FY 2007 MDUFMA FINANCIAL REPORT

REQUIRED BY THE

MEDICAL DEVICE USER FEE AND MODERNIZATION ACT OF 2002

AMENDED BY THE

MEDICAL DEVICE USER FEE STABILIZATION ACT OF 2005

FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

DATE: 6/24/08

Andrew C. von Eschenbach, M.D.
Commissioner of Food and Drugs

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

NOV - 7 2008

The Honorable Richard Cheney
President of the Senate
United States Senate
Washington, DC 20510

Dear Mr. President:

The Medical Device User Fee and Modernization Act (MDUFMA) of 2002, as amended, requires an annual financial report to Congress. I have enclosed the fifth annual financial report to Congress which documents how the Food and Drug Administration (FDA) met each of the necessary conditions specified in MDUFMA for continued collection of medical device user fees. Availability of these fees makes FDA better able to strengthen its medical device review process and meet the performance goals established for this program.

I appreciate the timely action of Congress in reauthorizing MDUFMA for an additional five years in the Food and Drug Administration Amendments Act of 2007.

Sincerely,

Michael O. Leavitt

Enclosure

Identical letters to:
Speaker of the House of Representatives
Chairman and Ranking Minority Member, Committee on Health, Education, Labor, and Pensions, United States Senate
Chairman and Ranking Minority Member, Committee on Energy and Commerce, House of Representatives

EXECUTIVE SUMMARY

The Medical Device User Fee and Modernization Act (MDUFMA) of 2002 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) 2007.

MDUFMA, amended by the Medical Device User Fee Stabilization Act (MDUFSA) of 2005, specifies that three conditions must be satisfied in order for FDA to collect and spend MDUFMA fees:

1. Within FDA's salaries and expenses appropriation, the amount appropriated for devices and radiological health after FY 2004 must be at least $205,720,000, excluding fees, adjusted for inflation.
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, adjusted for inflation.

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 5 percent in each fiscal year.

This report explains how FDA met the four statutory conditions in FY 2007. The report also provides information on user fee collections, expenditures, and carryover balances. In FY 2007, FDA net collections totaled $30 million from fees. FDA obligated $35 million from MDUFMA collections to support FDA's medical device review program. FDA carried forward into FY 2008 a balance of $11 million—about $5.4 million less than the carryover balance at the end of FY 2006. About 66 percent of the total expenses for the medical device review program in FY 2007 went for personnel salary and benefit costs. The remaining 34 percent was spent on operating and the infrastructure costs necessary to support the medical device review program.

MDUFMA fees, along with the increased appropriations from Congress, enabled FDA to dedicate 242 more full-time equivalents (FTEs) to the medical device review program in FY 2007 than in FY 2002—the year before MDUFMA was enacted. An additional 76 contractor staff-years were also dedicated to the device review in FY 2007 compared with FY 2002. These resources have enabled FDA to achieve the performance goals associated with the enactment of MDUFMA and strengthen FDA's medical device review program. FDA looks forward to continued strengthening of the medical device review program in FY 2008.

TABLE OF CONTENTS

APPENDICES

BACKGROUND

MDUFMA authorizes FDA to collect fees from the medical device industry to augment appropriated funds for the medical device review process. MDUFMA also requires additional funding from appropriations. FDA uses 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 reach the American public more quickly.

Under MDUFMA, 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, and premarket notification submissions (510(k)s). A fee for each application type is fixed in statute as a percent of a standard fee for a PMA. The MDUFSA, Public Law 109-43, amended MDUFMA on August 1, 2005. MDUFSA set the standard fee for a premarket application for FY 2007 at $281,600. FDA then established fee rates for all other applications based on the percents specified in the statute. Unlike the Prescription Drug User Fee Act (PDUFA), MDUFMA does not have product or establishment fees in the first 5 years.

MDUFMA requires FDA to submit two reports to Congress each fiscal year: 1) a performance report is to be sent within 60 days after the end of each fiscal year, and 2) a financial report is to be sent within 120 days after the end of each fiscal year. FDA is separately transmitting the FY 2007 MDUFMA Performance Report that discusses FDA's progress in meeting the goals referred to in MDUFMA. This report is FDA's FY 2007 MDUFMA Financial Report covering the period October 1, 2006 through September 30, 2007.

