b>	<b>\$47,302,744</b>	<b>\$57,187,100</b>

<sup>1</sup>Other includes expense categories like printing & reproduction, and other miscellaneous expenses.

More information about the costs of the process for device review, as defined in MDUFMA, begins on page 7.

## CARRYOVER BALANCES

Under MDUFMA, fees collected, appropriated, and not obligated by the end of a fiscal year remain available to FDA for future fiscal years. They are referred to as carryover balances. Operations in FY 2010 resulted in an increase of carryover balances of \$6,350,642, and increased the net carryover balance from \$37,886,475 to \$44,237,117 by the end of the year.

Table 3 captures FDA's carryover balances at the beginning of each fiscal year since the beginning of MDUFMA in FY 2003.

**TABLE 3**  
**STATEMENT OF CASH, OBLIGATIONS, AND**  
**CARRYOVER BALANCES BY FISCAL YEAR**  
**AS OF SEPTEMBER 30 OF EACH FISCAL YEAR**

<b>Fiscal Year</b>	<b>Beginning Carryover</b>	<b>Net Cash</b>	<b>Obligations</b>	<b>Year-End Carryover</b>
<b>2003</b>	-	\$21,936,910	\$14,837,600	\$7,099,310
<b>2004</b>	\$7,099,310	\$26,828,534	\$23,875,200	\$10,052,644
<b>2005</b>	\$10,052,644	\$31,102,864	\$27,171,400	\$13,984,108
<b>2006</b>	\$13,984,108	\$34,325,120	\$32,068,610	\$16,240,618
<b>2007</b>	\$16,240,618	\$29,824,954	\$35,202,700	\$10,862,872
<b>2008</b>	\$10,862,872	\$48,956,327	\$36,422,900	\$23,396,299
<b>2009</b>	\$23,396,299	\$61,792,920	\$47,302,744	\$37,886,475
<b>2010</b>	\$37,886,475	\$63,537,742	\$57,187,100	\$44,237,117
<b>2011</b>	\$44,237,117			

The carryover balances in table 3 reflect the cumulative cash from the beginning to the end of each fiscal year, the net cash collected, and any refunds or other adjustments that occurred during each fiscal year. The net cash amount for FY 2010 is different from the fees credited to FY 2010, shown on page 3. The reason for this is that some of the cash collected in FY 2010 was for fees owed from previous years. Net cash also reflects all refunds processed in FY 2010 even if the fee was paid in a previous fiscal year.

**FEE AMOUNTS APPROPRIATED, FEES COLLECTED, AND DIFFERENCES**

Under MDUFMA II, if cumulative collections through FY 2010 and estimated collections for FY 2011 exceed cumulative fees authorized to be appropriated for the same period, FDA will reduce fees when fees are set for FY 2012 by the cumulative amount by which fees collected over this period exceed fees authorized to be appropriated over the same period. Table 4 provides annual cumulative net collections, collection ceilings (appropriated amount of fees that may be collected each year), and differences through the end of FY 2010.

**TABLE 4  
STATEMENT OF FEES APPROPRIATED, FEES COLLECTED, AND DIFFERENCES  
AS OF SEPTEMBER 30, 2010**

<b>Fiscal Year</b>	<b>Fees Appropriated</b>	<b>Fees Collected</b>	<b>Differences</b>
2003	\$25,125,000	\$21,620,549	(\$3,504,451)
2004	\$31,654,000	\$26,280,073	(\$5,373,927)
2005	\$33,938,000	\$31,817,879	(\$2,120,121)
2006	\$40,300,000	\$35,059,601	(\$5,240,399)
2007	\$43,726,000	\$28,726,239	(\$14,999,761)
<b>MDUFMA I Total</b>	<b>\$174,743,000</b>	<b>\$143,504,341</b>	<b>(\$31,238,659)</b>
2008	\$48,431,000	\$49,314,691	\$883,691
2009	\$52,547,000	\$59,731,482	\$7,184,482
2010	\$57,014,000	\$66,949,587	\$9,935,587
<b>MDUFMA II Total</b>	<b>\$157,992,000</b>	<b>\$175,995,760</b>	<b>\$18,003,760</b>

As table 4 shows, the total amount of fees collected for each year of MDUFMA I fell short of the amount appropriated every year. In FY 2010, for the third consecutive year under MDUFMA II, fees collected exceeded the appropriation, by a total of \$9,935,587. Amounts collected in excess of appropriations for FY 2008 through FY 2010 total \$18,003,760. Cumulative excess collections from FY 2008 through 2010, and estimated collections for FY 2011, if positive, would offset (reduce) fee amounts when they are set for FY 2012.

