FY 2006 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

SEPTEMBER 2007

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

September 13, 2007

The Honorable Richard Cheney
President of the Senate
United States Senate
Washington, D.C. 20510

Dear Mr. President:

Enclosed is the fourth annual financial report to Congress required by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA). This report covers fiscal year (FY) 2006, documenting how the Food and Drug Administration (FDA) satisfied the conditions specified in MDUFMA for continuing to collect and spend medical device user fees.

The report also presents the user fee collections and related expenses for FY 2006, and details the amount carried over to FY 2007. In FY 2006, FDA received $34 million and obligated $32 million of user fee collections. In addition, FDA received an increase in appropriations for its medical device program in FY 2006. About 72 percent of total expenses for medical device review went for FDA staff salaries and benefits. The remainder went toward the operating and the infrastructure to support the medical device review program. The infusion of resources is essential to enabling FDA to meet the performance goals associated with MDUFMA.

Two years ago the survival of this crucial program was in jeopardy. I urged Congress to quickly enact legislation needed to keep this program viable. Now, I want to express my gratitude to Congress for the enactment of the Medical Device User Fee Stabilization Act of 2005 (MDUFSA), signed by the President on August 1, 2005. Because of your quick action, this program will ensure a healthy medical device review program at FDA through FY 2007. Please accept my gratitude for your concern and timely action.

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 of 2002 (MDUFMA) requires the Food and Drug Administration (FDA) to report annually on the financial aspects of its implementation of MDUFMA. Required under MDUFMA, this is the fourth annual financial report to Congress that covers activities for fiscal year (FY) 2006.

MDUFMA, amended by the Medical Device User Fee Stabilization Act 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 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 2006. The report also provides information on user fee collections, expenditures, and carryover balances. In FY 2006, FDA net collections totaled $34 million from fees. FDA obligated $32 million from MDUFMA collections to support FDA's medical device review program. FDA carried forward into FY 2007 a balance of $16 million. About 72 percent of the total expenses for the medical device review program in FY 2006 went for personnel salary and benefit costs. The reminder (about 28 percent of the total expenses) was primarily the operating and the infrastructure costs necessary to support the medical device review program.

MDUFMA fees, with the increased appropriations from Congress enabled FDA to dedicate 191 more full-time equivalents (FTEs) to the medical device review program in FY 2006 than the FTEs dedicated in FY 2002. An additional 73 contractor staff-years were also dedicated to the device review in FY 2006 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 2007.

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BACKGROUND

The Medical Device User Fee and Modernization Act of 2002 (MDUFMA) authorizes the Food and Drug Administration (FDA) to collect fees from the medical device industry to augment appropriated expenses on 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 Medical Device User Fee Stabilization Act of 2005 (MDUFSA), Public Law 109-43, amended MDUFMA on August 1, 2005. MDUFSA sets the standard fee for a premarket application for fiscal year (FY) 2006 at $259,600. FDA then establishes 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.

MDUFMA requires FDA to submit two reports to Congress each fiscal year: 1) a performance report sent within 60 days, and 2) a financial report is to be sent within 120 days after September 30. FDA transmits separately to Congress the FY 2006 MDUFMA Performance Report that discusses FDA's progress in meeting the goals referred to in MDUFMA. This report is FDA's FY 2006 MDUFMA Financial Report covering the period October 1, 2005 through September 30, 2006.

As required by MDUFMA, this report reveals and discusses the following topics:

- FY 2006 collections, obligations, and carryover balances;
- the statutory conditions (Appendix A);
- the process for the review of medical devices as defined in MDUFMA (Appendix D); and
- the total costs of the process for the review of medical device applications, as defined in MDUFMA, from both fee collections and appropriations (Appendix E).

MEETING THE STATUTORY CONDITIONS FOR USER FEES IN FY 2006

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 2006. See summaries set forth below.