As required by MDUFMA, this report presents the statutory conditions or "triggers" that must be met as a condition for FDA to be able to collect and spend the fees, and explains how they were met in FY 2007. This report describes the process for the review of medical device applications, as defined in MDUFMA and states the total costs of this process in FY 2007, including costs paid from both fee collections and appropriations. The report also presents the FY 2007 fee collections, obligations, and carryover balances.

MEETING THE STATUTORY CONDITIONS FOR USER FEES IN FY 2007

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 2007. See summaries set forth below.

The **first condition** is a funding condition that affects FDA's fee collections in FY 2007. MDUFMA, as amended by MDUFSA, specifies a minimum amount that must be appropriated for the Device and Radiological Health line of FDA's appropriation, exclusive of user fees, for FY 2007. That minimum amount is $230,551,000 (rounded to the next whole thousand dollars). In FY 2007, the final appropriation for the Device and Radiological Health line of FDA's appropriation, exclusive of user fees, was $230,682,000. 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 Appropriation Acts of February 15, 2007. The President signed the FY 2007 Appropriation Act, Public Law 110-5. It states that the amounts collectable from medical device user fees are $43,726,000. 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, adjusted for inflation. That adjusted minimum level for FY 2007 is $134,117,560. FDA obligated $173,130,797 from appropriations. Because FDA spent more than the specified minimum level, FDA met the third condition.

MDUFMA also contains a provision that FDA obligations on medical device establishment inspections must be equal to or greater than 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 not allowed to use accredited third-parties to conduct certain medical device establishment inspections in the future years. FDA spending on medical device establishment inspections exceeded the specified minimum level for each of the most recent fiscal years, so FDA may continue to permit accredited third-parties to conduct certain medical device establishment inspections in the future years.

FDA provides more details on the calculations that show FDA satisfied these statutory conditions in Appendix A.

USER FEE COLLECTIONS

MDUFMA directs FDA to receive fees only from the medical device applications through FY 2007. The statute directs FDA to set the fee rate for each application type as a percentage of the standard fee for a PMA. For FY 2007, MDUFMA, as amended by MDUFSA, specified that the standard fee for a premarket application is $281,600. FDA, then, establishes other application fees based on the specified percents mentioned in MDUFMA. [1]

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. The cash balance carried to the next fiscal year is discussed on page 6, section CARRYOVER BALANCES. The table below shows the amount of user fees FDA has collected since MDUFMA began.

FOOD AND DRUG ADMINISTRATION
STATEMENT OF MEDICAL DEVICE FEE COLLECTIONS
AS OF SEPTEMBER 30, 2007

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007	Total
Total Fees Collected	$21,620,549	$25,280,073	$31,801,091	$35,288,344	$29,342,013	**$143,332,070**
Unearned Fees[1]				$721,156	$2,448,619	**$3,169,774**
Fees Receivables	$32,265				$221,056	**$253,321**

[1]Unearned Fees are fees collected for applications that had not been received by FDA as of September 30, 2007. They are included above in the 'Total Fees Collected' amounts.

Note that user fees collected (the first line above) are initially credited to the year the fee was received. However, the revenues are later reassigned to the year the application is received—referred to as the cohort year. Last year's report showed $35,358,220 of fees collected in FY 2006, of which $2,568,581 was shown as "unearned income" since the application for which the fee was paid had not been received by the end of FY 2006. The FY 2006 total fees collected line is reduced to $35,288,344 in this report, since all but $721,156 of the unearned income reported last year has now been either refunded or credited to FY 2007—the year the application was actually received. The total fees collected line for FY 2007, when seen in next year's FY 2008 report, will also be different from than the figure shown here—reflecting both the refund or reassignment of most of the unearned income to FY 2007, 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

[1] FDA published FY 2007 medical device user fee rates in a Federal Register Notice on August 2, 2006 (pages 43784 through 43786).

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 2007 is contained in Appendix B.

In addition to the revenue shown in the table above, a total of $32,265 is due from unpaid invoices for fees for applications that were submitted between October 1, 2002, and March 30, 2003. These FY 2003 accounts receivable have been turned over to a collection agency. After April 1, 2003, FDA no longer accepted applications for review unless a fee for the application had been received. Accounts receivable after that date reflect applications that initially paid a lower fee than FDA subsequently determined was appropriate for the submission.

A summary of FY 2007 waivers, reductions, and exemptions is provided in Appendix C.

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. In FY 2007, FDA obligated $35,202,700 (17 percent of the total) from user fee collections and $173,130,797 (83 percent of the total) from appropriations, as reflected in the table below.