**AVAILABILITY OF CARRYOVER BALANCES**

The total amount that FDA has collected from 2008 through 2010 that exceeds the amounts appropriated in each year, as shown on the last line of table 4 is \$18,003,760. Of this, \$8,491,930 is considered unearned revenue, which FDA is unable to obligate or offset until applications are submitted pertaining to these funds. For this reason the total amount of funds collected in excess of appropriations that can be subject to the offset provision is \$9,511,830.

FDA also holds \$1,000,000 in reserve for potential refunds in future years. In addition, MDUFMA requires FDA to have at least one month of operating funds from fees in reserve at the end of each fiscal year for use at the beginning of the next fiscal year. All three of these amounts must be held in reserve and are not available for allocation. Table 5 shows the amounts of carryover that must be held in reserve and the amount, \$19,757,062, available for allocation in subsequent fiscal years. (MDUFMA II anticipated a growing carryover balance through FY 2010, which would then be drawn down in the final two years.)

**TABLE 5  
MEDICAL DEVICE FEE REVENUE CARRYOVER BALANCE  
AS OF SEPTEMBER 30, 2010**

Status of Carryover Funds	Amount
Unearned Revenue/Excess Collections	\$18,003,760
Reserve for Future Refunds	\$1,000,000
1-Month Reserve for Next Fiscal Year	\$5,476,295
Available Cash for Allocation in future	\$19,757,062
<b>Total Carryover Balance</b>	

**TOTAL COSTS OF THE PROCESS FOR THE  
REVIEW OF MEDICAL DEVICE APPLICATIONS**

FDA uses data from time reporting surveys conducted during four two-week periods each fiscal year to determine the percent of cost of each organizational component devoted to activities included in the process for the review of device applications, as defined in MDUFMA. See Appendix D for the descriptions of the allowable activities and Appendix E for more detail on how FDA develops the costs of the process for the review of medical device applications.

Table 6 presents the total costs for the review of medical device applications for FY 2009 and FY 2010, by FDA organizational components and by source of funds (appropriations and user fee collections). The amounts are based upon obligations recorded as of the end of each fiscal year. In the past, over 81 percent of obligated funds in FDA were expended within one year, and 96 percent within two years. Thus, obligations represent an accurate measure of costs.

**TABLE 6  
PROCESS FOR THE REVIEW OF MEDICAL DEVICE APPLICATIONS  
TOTAL COSTS BY COMPONENTS AND FUNDS  
AS OF SEPTEMBER 30, 2010**

FDA Organizational Component	FY 2009	FY 2010
Center for Devices and Radiological Health	\$ 212,217,413	\$ 224,106,088
Center for Biologics Evaluation and Research	\$ 29,121,473	\$ 30,132,907
Field Inspection and Investigation	\$ 10,747,226	\$ 13,893,434
Agency General and Administrative Costs	\$ 18,762,325	\$ 24,575,111
Total Process Costs	\$270,848,437	\$292,707,540
Obligations from Appropriations	\$223,545,693	\$235,520,440
Obligations from Medical Device User Fee Collections	\$47,302,744	\$57,187,100

The costs for all components increased in FY 2010. The overall increase reflects both the increase in costs for pay and support for other areas, and an increase in the total number of FTEs devoted to the process for the review of medical devices in FY 2010.

**FULL TIME EQUIVALENTS (FTEs)**

Table 7 presents FTE levels that support the medical device application review process by FDA organizational component. This is a measure of paid staff years devoted to device review. In FY 2010, FDA spent about 55 percent of its total funds for the salaries and benefits of the medical device review process FTEs, and the balance of the funds went for support of these employees.

**TABLE 7  
PROCESS FOR THE REVIEW OF MEDICAL DEVICE APPLICATIONS  
TOTAL FTEs  
AS OF SEPTEMBER 30, 2010**

Organization	Fiscal Year	FTE Used Each Year						
		2004	2005	2006	2007	2008	2009	2010
Center for Devices and Radiological Health (CDRH)		713	794	765	806	843	853	949
Center for Biologics Evaluation and Research (CBER)		70	87	108	105	109	109	120
Office of Regulatory Affairs (ORA)		60	64	65	68	66	60	72
Office of the Commissioner (OC)		72	89	82	92	77	87	89
<b>Total FTE</b>		<b>915</b>	<b>1,034</b>	<b>1,020</b>	<b>1,071</b>	<b>1,095</b>	<b>1,109</b>	<b>1,230</b>

FTE numbers in table 7 show CDRH, CBER, and ORA staff transferred to the consolidated shared-services organization in OC as if they were still in CDRH, CBER, and ORA.