The **first condition** is a funding condition that affects FDA's fee collections in FY 2006. MDUFMA, as amended by MDUFSA, sets the funding condition for FY 2006 equaling $205,720,000 multiplied by an adjustment factor. FDA must meet this condition before it can collect fees for FY 2006. To collect fees in FY 2006, the appropriation for the Devices and Radiological Health budget line must equal no more than 1 percent less than the funding condition that is $222,653,571 after applying the adjustment factor. In FY 2006, FDA received $220,564,000 after rescission, which is within the 1 percent condition. 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 November 10, 2005. The President signed the FY 2006 Appropriation Act, Public Law 109-97. It states that the amounts collectable from medical device user fees are $40,300,000. Therefore, FDA met the second condition.

The **third condition** is that FDA must spend at or above a minimum level of appropriated funds 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 2006 is $129,523,753. FDA obligated $167,425,661 from appropriations. Because FDA spent more than the minimum level, it 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 with an increase of 5 percent for 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 medical device establishment inspections in the future years. FDA spent more in FY 2003, FY 2004, and FY 2006. Because FDA only failed to meet the condition in 1 year (FY 2005), FDA satisfied this requirement to continue to allow accredited third parties to conduct device establishment inspections in FY 2007.

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

USER FEE COLLECTIONS

MDUFMA directs FDA to receive fees only from the medical device applications, and set the application fee rates annually to cover the increases for inflation and workload. The statute directs FDA to set the fee rate for each application type as a percentage of the standard fee for a PMA. MDUFSA specifies that the standard fee for a premarket application for FY 2006 is $259,600. FDA, then, establishes other application fees[1] based on the specified percents mentioned in MDUFMA.

Under MDUFMA, collections of medical device user fees continue to remain available to FDA if they are not spent at the end of a fiscal year. The cash balance carried to the next fiscal year is discussed on page 9, 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, 2006

	FY 2003	FY 2004	FY 2005	FY 2006	Total
Total Fees Collected	$21,619,813	$25,309,853	$31,905,542	$35,358,220	$114,193,428
Unearned Fees[1]	$0	$0	($14,008)	($2,568,581)	($2,582,589)
Fees Receivables	$58,509	$155,108	$0	$6,849	$220,466

[1]Unearned Fees are fees collected for applications that had not been received by FDA as of September 30, 2006. They are included above in the 'Total Fees Collected' amounts.

Please note that the collections are reported in the year that the fees were originally due– referred to as the cohort years. For example, a fee originally due in FY 2005, even if it is received in FY 2006, is attributed to FY 2005 collections. The same concept applies to the refunds. In addition, the collections reported in the table for each fiscal year are net of refunds for that year, as of September 30. The collections do not take into account the refunds that were processed by FDA after September 30.

Last year's financial report showed FDA collected $32,781,347 in FY 2005. FDA reduced the FY 2005 collected fees to $31,905,542 in this report because FDA processed some refunds in FY 2006 that belong to FY 2005 cohort year. Refunds reduce collections.

Unearned fees are included in the fee collected amounts. The unearned fees exist because FDA received the fees for the applications that did not arrive to FDA before September 30. FDA reduces the unearned fees after received the applications from the companies.

[1] FDA published FY 2006 medical device user fee rates in the Federal Register Notice – FR Doc. 05–15863.

In addition to the collections shown in the table, FDA reported the fees receivables. They exist for three reasons: 1) FY 2003 outstanding invoices, 2) FY 2005 error entry in FDA accounting system, and 3) FY 2006 partial payments. $58,509 is due to unpaid fees for the applications that were submitted to FDA in FY 2003. The FY 2003 fees receivables are over 120 days old, and have been turned over to a collection agency. After April 1, 2003, FDA no longer accepts unpaid applications for review. The fees receivables for FY 2005 were mistakenly recorded by FDA. FDA will make a correction to write-off this amount in FY 2007. The FY 2006 fees receivables are the partial payments outstanding as of September 30, 2006 when the medical device companies paid the fees in FY 2005 and submitted the applications to FDA in FY 2006. Because the applications arrived in FY 2006, the companies had to pay the differences to make up FY 2006 new rates. This amount will be reduced to zero in FY 2007 after FDA receives all the partial payments.