FOOD AND DRUG ADMINISTRATION
FY 2007 MEDICAL DEVICE REVIEW OBLIGATIONS
BY EXPENSE CATEGORY AND REVENUE SOURCE
AS OF SEPTEMBER 30, 2007

Expense Category	From Appropriations	From Fees	Total
Personnel Compensation and Benefits	$112,261,370	$25,312,174	$137,573,544
Travel and Transportation	$2,086,865	$290,248	$2,377,113
GSA Rent	$12,855,664	$2,348,500	$15,204,164
Communications	$3,064,112	$180,859	$3,244,971
Contract Services	$33,938,817	$6,412,302	$40,351,119
Equipment and Supplies	$6,060,452	$419,676	$6,480,128
Other[1]	$2,863,518	$238,941	$3,102,459
Total Obligations	**$173,130,797**	**$35,202,700**	**$208,333,497**

[1]Other includes expense categories like rent payments to others, printing & reproduction, and other miscellaneous expenses.

More information about the costs of the process for device review, as defined in MDUFMA, begins on page 8.

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 2007 resulted in a reduction of carryover balances of $5,377,746, and reduced the net carryover balance from $16,240,618 to $10,862,872 by the end of the year.

The table below captures FDA's carryover balances at the beginning and each fiscal year since the beginning of MDUFMA in FY 2003.

FOOD AND DRUG ADMINISTRATION
STATEMENT OF CASH, OBLIGATIONS, AND
CARRYOVER BALANCES BY FISCAL YEAR
AS OF SEPTEMBER 30, 2007

Fiscal Year	Beginning Carryover	Net Cash	Obligations	Year-End Carryover
2003	-	$21,936,910	$14,837,600	$7,099,310
2004	$7,099,310	$26,828,534	$23,875,200	$10,052,644
2005	$10,052,644	$31,102,864	$27,171,400	$13,984,108
2006	$13,984,108	$34,325,120	$32,068,610	$16,240,618
2007	$16,240,618	$29,824,954	$35,202,700	$10,862,872
2008	$10,862,872			

The carryover balances in the table 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 2007 is more than the fees credited to FY 2007, shown on page 3. Some of the cash collected in 2007 was for fees owed for previous years, and reflected as previous year collections in the table on page 3. The net collection in FY 2007 also reflects refunds made in FY 2007.

FEE AMOUNTS APPROPRIATED, FEES COLLECTED, AND DIFFERENCES

Under MDUFMA, if fees are collected in excess of the amount of fees appropriated each year, the differences may be kept and used to reduce fees that would otherwise be assessed in a later fiscal year. The following table depicts for each year cumulative net collections, collection ceilings (appropriated amount of fees that may be collected each year), and differences through the end of FY 2007.

FOOD AND DRUG ADMINISTRATION
STATEMENT OF FEES APPROPRIATED, FEES COLLECTED, AND DIFFERENCES
AS OF SEPTEMBER 30, 2007

Fiscal Year	Fees Appropriated	Fees Collected	Differences
2003	$25,125,000	$21,620,549	($3,504,451)
2004	$31,654,000	$26,280,073	($6,373,927)
2005	$33,938,000	$31,801,091	($2,136,909)
2006	$40,300,000	$35,288,344	($5,011,656)
2007	$43,726,000	$29,342,013	($14,383,987)
Total	**$174,743,000**	**$143,332,070**	**($31,410,930)**

As the table shows, the total amount of fees collected in each year always fell short of the amount appropriated for that year, and over the 5 years of MDUFMA, the total fee collections have been $31.4 million less than fee appropriations. As a result, there have been no excess collections in any year that need to be used to reduce future years' collections.

AVAILABILITY OF CARRYOVER BALANCES

Of the FY 2007 carryover balance, $3,169,774 is the unearned fees from applications that are not yet received by FDA. FDA also holds $1,000,000 in reserve for potential refunds in future years. In addition, MDUFMA requires FDA to have at least 1 month of operating expenses 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. The table below shows the amounts of carryover that must be held in reserve and the amount available for allocation in FY 2008.