In FY 2010 the medical device program experienced its largest increase in FTEs since FY 2005. The CDRH FTEs increased by 11 percent (853 to 949) in FY 2010 while the CBER FTE showed a 12 percent increase (109 to 120).

In addition to the FTE numbers shown in table 7, CDRH also expended 77 more contractor staff-years on the medical device review process in FY 2010 than it did in FY 2002.

## MANAGEMENT CHALLENGES FOR FY 2011

On September 27, 2007, the President signed the Food and Drug Administration Amendments Act of 2007 (FDAAA). Title II of FDAAA, the Medical Device User Fee Amendments of 2007, reauthorizes medical device user fees for FY 2008 through FY 2012 (MDUFMA II). MDUFMA II calls for a new set of challenging performance goals and a new fee structure.

FDA will continue to monitor performance against the goals for the MDUFMA I cohorts that remain open (FY 2004 through FY 2007; the FY 2003 cohort is now closed) and against the new performance goals of MDUFMA II.

The performance goals for applications filed or accepted from FY 2008 through FY 2012 are defined in a September 27, 2007, letter from former HHS Secretary Michael O. Leavitt to Congress; see the following table for a summary of these goals.

Medical Device Review Performance Goals for FY 2008 through FY 2012			
Application Type	Type of Goal	Review Time Goal	Performance Goal
Premarket approval application (PMA), panel-track PMA supplement, premarket report	FDA Decision	180 days	60%
		295 days	90%
Expedited PMA, expedited panel-track PMA supplement	FDA Decision	180 days	50%
		280 days	90%
PMA module	FDA Action	90 days	75%
		120 days	90%
180-day PMA supplement	FDA Decision	180 days	85%
		210 days	95%

Real-time PMA supplement	FDA Decision	60 days	80%
		90 days	90%
510(k) premarket notification	Substantially Equivalent (SE) or Not Substantially Equivalent (NSE) Decision	90 days	90%
		150 days	98%

An "FDA Decision" is any of the following: an approvable letter (including approvable pending GMP inspection), a non-approvable letter, a withdrawal, or a denial order.

An "FDA Action" on a PMA module is any of the following: accepting the module, a request for additional information, receipt of the PMA, or withdrawal of the module.

These goals are structured in ways that differ from the goals for FY 2003 through FY 2007:

- The FY 2008 – FY 2012 goals do not vary from one fiscal year to the next. Instead, each goal will apply throughout the five years from FY 2008 through FY 2012.
- Except for PMA modules, all of FDA's performance goals focus on making an "FDA decision" and FDA will not have any cycle goals. PMA decisions are approval, approvable, approvable pending Good Manufacturing Practices (GMP) inspection, not approvable, withdrawal, and denial. 510(k) decisions are substantially equivalent (SE) or not substantially equivalent (NSE).
- For PMA modules only, FDA's performance goals focus on FDA taking an "action" on the module. An "FDA action" on a PMA module is any of the following: accepting the module, a request for additional information, receipt of the PMA, or withdrawal of the module. PMA modules are not subject to a decision goal, because the modular submission is converted to a PMA upon submission of the final module.
- Each goal has two tiers, and all submissions are measured in both tiers. Compared with the lower tier, the upper tier of each goal provides for additional review time, but requires a higher percentage of reviews to have an FDA decision (or, in the case of PMA modules, an FDA action) within the specified review time. The use of two tiers helps ensure that FDA focuses on all applications within a cohort, rather than just those that are most likely to reach an FDA decision quickly.

FDA is also working diligently to implement key provisions of FDAAA by developing and promulgating regulations. FDA is developing —

- a proposed rule amending 21 Code of Federal Regulations (CFR) Part 807 to require medical device establishments to register and list by electronic means, during the period 10/1 through 12/31 each year, and
- a rule amending 21 CFR Part 814 to implement section 515A of the FD&C Act, concerning pediatric uses of devices.

In addition, FDA is gathering data and comments to help develop a rule providing for a unique device identification system, as required by section 519(f) of the FD&C Act.

These actions will strengthen FDA's ability to meet its regulatory responsibilities and public health missions.

STATUTORY CONDITIONS FOR COLLECTION AND USE OF FEES

The FD&C Act was amended by MDUFMA (Public Law 107-250), by the Medical Device User Fee and Stabilization Act (MDUFSA, Public Law 109-43), and by MDUFMA II (Public Law 110-85). It specifies three statutory conditions that must be satisfied before FDA can collect and spend medical device user fees. A summary of these conditions is introduced on page 2. Appendix A describes each of the conditions and explains in more detail how FDA met the conditions in FY 2010.