OBLIGATION OF USER FEE COLLECTIONS

The user fee collections are expended only for costs necessary to support the process for the review of medical device applications, as defined in MDUFMA. The allowable and the excludable costs for the process for the review of medical device applications are defined in Appendix D.

In FY 2006, FDA obligated $32,068,610 or 16 percent from user fee collections and $167,425,661 or 84 percent from appropriations. See table below.

FOOD AND DRUG ADMINISTRATION
FY 2006 MEDICAL DEVICE REVIEW OBLIGATIONS
BY EXPENSE CATEGORY AND REVENUE SOURCE
As of September 30, 2006

Expense Category	From Appropriations	From Fees	Total
Personnel Compensation and Benefits	$120,815,520	$21,786,793	$142,602,313
Travel and Transportation	$1,772,147	$409,542	$2,181,689
GSA Rent	$10,865,220	$2,236,700	$13,101,920
Communications	$2,212,496	$720,006	$2,932,502
Contract Services	$26,064,157	$5,962,800	$32,026,957
Equipment and Supplies	$3,364,752	$833,022	$4,197,774
Other[1]	$2,331,369	$119,747	$2,451,116
Total Obligations	**$167,425,661**	**$32,068,610**	**$199,494,271**

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

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 2006 resulted in a net carryover balance of $16,240,618.

The table below captures FDA's carryover balances from FY 2003 to FY 2006.

FOOD AND DRUG ADMINISTRATION
STATEMENT OF CASH, OBLIGATIONS, AND
CARRYOVER BALANCES BY FISCAL YEAR
As of September 30, 2006

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			

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 adjustments occurred during each fiscal year. FDA subtracts the obligations to obtain year-end carryovers.

AVAILABILITY OF CARRYOVER BALANCES

Of the FY 2006 carryover balance, $2,582,589 is the unearned fees from applications that are not yet received by FDA. It must be held in reserve. In addition, FDA holds $1,000,000 in reserve for potential refunds in future years. MDUFSA requires FDA to have at least 1 month reserve at the end of FY 2007 for future operations when the MDUFMA program sunsets. The table below shows the proposed allocation of FDA's carryover balance.

FOOD AND DRUG ADMINISTRATION
PROPOSED ALLOCATIONS OF MEDICAL DEVICE FEE REVENUE
CARRYOVER BALANCE
As of September 30, 2006

Status of Carryover Funds	Amount
Unearned fees	$2,582,589
Reserve for Future Refunds	$1,000,000
1-Month Reserve	$3,600,000
Available Cash for allocation in FY 2007	$9,058,029
Total Carryover Balance	**$16,240,618**

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

FDA studies and records the MDUFMA costs by using time reporting surveys. The surveys determine a percentage of time each FDA organizational component (such as the Center for Devices and Radiological Health (CDRH), the Center for Biologics Evaluation and Research (CBER), or the Office of Regulatory Affairs (ORA)) devote to the process for the review of medical device applications. The percentages allow FDA to calculate the costs for the allowable activities in the medical device application review process. FDA reassesses the percentages on a regular basis with the results of the time reporting surveys to closely monitor the costs for the medical device review process. See Appendix D for the descriptions of the allowable activities and Appendix E for more discussions on cost development associated with 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 2005 and FY 2006, by FDA organizational components and by 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 are 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, 2006

FDA Organizational Component	FY 2005	FY 2006
Center for Devices and Radiological Health	$140,704,264	$155,850,979
Center for Biologics Evaluation and Research	$15,534,783	$20,830,565
Field Inspection and Investigation	$9,674,368	$10,499,258
Agency General and Administrative Costs	$11,805,241	$12,313,468
Total Process Costs	**$177,718,656**	**$199,494,271**
Obligations from Appropriations	$150,547,256	$167,425,661
Obligations from Medical Device User Fee Collections	$27,171,400	$32,068,610

The costs for all organizational components increased in FY 2006. The increase primarily reflects enhanced spending for medical device review program from appropriations and user fee collections in FY 2006.