FOOD AND DRUG ADMINISTRATION
PROPOSED ALLOCATIONS OF MEDICAL DEVICE FEE REVENUE
CARRYOVER BALANCE
AS OF SEPTEMBER 30, 2007

Status of Carryover Funds	Amount
Unearned Fees	$3,169,774
Reserve for Future Refunds	$1,000,000
1-Month Reserve for Next Fiscal Year	$4,031,000
Available Cash for Allocation in FY 2008	$2,662,098
Total Carryover Balance	**$10,862,872**

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

FDA uses data from time reporting surveys conducted during four 2-week periods each fiscal year to determine the percent of cost of each organizational component devoted to activities that are 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.

The following table presents the total costs for the review of medical device applications for FY 2006 and FY 2007, 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 1 year, and 96 percent within 2 years. Thus, obligations represent an accurate measure of costs.

FOOD AND DRUG ADMINISTRATION
PROCESS FOR THE REVIEW OF MEDICAL DEVICE APPLICATIONS
TOTAL COSTS BY COMPONENTS AND FUNDS
AS OF SEPTEMBER 30, 2007

FDA Organizational Component	FY 2006	FY 2007
Center for Devices and Radiological Health	$155,850,979	$159,387,019
Center for Biologics Evaluation and Research	$20,830,565	$22,889,470
Field Inspection and Investigation	$10,499,258	$11,511,598
Agency General and Administrative Costs	$12,313,468	$14,545,410
Total Process Costs	**$199,494,271**	**$208,333,497**
Obligations from Appropriations	$167,425,661	$173,130,797
Obligations from Medical Device User Fee Collections	$32,068,610	$35,202,700

The costs for all components increased in FY 2007. The increase reflects both the increase in costs for pay and support, and an increase in the total number of FTEs devoted to the process for the review of medical devices in FY 2007.

FULL TIME EQUIVALENTS (FTES)

The table below presents FTE levels that support the medical device application review process by FDA organizational components. This is a measure of paid staff years devoted to device review. In FY 2007, FDA spent about 60 percent of its total funds for the salaries and benefits of the medical device process FTEs, and the balance of the funds went for support of these employees.

FOOD AND DRUG ADMINISTRATION
PROCESS FOR THE REVIEW OF MEDICAL DEVICE APPLICATIONS
TOTAL FTES
AS OF SEPTEMBER 30, 2007

	FTE Used Each Year				
Organization \ Fiscal Year	**2003**	**2004**	**2005**	**2006**	**2007**
Center for Devices and Radiological Health (CDRH)	662	713	794	765	806
Center for Biologics Evaluation and Research (CBER)	59	70	87	108	105
Office of Regulatory Affairs (ORA)	59	60	64	65	68
Office of the Commissioner (OC)	77	72	89	82	92
Total FTE	**857**	**915**	**1,034**	**1,020**	**1,071**

FTE numbers for FY 2004 through FY 2007 show CDRH, CBER, and ORA staff transferred to the consolidated shared services organization in OC as if they are still in CDRH, CBER, and ORA, to make the numbers comparable to the FY 2002 and FY 2003 numbers.

The increase in CDRH FTEs from FY 2006 to FY 2007 resulted from hiring completed at various times during FY 2006 and FY 2007.

In addition to the FTE numbers shown in the table, CDRH also expended 76 more contractor staff-years on the medical device review process in FY 2007 than it did in FY 2002.

The change in CBER's FTE between FY 2006 and FY 2007 is the result of minor variations in workload.

PERFORMANCE GOALS

In FY 2007, FDA made steady progress in implementing MDUFMA. FDA continued to focus on consulting with its stakeholders, developing guidance documents, and implementing new review processes and process improvements required to meet MDUFMA's progressively challenging performance goals. Among the key activities and accomplishments during FY 2007 were:

- **Steady progress in meeting MDUFMA performance goals**. FDA's overall performance for the FY 2003 through FY 2007 receipt cohorts indicates FDA is meeting or exceeding most MDUFMA performance goals.

- **Guidance Documents.** FDA issued two guidance documents that related to MDUFMA during FY 2007.

- FY 2007 Medical Device Small Business Qualification Worksheet and Certification (replaced guidance for FY 2006), available at: http://www.fda.gov/cdrh/mdufma/guidance/2007.pdf.
- Bundling Multiple Devices or Multiple Indications in a Single Submission (replaced earlier edition), available at: http://www.fda.gov/cdrh/mdufma/guidance/1215.pdf.

- **Stakeholder communication and consultation.** During FY 2007, FDA's consultations with stakeholders focused on reauthorization of medical device user fees and performance goals for FY 2008 through FY 2012. On April 30, 2007, FDA held an open public meeting to discuss proposals for reauthorization.