In order to determine whether the statutory conditions are satisfied, FDA must calculate and apply an adjustment factor, defined in section 737(10) of the FD&C Act, as amended, in the assessments of the first and third conditions. The FD&C Act defines the term “adjustment factor” as follows:

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 2001.

The October preceding FY 2010, which began on October 1, 2009, was October 2008. The Consumer Price Index (CPI) for October 2008 was 216.573. The CPI for October 2001 was 177.7. Dividing the CPI of October 2008 by the CPI of October 2001 yields an adjustment factor of 1.218756 (rounded to 6 decimal places) for FY 2010.

The **first condition** is a funding condition that affects the collection of fees in FY 2010 and is found in section 738(g)(1) of the FD&C Act.

This provision specifies a minimum amount of budget authority that must be appropriated each year for the Device and Radiological Health line of FDA’s appropriation, exclusive of user fees. That minimum amount for FY 2010 is \$205,720,000 multiplied by the adjustment factor (1.218756), or \$250,722,000 (rounded to the nearest thousand dollars). In FY 2010, the final appropriated budget authority for the Device and Radiological Health line of FDA’s Appropriation, exclusive of user fees, was \$315,377,000. This is the amount of appropriations for the Devices and Radiological Health line from P.L. 111-80, exclusive of user fees. Since this amount is greater than \$250,722,000, FDA’s appropriation for FY 2010 met the first condition.

The **second condition** comes from section 738(h)(2)(A)(i) of the FD&C Act. It states that fees “shall be retained 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 second condition means FDA cannot obligate user fees in excess of appropriations; fees collected during MDUFMA II that exceed cumulative fee appropriations are subject to the offset provision of section 738(h)(4) of the FD&C Act.

On October 21, 2009, the President signed the FY 2010 Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriation Act, Public Law 111-80, which appropriated \$57,014,000 from medical device user fees for FDA in FY 2010. Therefore, the second condition was met.

The **third condition** requires a minimum spending from appropriations, exclusive of user fees, on the process for medical device review as defined in MDUFMA. This condition, in section 738(h)(2)(A)(ii) of the FD&C Act, states that fees:

shall only be collected and 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 2002 multiplied by the adjustment factor.

In FY 2002, FDA's obligations for the process for the review of medical device applications totaled \$119,673,026, as reported in the FY 2003 MDUFMA Financial Report. The adjustment factor for FY 2010 is 1.218756. Multiplying by the adjustment factor, FDA calculates the minimum spending from appropriations for the medical device review process in FY 2010 must be at least \$145,852,218.

As this report documents, FDA obligated \$235,520,440 from appropriations, exclusive of user fees, for the process for the review of medical device applications in FY 2010. Since this amount is greater than the minimum spending from appropriations required under MDUFMA, FDA met the third condition.

Table 8 shows FDA obligations for the process for the review of medical device applications in FY 2009 and FY 2010. The table separates the obligations that were funded by appropriations and user fees.

**TABLE 8**  
**OBLIGATIONS FOR THE PROCESS FOR THE REVIEW**  
**OF MEDICAL DEVICE APPLICATIONS**  
**AS OF SEPTEMBER 30, 2010**

	FY 2009	FY 2010
From Appropriations	\$223,545,693	\$235,520,440
From Medical Device Fee Collections	\$47,302,744	\$57,187,100
<b>Total Obligations</b>	<b>\$270,848,437</b>	<b>\$292,707,540</b>

In addition, MDUFMA 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 five percent increase for each fiscal year. If FDA does not satisfy this condition for two consecutive years, FDA is prohibited from allowing accredited third-parties to conduct device establishment inspections in the future years. 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 (2002 level increased by five percent each year, rounded to the nearest thousand dollars) and FDA obligations for medical device establishment inspections from FY 2002 to FY 2010. Because FDA has spent more than the statutory minimum for device inspection for each of the past two fiscal years, FDA may continue to allow accredited third-parties to conduct certain device establishment inspections in future years.