The agency's general and administrative costs continued to decline as a percent of total spending on the medical device review process. The percent of medical device review process costs devoted to agency's general and administrative costs decreased from 8.6

percent in FY 2002, to 7.3 percent in FY 2003, to 7.2 percent in FY 2004, to 6.6 percent in FY 2005, and to 6.2 percent in FY 2006.

FULL TIME EQUIVALENTS

The table below presents the Full Time Equivalent (FTE) levels that support the medical device application review process by FDA organizational components. In FY 2006, FDA spent about 72 percent of its total funds for the salaries and benefits of the medical device process FTEs.

FOOD AND DRUG ADMINISTRATION
PROCESS FOR THE REVIEW OF MEDICAL DEVICE APPLICATIONS
TOTAL FTES
As of September 30, 2006

	Fiscal Years				
	2002	**2003**	**2004**	**2005**	**2006**
Center for Devices and Radiological Health	650	662	713	794	765
Center for Biologics Evaluation and Research	45	59	70	87	108
Office of Regulatory Affairs	54	59	60	64	65
Office of the Commissioner	80	77	72	89	82
Total FTE	**829**	**857**	**915**	**1,034**	**1,020**

Note: For comparability purpose, FY 2004 to FY 2006 FTEs represent all centers and offices and include Shared Services MDUFMA process FTEs.

In the table, the FTEs reported for FY 2004 through FY 2006 continue to show staff transferred to FDA's consolidated Shared Services organization in the Office of the Commissioner (OC) as if they were still in CDRH, CBER, and ORA. FDA uses this approach to make the data reported for FY 2004 through FY 2006 comparable to the data reported for FY 2002 and FY 2003.

Please note that CDRH had decreases in FTEs in FY 2006 compared to FY 2005. There are two reasons for this decrease.

1. The uncertainties about MDUFSA led to a hiring freeze in FY 2005, which reduced hiring in CDRH. Restarting the hiring cycle took time. Many of the new employees were hired in the middle or at the end of FY 2006. Staff hired in FY 2006 will contribute a full-year work effort in FY 2007.

2. 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 parts of the MDUFMA process. These changes allowed CDRH to better distinguish between premarket and postmarket efforts.

Therefore, the decrease in FTEs from FY 2005 to FY 2006 is in part due to a change in time-reporting methodology.

In addition to the FTE numbers shown in the table, CDRH also expended 73 more contractor staff-years on the medical device review process in FY 2006 than it did in FY 2002. CBER's FTE increase between FY 2005 and FY 2006 is the result of increased MDUFMA-related work effort.

PERFORMANCE GOALS

In FY 2006, 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 2006 were:

- **Steady progress in meeting MDUFMA performance goals**. FDA is meeting, or is on track to meet, nearly all of the performance goals for FY 2003, FY 2004, FY 2005, and FY 2006 receipt cohorts.
- **Guidance documents.** FDA issued six MDUFMA guidance documents during FY 2006; four provided new guidance and two provided updated editions of earlier guidance. These include the final guidance, *Compliance with Section 301 of the Medical Device User Fee and Modernization Act of 2002, as amended — Prominent and Conspicuous Mark of Manufacturers on Single-Use Devices*, and new guidance on *The Review and Inspection of Premarket Approval Application Manufacturing Information and Operations.*
- **Stakeholder communication and consultation.** FDA expanded its outreach to stakeholders, providing additional information through the MDUFMA internet site (http://www.fda.gov/cdrh/mdufma), FDA presentations at industry and professional meetings, and quarterly meetings with stakeholders. In November 2005, FDA held its Annual Stakeholder Meeting to report on the implementation of MDUFMA and to hear directly from stakeholders. And in May 2006, FDA held a public meeting to consult with stakeholders and determine whether it is appropriate to implement two contingent decision goals for FY 2007. With stakeholder input, FDA decided to implement the two review performance goals for FY 2007: 1) 50 percent of premarket approval applications received in FY 2007 will have an FDA decision in 180 days; and 2) 80 percent of premarket notifications received in FY 2007 will have an FDA decision in 90 days.
- **Public notification.** During FY 2006, FDA published 14 *Federal Register* notices to provide essential information to stakeholders on new guidance documents, proposed rules, regulatory actions, user fees, and other topics, and to also request comments