- **Reports to Congress issued in FY 2007.** During FY 2007, FDA submitted three annual reports required by MDUFMA to Congress: 1) FY 2006 MDUFMA Performance Report, 2) FY 2006 MDUFMA Financial Report, and 3) FY 2006 Office of Combination Products Report. FDA also submitted three topical reports required under MDUFMA:

  1) ***Postmarket Surveillance of Medical Devices Used in Pediatric Populations:*** A report concerning the adequacy of existing postmarket surveillance of implanted devices used in children and devices used in pediatric populations. The report followed, and was based on, a study conducted by the Institute of Medicine under an agreement with FDA. This report was required by section 212(c) of MDUFMA.

  2) ***Effect of the Medical Device User Fee Program on Postmarket Surveillance of Medical Devices:*** A study of the effects of medical device user fees on FDA's ability to conduct postmarket surveillance, the extent to which device companies comply with postmarket surveillance requirements, and improvements needed for adequate postmarket surveillance. This report was required by section 104(b) of MDUFMA.

  3) ***Third-Party Review of Medical Device Premarket Notifications:*** A study of FDA's experience with third-party reviews of 510(k) premarket notifications. This report was required by section 523(d) of the Food, Drug, and Cosmetic (FD&C) Act, a provision added by MDUFMA.

CBER expects to achieve all its FY 2007 MDUFMA performance goals when the cohort is completed. Thus far, CBER has met or exceeded all the FY 2007 MDUFMA decision-performance goals. CBER continues to emphasize the medical device review process oversight, such as focusing on communication with sponsors during the first review cycle and updating 510(k) standard operating procedures and policies to implement process improvements. CBER also continues to harmonize with CDRH on revisions or updates of common device review processes and policies to improve review efficiency, such as review of the Quality System Record section of a PMA, when to file supplements to PMAs and

review of PMA annual reports. During FY 2007, CBER made a number of modifications for information technology systems, Regulatory Management Systems/Biologics Licensing Application, and Blood Logging and Tracking. These changes include updates to fields, forms, views, and reports for payment information and bundled submissions. These enhancements facilitate the transfer of data between CBER and the Office of Financial Management for MDUFMA payments to expedite the start of application review.

MANAGEMENT CHALLENGES FOR FY 2008

On September 27, 2007, the President signed the Food and Drug Act Amendments Act (FDAAA) of 2007, Title II of which reauthorizes medical device user fees for an additional 5 years, for FY 2008 through FY 2012. This reauthorization of MDUFMA (referred to as MDUFMA II) calls for both challenging performance goals and a new fee structure.

During FY 2008, FDA will focus on implementing the Medical Device User Fee Amendments of 2007 (Title II of FDAAA of 2007, P.L. 110-85, enacted September 27, 2007). The 2007 Amendments provides a significantly changed fee structure. All fees established under MDUFMA I have been significantly reduced (for example the standard fee for a 510(k) premarket notification submitted during FY 2008 is 18 percent less than the fee for an FY 2007 submission, and the standard fee for a premarket application submitted during FY 2008 is 34 percent less than the fee for an FY 2007 submission). Small businesses receive more generous discounts than under MDUFMA I (for example the small business fee for a 510(k) premarket notification submitted during FY 2008 is 49 percent less than the fee for an FY 2007 submission, and the small business fee for a premarket application submitted during FY 2008 is 57 percent less than the fee for an FY 2007 submission).

These fee reductions are made possible by new categories of fees, most notably a new annual registration fee that will apply to certain medical device establishments; establishment registration fees are to supply about 45 percent of the anticipated device fee revenue in FY 2008. Implementation of the annual establishment registration fee is a particularly complex challenge, because this new fee should be paid by almost 13,000 establishments worldwide. This is a much larger volume of user fee transactions than FDA has had to process before, and the fee payments are also linked to the on-line registration of these establishments, which is also required by the 2007 Amendments beginning with registrations for FY 2008. To effectively implement and oversee the changes made by the 2007 Amendments, FDA must:

- develop new IT systems to process on-line registrations and associated fee payments;
- develop new IT systems to track FDA's performance against the new set of performance goals for FY 2008 - FY 2012;
- develop new control mechanisms; and
- educate the industry concerning the new provisions.