**TABLE 9**  
**OBLIGATIONS FOR THE INSPECTION OF MEDICAL DEVICE ESTABLISHMENTS**  
**(ROUNDED TO \$000)**  
**AS OF SEPTEMBER 30, 2010**

Fiscal Year	Minimum--2002 Obligations Increased by 5% per year	Actual Obligations	Excess or Shortfall
FY 2002 Base	\$19,425,000	\$19,425,000	\$0
FY 2003	\$20,396,000	\$22,576,000	\$2,180,000
FY 2004	\$21,416,000	\$21,430,000	\$14,000
FY 2005	\$22,487,000	\$21,515,000	(\$972,000)
FY 2006	\$23,611,000	\$29,230,000	\$5,619,000
FY 2007	\$24,792,000	\$31,926,000	\$7,134,000
FY 2008	\$26,031,000	\$32,989,000	\$6,958,000
FY 2009	\$27,332,926	\$35,927,125	\$8,594,199
FY 2010	\$28,699,572	\$41,596,442	\$12,896,870

**DEVICE FEES IN FY 2010**

Under MDUFMA II, fee rates for PMA and BLA fees and for annual establishment registration are set in the statute. The rates for all other fees are statutorily set as a percent of the full PMA fee rate. 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 seven 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 1.84 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 \$30,000,000 or less in gross receipts or sales in its most recent Federal income tax return) pay 25 percent of the specified fee, except that for premarket notifications (510(k)s), 30-day notices, and requests for classification they pay 50 percent of the specified rate. There is no small business rate for annual establishment registrations. Table 10 exhibits the rates for all types in FY 2009 (Second year of MDUFMA II) and FY 2010 (Third year of MDUFMA II).

**TABLE 10  
MEDICAL DEVICE USER FEE RATES  
AS OF SEPTEMBER 30, 2010**

Application Type	FY 2009	FY 2010
Full Fee Applications	\$200,725	\$217,787
<i>Small Business Rate</i>	<i>\$50,181</i>	<i>\$54,447</i>
Panel Track Supplement	\$150,544	\$163,340
<i>Small Business Rate</i>	<i>\$37,636</i>	<i>\$40,835</i>
180-Day Supplements	\$30,109	\$32,668
<i>Small Business Rate</i>	<i>\$7,527</i>	<i>\$8,167</i>
Real-Time Supplements	\$14,051	\$15,245
<i>Small Business Rate</i>	<i>\$3,513</i>	<i>\$3,811</i>
510(k)s	\$3,693	\$4,007
<i>Small Business Rate</i>	<i>\$1,847</i>	<i>\$2,004</i>
30-Day Notice	\$3,212	\$3,485
<i>Small Business Rate</i>	<i>\$1,606</i>	<i>\$1,742</i>
513(g) Request for Classification Information	\$2,710	\$2,940
<i>Small Business Rate</i>	<i>\$1,355</i>	<i>\$1,470</i>
Annual Fee for Class III Periodic Report	\$7,025	\$7,623
<i>Small Business Rate</i>	<i>\$1,756</i>	<i>\$1,906</i>
Annual Establishment Registration	\$1,851	\$2,008

Table 11 summarizes the number of applications/fees received by FDA in each year, FY 2008 through FY 2010, for which the fees had been paid in full by the companies before September 30.

**TABLE 11**  
**APPLICATIONS FOR WHICH FEES WERE PAID AND ESTABLISHMENT AND REPORT FEES**  
**PAID AS OF SEPTEMBER 30, 2010**

Application Type	FY 2008 Actual	FY 2009 Actual	FY 2010 Actual
Full Fee Applications	17	32	32
<i>Small Business</i>	7	10	8
Panel Track Supplement	8	13	11
<i>Small Business</i>	0	1	2
180-Day Supplements	126	132	103
<i>Small Business</i>	18	18	20
Real-Time Supplements	165	186	146
<i>Small Business</i>	22	24	20
510(k)s	2,781	2,881	2,367
<i>Small Business</i>	846	1,037	1,032
30-Day Notice	597	596	669
<i>Small Business</i>	59	71	78
513(g) Request for Classification Information	64	58	56
<i>Small Business</i>	26	39	25
Annual Fee for Periodic Reporting	467	460	427
<i>Small Business</i>	50	70	78
Establishment Registration	13,835	14,252	15,518

Please note that 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 for the following reasons:

- first applications submitted by small businesses;
- applications bundled under one fee because of similarity of medical device review issues;
- applications exempted from fees for pediatric indications;
- applications for IDEs and PMA supplements other than Real-Time and 180-Day Supplements;
- other applications for which no fee is charged, such as requests for investigational device exemption and requests for humanitarian device exemption; and
- annual report submissions that must be examined but that have no fees associated with them.

### WAIVERS, REDUCTIONS, AND EXEMPTIONS

MDUFMA directs FDA to waive the first premarket application fee from a qualified small business and the fee for an application submitted solely for pediatric indications. It also directs FDA to reduce fees for subsequent applications from qualified small businesses in all categories except the annual establishment registration fee. In addition, FDA does not collect fees for the following application types:

- applications for Humanitarian Device Exemptions (HDE) 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.