and suggestions from stakeholders.

CBER expects to achieve all its FY 2005 MDUFMA performance goals when the cohort is completed. Thus far, CBER has met or exceeded all the FY 2006 MDUFMA decision-performance goals, but missed two interim action 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 2006, 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 2007

The most important challenge for FY 2007 is to secure reauthorization of medical device user fees for FY 2008 through FY 2012. The authority provided under MDUFMA will, under the current law, sunset on September 30, 2007. During 2007, FDA consulted with stakeholders and has held a public meeting to discuss recommendations for Congressional consideration. Timely reauthorization is critical to the continued success of FDA's medical device review program.

FDA faces continuing challenges in meeting MDUFMA's performance goals and commitments. These include building critical infrastructure, hiring and training additional staff, making greater use of external expertise, and reengineering our review processes to implement new and more demanding performance goals for FY 2007, providing more timely and efficient device reviews.

During FY 2007, FDA needs to address the following specific challenges to achieve the improvements promised by MDUFMA.

- Develop data systems that ensure each device review subject to a user fee is linked to the correct user fee payment and systems to measure FDA's review performance against the many goals established under MDUFMA. This will require new internal systems, as well as systems to link very different databases in FDA's OC, CBER, and CDRH.
- Move forward with electronic application submission and review systems and processes.
- Continue to hire and train additional FDA scientists, engineers, statisticians, and other staff to: better distribute review workloads, expand the opportunity for meetings and other interactions with applicants, expand and update guidance documents used by applicants to prepare high-quality applications, and undertake the many additional efforts that will be required to meet or exceed MDUFMA's performance goals.
- Make appropriate use of external expertise to ensure timely action on medical device reviews that involve novel new technologies or unusual efforts.
- Ensure timely pre-approval inspections, both within the United States and abroad.
- Refine the processes for modular PMA reviews, and to work with stakeholders to develop meaningful performance goals for these reviews.
- Ensure that device reviews are completed in as few cycles as possible, thereby speeding the introduction of important new medical technologies and providing greater predictability in the reviews.

Appendix A

STATUTORY CONDITIONS FOR COLLECTION AND USE OF FEES

The Federal Food, Drug, and Cosmetic Act (the 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 2006 in more details.

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 2006, which began on October 1, 2005, was April 2005. The Consumer Price Index (CPI) for April 2005 was 194.6. The CPI for April 2002 was 179.8. Dividing the CPI of April 2005 by the CPI of April 2002 yields an adjustment factor of **1.0823** for FY 2006.

The **first condition** is a funding condition that affects the collection of fees in FY 2006. MDUFMA, amended by MDUFSA, sets the funding condition for FY 2006 equaling $205,720,000 multiplied by an adjustment factor. FDA must meet this condition before it can collect fees for FY 2006. To collect fees in FY 2006, the appropriation for the Devices and Radiological Health budget line[2] must equal no more than one percent less than the funding condition that is $222,653,571[3], or $205,720,000 multiplied by the adjustment factor of 1.0823. $222,653,571 after one percent reduction is $220,427,035. In FY 2006, FDA received $220,564,000 after rescission, which is $136,965 greater than $220,427,035. Therefore, FDA 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.