The performance goals for applications filed or accepted from FY 2008 through FY 2012 are defined in a September 27, 2007, letter from 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	SE or NSE Decision	90 days	90%
		150 days	98%

An "FDA Decision" is any of the following: a denial order, an approvable letter (including approvable pending GMP inspection), a not 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 5 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. An "FDA decision" is any of the following: a denial order, an approvable letter (including approvable pending Good Manufacturing Practice (GMP) inspection), a not approvable letter, a withdrawal, or a denial order.
- 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 new goals are very challenging, and FDA will have to carefully monitor our review processes to ensure we meet each goal.

Appendix A

STATUTORY CONDITIONS FOR COLLECTION AND USE OF FEES

The FD&C Act was amended by MDUFMA, Public Law 107-250, and by MDUFSA, Public Law 109-43. The Act specifies three statutory conditions that must be satisfied before FDA can collect and spend medical device user fees. A summary of these conditions has been introduced on page 2. Appendix A describes each of the conditions and explains how FDA met the conditions in FY 2007 in more detail.

In order to determine whether the statutory conditions are satisfied, FDA must calculate and apply an adjustment factor, defined in section 737(7) of the Act, in the assessments of the first and third conditions. The 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 April of the preceding fiscal year divided by such Index for April 2002.

The April preceding FY 2007, which began on October 1, 2006, was April 2006. The Consumer Price Index (CPI) for April 2006 was 201.5. The CPI for April 2002 was 179.8. Dividing the CPI of April 2006 by the CPI of April 2002 yields an adjustment factor of 1.1207 for FY 2007.

The **first condition** is a funding condition that affects the collection of fees in FY 2007.

MDUFMA, amended by MDUFSA, specifies a minimum amount of budget authority that must be appropriated for the Device and Radiological Health line of FDA's appropriation, exclusive of user fees, for FY 2007. That minimum amount for FY 2007 is $205,720,000 multiplied by the adjustment factor (1.1207), or $230,551,000 (rounded to the next whole thousand dollars). In FY 2007, after rescission, the final appropriated budget authority for the Device and Radiological Health line of FDA's Appropriation, exclusive of user fees, was $230,682,000. Since this amount is greater than $230,551,000, FDA's appropriation for FY 2007 met the first condition.

The **second condition** comes from section 738(h)(2)(A)(i). 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 can not collect medical device user fees without an appropriation.

On February 15, 2007, the President signed FY 2007 Appropriation Act, Public Law 110-5, which appropriated $43,726,000 from medical device user fees for FDA in FY 2007. Therefore, FDA met the second condition.

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), 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 2007 is 1.1207. Multiplying by the adjustment factor, FDA calculates the minimum spending from appropriations for the medical device review process in FY 2007 must be at least $134,117,560.

As this report documents, FDA obligated $173,130,797 from appropriations for the process for the review of medical device applications in FY 2007. Since this amount is greater than the minimum spending from appropriation required under MDUFMA, FDA met the third condition.

The table below shows FDA obligations on the process for the review of medical device applications in FY 2006 and FY 2007. The table separates the obligations that were funded by appropriations and user fees.

FOOD AND DRUG ADMINISTRATION
OBLIGATIONS FOR THE PROCESS FOR THE REVIEW
OF MEDICAL DEVICE APPLICATIONS
AS OF SEPTEMBER 30, 2007

	FY 2006	FY 2007
From Appropriations	$167,425,661	$173,130,797
From Medical Device Fee Collections	$32,068,610	$35,202,700
Total Obligations	**$199,494,271**	**$208,333,497**

In addition, MDUFMA imposes a provision that FDA obligations on 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 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 Act.

The table below shows the statutory minimum to be obligated for device establishment inspections (2002 level increased by 5 percent each year) and FDA obligations for medical device establishment inspections from FY 2002 to FY 2007. Because FDA has spent more than the statutory minimum for device inspection for each of the past 2 fiscal years, FDA may continue to allow accredited third-parties to conduct certain device establishment inspections in future years.