In this appendix FDA provides a summary of MDUFMA fee waivers, reductions, and exemptions granted in FY 2010.

FDA responded to thousands of e-mails and phone calls from companies asking for information regarding the small-business waiver or reduction of MDUFMA fees. After carefully reviewing the requests from companies, FDA waived 16 fees for first-time submissions of PMAs or BLAs, and reduced a total of 1,279 fees. Table 12 displays the number of small-business application fees that were waived or reduced by FDA, and the value of each such waiver or reduction in FY 2010.

**TABLE 12**  
**FY 2010 SMALL BUSINESS FEE WAIVERS AND REDUCTIONS GRANTED**  
**AS OF SEPTEMBER 30, 2010**

Category	Number	Amount Reduced per Fee	Total Value
Full Fees Waived	16	\$217,787	\$3,484,592
Full Fees Reduced	8	\$163,340	\$1,306,720
Panel Track Supplements Reduced	2	\$122,505	\$245,010
180-Day Supplements Reduced	20	\$24,505	\$490,020
Real-Time Supplements Reduced	20	\$11,434	\$228,680
510(k)s Fees Reduced	1,032	\$2,003	\$2,067,096
30-day Notice Fees Reduced	78	\$1,743	\$135,954
513(g)s Fees Reduced	25	\$1,470	\$36,750
Annual Periodic Report Fees Reduced	78	\$4,817	\$375,726
<b>Total</b>	<b>1,279</b>		<b>8,370,548</b>

Note: Amount of reduction per fee type = full fee rate - small business fee rate

FDA collected \$63,537,742 in fee revenue during FY 2010. Had there been no small-business waivers or reductions, FDA would have collected an additional \$8,370,548, or an additional 13 percent of collections.

FDA received 7 HDE applications and 60 supplements in FY 2010. None of these are subject to MDUFMA fees. FDA does not know if any of them would have been submitted had they been subject to a fee. Therefore, FDA does not know the extent to which this exemption resulted in any loss of revenue.

CBER received no exemption requests in FY 2010 for applications submitted under section 351 of the PHS Act for a product licensed for further manufacturing use only.

FDA did not receive any requests from State or Federal government entities for exemptions in FY 2010 for products that were not intended for commercial distribution.

FDA granted exemptions for pediatric indications in FY 2010 to one original premarket application, seven 510(k)s, two real-time supplements, two 180-day supplements, and one panel-track supplement. The total value of these exemptions was \$505,002.

FDA received 244 510(k) submissions subject to third-party review in FY 2010 compared to 304 in FY 2008 and 282 in FY 2009. FDA exempted fees for these 244 submissions. The total value of these exemptions in FY 2010 was \$831,015 – assuming that 30 percent (the same percent of total 2010 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**  
**SUMMARY AND TOTAL VALUE OF ALL FEE WAIVERS,**  
**REDUCTIONS, AND EXEMPTIONS GRANTED**  
**AS OF SEPTEMBER 30, 2010**

Reason	FY 2009	FY 2010
Small Business	\$7,738,614	\$8,370,548
Govt. Sponsored Application not for Commercial Distribution	\$0	\$0
Pediatric Indications	\$259,709	\$505,002
510(k)s Subject to Third-Party Review	\$963,894	\$831,015
<b>Total Value</b>	<b>\$8,962,217</b>	<b>\$9,706,565</b>

**ALLOWABLE AND EXCLUDED COSTS FOR THE PROCESS FOR THE REVIEW OF DEVICE APPLICATIONS**

The FD&C Act, as amended by the Medical Device User Fee Amendments of 2007, defines the process for the review of medical device applications and the costs that may be included in that process. Using these definitions (and further refinements identified below) and the methodologies described in this report, FDA identified those activities that were applicable to the process for the review of device applications.

In the past, over 81 percent of FDA obligations were expended within one year, and 96 percent within two years. Therefore, obligations represent an accurate measure of costs.

**MDUFMA Related Costs**

**Included Activities**

**Section 737(8)(A) - The activities necessary for the review of premarket applications, premarket reports, supplements, and premarket notification submissions, including, but 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 Expedited 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, 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
- Information Technology (IT) support for review activities
- 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 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 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 investigational device exemption (IDE) under section 520(g) and activities conducted in anticipation of the submission of such applications under section 505(i) and 520(g).** This would include the 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 listed above.** 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 to 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 post-market studies required as a condition of approval of a premarket application or premarket report under section 515 or section 351 of the PHS Act.** This would include activities such as the review of:

- 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 process for the review of medical device applications.**

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 incurred in connection with this process for:

- (A) officers and employees of the FDA, contractors of the FDA, advisory committees, and costs related to such officers, employees, committees and contracts;
- (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 standard 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 (CLIA).