FOOD AND DRUG ADMINISTRATION
OBLIGATIONS FOR THE INSPECTION OF MEDICAL DEVICE ESTABLISHMENTS
(ROUNDED TO $000)
AS OF SEPTEMBER 30, 2007

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

Appendix B

NUMBER OF FEE PAID APPLICATIONS IN FY 2007

Under MDUFMA, FDA sets four fee rates for full fee applications, 180-day supplements, real-time supplements, and 510(k)s. The full fee application rates cover PMAs, PDPs, BLAs, PMRs, panel track supplements, and efficacy supplements. Under MDUFMA, a fee rate for each application type is a percentage of a standard fee for a PMA or a full fee application. Of a full fee application, 180-day supplement is 21.5 percent; real-time supplement is 7.2 percent; and 510(k) is 1.42 percent in aggregate. A small business rate for each application type, except 510(k), is 38 percent of its rate. A small business rate for 510(k) is 80 percent of $4,158. The table below exhibits the rates for all types in FY 2006 and FY 2007.

FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE RATES
AS OF SEPTEMBER 30, 2007

Application Type	FY 2006	FY 2007
Full Fee Applications	$259,600	$281,600
Small Business Rate	$98,648	$107,008
180-Day Supplements	$55,814	$60,544
Small Business Rate	$21,209	$23,007
Real-Time Supplements	$18,691	$20,275
Small Business Rate	$7,103	$7,705
510(k)s	$3,833	$4,158
Small Business Rate	$3,066	$3,326

The next table summarizes the number of applications received by FDA in FY 2006 and FY 2007. These applications have been paid in full by the companies before September 30.

FOOD AND DRUG ADMINISTRATION
APPLICATIONS RECEIVED AND PAID FEES
AS OF SEPTEMBER 30, 2007

Application Type	FY 2006 Actual	FY 2007 Actual
Full Fee Applications	51	24
Small Business	7	2
180-Day Supplements	76	99
Small Business	25	23
Real-Time Supplements	156	141
Small Business	16	21
510(k)s	2,988	2,849
Small Business	652	652

Please note that the numbers of 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; and
- applications for investigational device exemptions (IDEs) and PMA supplements other than Real-Time and 180-Day Supplements;
- other applications for which no fee is charged, such as 30 day notices and 513(g) submissions; and
- annual report submissions that must be examined but that have no fees associated with them.

Appendix C

WAIVERS, REDUCTIONS, AND EXEMPTIONS

MDUFMA directs FDA to waive the first premarket application fee from a qualified small business and an application fee submitted solely for pediatric indications. It also directs FDA to reduce premarket application and supplement fees for subsequent applications from qualified small businesses. Beginning in FY 2004, FDA also charged a reduced rate for 510(k)s from qualified small businesses. In addition, FDA does not collect fees for the followings types:

- applications for Humanitarian Device Exemptions (HDE) submitted under section 520(m);
- 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.

FDA provides a summary of MDUFMA fee waivers, reductions, and exemptions granted in FY 2007 in this appendix.

FDA responded to thousands of e-mails and phone calls from companies asking for information regarding the small business waiver for MDUFMA fees. After carefully reviewing the requests from companies, FDA granted 782 of 807 written requests for small business status in FY 2007. FDA waived or reduced 664 applications under small business criteria in FY 2007. This is smaller than the number of requests for waiver granted, since some of the parties to whom a request was granted did not submit the applications in FY 2007. The following table portrays the number of small business application fees that were waived or reduced by FDA, and the value of each category in FY 2007.

FOOD AND DRUG ADMINISTRATION
FY 2007 SMALL BUSINESS FEE WAIVERS AND REDUCTIONS GRANTED
AS OF SEPTEMBER 30, 2007

Category	Number	Amount	Total Value
Full Fees Waived	6	$281,600	$1,689,600
Full Fees Reduced	1	$174,592	$174,592
Panel Track Supplements Reduced	0	$174,592	$0
180-Day Supplements Reduced	19	$37,537	$713,203
Real-Time Supplements Reduced	20	$12,570	$252,002
510(k)s Fees Reduced	618	$832	$523,607
Total	**664**		**$3,353,004**

Note: reduced fee rate = full fee rate - small business fee rate

FDA collected $29,824,954 fees or net cash in fiscal year 2007. Had there been no small business waivers and reductions, FDA would have collected an additional $3,353,004, or an additional 11 percent of collections. The value of the 510(k) waivers is not included in the table above because under MDUFMA the fees for 510(k)s from large firms are increased slightly to offset the reduction in 510(k) fees charged to qualifying small businesses.

FDA received 6 HDE applications and 23 supplements in FY 2007. 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 two exemption requests in FY 2007 for applications submitted under section 351 of the PHS Act for a product licensed for further manufacturing use only. Because these were bundled with other applications, there would not have been a charge for these if they had not been exempt, so in this case there was no financial impact for these two exemptions.

FDA received and granted three requests from State or Federal government entities for exemptions for 510(k)s that were not intended for commercial distribution. Total cost of the exemptions in FY 2007 was $12,474.

FDA granted exemptions for pediatric indications in FY 2007 to 33 510(k)s, 3 180-day supplements, and 2 real-time. Total value of these exemptions was $359,396.

The 510(k) Third-Party Review Program decreased by 18 percent from FY 2006 to FY 2007. FDA received 235 510(k) submissions subject to third-party review in FY 2007 compared to 287 in FY 2006. FDA exempted fees for the 235 submissions. The total value of these exemptions in FY 2007 was $948,010 – assuming that 15 percent of the third-party submissions would have paid the reduced small business fee.

FOOD AND DRUG ADMINISTRATION
SUMMARY AND TOTAL VALUE OF ALL FEE WAIVERS, REDUCTIONS, AND EXEMPTIONS GRANTED
AS OF SEPTEMBER 30, 2007

Reason	FY 2006	FY 2007
Small Business	$4,274,178	$3,353,004
Govt. Sponsored Application not for Commercial Distribution	$15,332	$12,474
Pediatric Indications	$405,254	$359,396
510(k)s Reviewed by Third-Party Review	$996,411	$948,010
Total Value	**$5,691,175**	**$4,672,884**

Appendix D

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

The Act, as amended by MDUFMA, 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, the agency identified those activities that were applicable to the "process for the review of device applications."

In the past, over 81 percent of obligated funds in FDA are expended within 1 year, and 96 percent within 2 years. Therefore, obligations represent an accurate measure of costs.

MDUFMA Related Costs

Included Activities

[Section 737(5)(A)] The activities necessary for or in anticipation of 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(5)(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(5)(C)] The inspection of manufacturing establishments and facilities undertaken as part of the review of pending premarket applications, premarket reports, and supplements to include activities such as the review of manufacturing information submitted in premarket applications, pre-approval GMP inspections, and resolution of any identified GMP issues.

[Section 737(5)(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 on-going clinical trials; and
- Good Laboratory Practice inspections (21 CFR Part 58).

[Section 737(5)(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(5)(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 to 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(5)(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(5)(H)] The provision of technical assistance to device manufacturers in connection with the submission of such applications, reports, supplements, or submissions to 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(5)(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(5)(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(5)(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 to 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 to 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(6) of the Act defines the "costs of resources allocated for the process for the review of medical 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
- 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 Laboratories Improvement Amendments.

Appendix E

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:

Cost Category	FDA Organization
Costs for 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 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 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 8 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 organizations. In most years over 60 percent of all FDA funds go to pay for employee salaries and benefits. Almost all other costs directly support these employees. Thus the percent of time reported during this 8-week period as having been expended on allowable device review process activities for each cost-center (usually an organization component at the Division level) was then applied to all costs incurred for that cost-center for the entire FY 2003.

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 2-week period during each quarter of the fiscal year. The results from the 8 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. 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 just after PDUFA was initiated in 1993. 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.

CBER's existing time-reporting system was also modified to assure 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 2-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 costs for the process for the review of human drug applications was validated by Arthur Andersen 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, Training, and Manufacturers Assistance.

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 agency 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. The following table summarizes the calculation for the FY 2006 and FY 2007, respectively.

FOOD AND DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS
COSTS OF THE PROCESS FOR THE REVIEW OF MEDICAL DEVICE APPLICATIONS
AS OF SEPTEMBER 30, 2007

Cost Component	FY 2006	FY 2007
Staff Years Utilized	64	64
ORA Average Salary and Benefits	$99,675	$104,700
Total Salary and Benefits	$6,379,211	$6,700,800
Operating and Other Costs[1]	$4,120,047	$4,810,798
Total	**$10,499,258**	**$11,511,598**

[1]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 the table 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 2007, 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 and Diversity Management
- Office of International and Special Programs
- Office of Operations
- Office of Policy, Planning and Preparedness
- Office of Scientific and Medical Programs

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 the Office of the Commissioner. 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 $12,313,468 and $14,545,410 in general and administrative expenses to the medical device review process in FYs 2006 and 2007, respectively. The FY 2007 general and administrative obligations from appropriations and user fees combined accounted for about 7 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 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 2007 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 2007 comparable with figures prior to FY 2004.