**DEVELOPMENT OF COSTS FOR THE  
PROCESS FOR THE REVIEW OF DEVICE APPLICATIONS**

**GENERAL METHODOLOGY**

The costs associated with the process for the review of medical device applications are based on obligations recorded within FDA’s CDRH, CBER, ORA, and OC. These organizations correspond to the cost categories presented as follows:

<u>Cost Category</u>	<u>FDA Organization</u>
Costs for the Review of PMAs, PDPs, PMRs, Modular PMAs, Supplements, and 510(k)s	CDRH
Costs for the Review of BLAs, PMAs, Supplements, and 510(k)s	CBER
Costs for Field Inspection and Investigation	ORA
Costs for Agency General and Administration	OC

The costs were accumulated using a variety of methods. Using the definitions of costs and activities included in the process for the review of device applications in the FD&C Act, as expanded in the discussion in Appendix D, the cost categories within each organization listed above were identified as parts of the medical device review process.

**CENTER COSTS**

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

- direct review and laboratory;
- indirect review and support; and
- 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 process for the review of device applications 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 MDUFMA, so that time could be reported in categories that could be separated into allowable and excluded activities with respect to the process for the review of device applications, as defined in MDUFMA and as further defined in Appendix D. This process is further explained below.

Ten years prior to the enactment of MDUFMA, CDRH's time-reporting system had been used to gather information about employee time for a 2-week period one or two times each year. After the definitions of allowable and excluded costs for the process for the review of device applications under MDUFMA were further refined, as presented in Appendix D, the time-reporting categories in the CDRH time-reporting system were modified so that all data captured would fit into either allowable or excluded costs. These modifications to the system were completed in mid-June 2003.

Once these modifications were completed, all CDRH employees other than management and administrative personnel reported all of the time they worked against these revised categories for a period of eight consecutive weeks, from June 29 through August 23, 2003. Whether time categories were counted as allowable or excluded was not apparent to employees as they reported their time.

FDA Centers are very payroll-intensive. In most years about 60 percent of all FDA funds go to pay for employee salaries and benefits. Almost all other costs directly support these employees. Given this payroll intense cost structure, 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.

Further, since these percentages of allowable costs had never been collected for earlier periods, the percentages of allowable costs reported in this 8-week period were likewise applied to each cost-center's direct costs (obligations) incurred in FY 2002, to get the baseline FY 2002 device review process cost data required under MDUFMA.

For FY 2004 and FY 2005, all CDRH employees, other than management and administrative personnel, reported all of the time they worked against these revised categories for one two-week period during each quarter of the fiscal year. The results from the eight weeks of time reporting data were then averaged and extrapolated to the entire year. This served as the basis for measuring CDRH costs for the device review process for direct review and laboratory components, and the same pattern has been

followed in subsequent years. In addition, further modifications were made in FY 2005 to be able to break out time for various specific types of application review.

In FY 2006, CDRH modified its time reporting categories to better account for effort on training, guidance document and standards development, and outreach initiatives. Prior to FY 2006, most of these areas were considered part of the MDUFMA process. These changes allowed CDRH to better distinguish between premarket and postmarket efforts.

In FY 2007, CDRH continued to make minor refinements to the CDRH automated time reporting system. Based on requests from staff, CDRH added several reporting activities to improve reporting accuracy. New activity codes were created to further define premarket review activities, reflect organizational transformation initiatives, and differentiate between user fee and appropriated MQSA program management activity. CDRH also added numerous "sub-activities" to the existing activities in all program areas so that staff could easily identify and report their time in the appropriate categories. Further refinements were made in FY 2008 to accommodate changes under MDUFMA II (e.g., added time categories for 30-day notices, PMA supplements, and PMA annual reports). These enhancements did not have a significant effect on FDA's MDUFMA process calculations.

A similar procedure is used in CBER to measure the direct review and laboratory components costs for the device review process. CBER was able to use the time-reporting system it has had in place for over 10 years prior to the enactment of MDUFMA, 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 two-week period during each quarter of the fiscal year.

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

CBER's process for determining allowable and excluded costs for MDUFMA direct review and laboratory costs is identical to how CBER determines costs for the process for the review of human drug applications. This process was validated by Arthur Andersen, LLC under PDUFA for 1992 and 1993.

### **Center 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, Office of Information Technology, 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 expenses are paid for centrally from FDA funds each year rather than from funds allocated to the Centers. These costs include rent, utilities, some computer equipment, facilities repair and maintenance, and some extramural and service contracts.

Many of these costs, such as building rent, can be traced back to the specific organization component that generated the cost and were assigned the user fee related percentage calculated for the division to which the expenditure related. For the costs that benefited the Center as a whole and could not be traced to a specific division, a weighted average user fee percentage was calculated based on the level of user fee related costs to total costs in the Center.

### **FIELD INSPECTION AND INVESTIGATION COSTS**

All field inspection and investigation costs are incurred by FDA's ORA. ORA costs are incurred in both district offices (the "field") and headquarters support offices. In FY 2002, the Agency began tracking accumulated ORA costs through the use of the Field Accomplishment and Compliance Tracking System (FACTS). FACTS is a time and activity tracking system which captures time in a variety of categories, including pre-approval inspections of manufacturing facilities, investigations of clinical studies, and analytical testing of samples--which are included in the process for the review of device applications.

Total direct hours reported in FACTS are used to calculate the total number of staff-years required by ORA to perform activities in the process for the review of device applications as defined in MDUFMA. In addition to the direct time, an allocation of support time is also included to represent the work done by the ORA administrative and management personnel. The Agency then applies the total number of staff years devoted to the process for the review of device applications to the average salary cost in ORA to arrive at the ORA salary costs for the process for the review of device applications as defined in MDUFMA. The final step is to allocate ORA obligations for operations and rent to the device review process based upon the ratio of user fee related staff years to total ORA staff years. Table 14 summarizes the calculation for FY 2009 and FY 2010, respectively.

**TABLE 14**  
**OFFICE OF REGULATORY AFFAIRS**  
**COSTS OF THE PROCESS FOR THE REVIEW OF MEDICAL DEVICE APPLICATIONS**  
**AS OF SEPTEMBER 30, 2010**

Cost Component	FY 2009	FY 2010
Staff Years Utilized	57	69
ORA Average Salary and Benefits	\$107,401	\$108,065
Total Salary and Benefits	\$6,121,857	\$7,456,485
Operating and Other Costs <sup>1</sup>	\$4,625,369	\$6,436,949
<b>Total</b>	<b>\$10,747,226</b>	<b>\$13,893,434</b>

<sup>1</sup>Other costs are central, GSA rent, rent-related, and Shared Services costs that are applicable to the process for the review of device applications.

The ORA costs for the process for the review of medical device applications shown in table 14 include costs paid from appropriations and user fee collections.

**AGENCY GENERAL AND ADMINISTRATIVE COSTS**

The Agency general and administrative costs are incurred in the FDA's OC. At the end of FY 2010, OC was comprised of the following offices:

- Immediate Office of the Commissioner
- Office of the Chief Counsel
- Office of the Chief of Staff
- Office of the Administrative Law Judge
- Office of Equal Employment Opportunity and Diversity Management
- Office of International Programs
- Office of Administration
- Office of Policy, Planning and Budget
- Office of Special Medical Programs
- Office of Legislation
- Office of the Counselor to the Commissioner
- Office of Women's Health
- Office of Foods
- Office of the Chief Scientist
- Office of International Programs
- Office of External Affairs

The OC costs applicable to the process for the review of medical device applications were calculated using a method prescribed in 1993 by the Division of Cost Determination Management, Office of Finance, Office of the Secretary, Department of Health and Human

Services. (Today the Office of Finance is under the Office of the Assistant Secretary for Resources and Technology.) This method uses the percentage derived by dividing total Office of the Commissioner costs by the total FDA salary expenses after subtracting the salary expenses from OC. The percentage is then multiplied by the sum of salaries applicable to the process for the review of medical devices in CDRH, CBER, and ORA to derive the Agency general and administrative costs applicable to the process for the review of medical device applications.

Using this methodology, FDA dedicated \$18,762,325 and \$24,575,111 in general and administrative expenses to the medical device review process in FY 2009 and FY 2010, respectively. The FY 2010 general and administrative obligations from appropriations and user fees combined accounted for about 8 percent of the total cost of the process for the review of device applications

At the beginning of FY 2004, FDA implemented a reorganization and streamlining of its administrative support activities. Many functions and resources from FDA Centers, ORA, and components of the OC were consolidated into the Office of Shared Services under the Office of Management – a component of OC. This was done in an effort to achieve greater efficiency in the provision of these services. For reporting comparability purposes, however, resources expended by the Office of Shared Services in FY 2010 supporting the device review process are shown as having been incurred by CDRH, CBER, ORA, or OC, in proportion to the resources allocated from each these components to the Office of Shared Services. This makes the figures shown for FY 2010 comparable with figures reported in prior years.