[2] The Device and Radiological Health program line is sum of appropriations for Centers for Devices and Radiological Health (CDRH) and the related field activities in the Office of Regulatory Affairs (ORA).
[3] Number may be different due to rounding. The adjustment factor in this report is shown and rounded to the fourth decimal place. $222,653,571 is calculated from the adjustment factor with full decimal places.

On November 10, 2005, the President signed FY 2006 Appropriation Act, Public Law 109-97, that authorized and specified the amount collectable for the medical device user fees. This provision authorized FDA to collect $40,300,000 from medical device user fees. 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:

> (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. The adjustment factor for FY 2006 is 1.0823. Multiplying by the adjustment factor, FDA calculates the minimum spending from appropriations for the medical device review process in FY 2006 to be $129,523,753[4].

FDA obligated $167,425,661 from appropriations for the process for the review of medical device applications in FY 2006. It is $37,901,908 greater than the minimum spending from appropriation. Therefore, FDA met the third condition.

The table below shows FDA obligations on the process for the review of medical device applications in FY 2005 and FY 2006. The table separates the obligations that were charged to appropriations and user fee collections.

FOOD AND DRUG ADMINISTRATION
OBLIGATIONS FOR THE PROCESS FOR THE REVIEW OF MEDICAL DEVICE APPLICATIONS
As of September 30, 2006

	FY 2005	FY 2006
From Appropriations	$150,547,256	$167,425,661
From Medical Device Fee Collections	$27,171,400	$32,068,610
Total Obligations	**$177,718,656**	**$199,494,271**

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

[4] Number may be different due to rounding. The adjustment factor in this report is shown and rounded to the fourth decimal place. $129,523,753 is calculated from the adjustment factor with full decimal places.

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 to allow 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 FDA obligations for medical device establishment inspections from FY 2002 to FY 2006. FDA obligated $19,425,000 in FY 2002. When FDA adds a 5 percent increase adjustment to each fiscal year subsequent to FY 2002, FDA then compares them to its actual obligations to determine whether it meets this condition. FDA spent more in FY 2003, FY 2004, and FY 2006. Because FDA only failed to meet the condition in 1 year (FY 2005), FDA satisfied the MDUFMA financial requirement to allow accredited third parties to continue conducting medical device establishment inspections in FY 2007.

FOOD AND DRUG ADMINISTRATION
OBLIGATIONS FOR THE INSPECTION OF MEDICAL DEVICE ESTABLISHMENTS
(Rounded to $000)
As of September 30, 2006

	2002 Obligations (increase 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

Appendix B

NUMBER OF FEE PAID APPLICATIONS IN FY 2006

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 $3,833. Table below exhibits the rates for all types in FY 2005 and FY 2006.

FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE RATES
As of September 30, 2006

Application Type	FY 2005	FY 2006
Full Fee Applications	$239,237	$259,600
Small Business Rate	$90,910	$98,648
180-Day Supplements	$51,436	$55,814
Small Business Rate	$19,546	$21,209
Real-Time Supplements	$17,225	$18,691
Small Business Rate	$6,546	$7,103
510(k)s	$3,502	$3,833
Small Business Rate	$2,802	$3,066

The second table below summarizes the number of applications received by FDA in FY 2005 and FY 2006. 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, 2006

Application Type	FY 2005 Actual	FY 2006 Actual
Full Fee Applications	45	51
Small Business	7	7
180-Day Supplements	81	76
Small Business	9	25
Real-Time Supplements	140	156
Small Business	16	16
510(k)s	3,026	2,988
Small Business	537	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.

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 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 3rd party reviewers, rather than to FDA.

FDA provides a summary of MDUFMA fee waivers, reductions, and exemptions granted in FY 2006 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 698 of 717 written requests for small business status in FY 2006. FDA waived or reduced 669 applications under small business criteria in FY 2006. 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 2006.

FOOD AND DRUG ADMINISTRATION
FY 2006 SMALL BUSINESS FEE WAIVERS AND REDUCTIONS GRANTED
As of September 30, 2006

Category	Number	Amount	Total Value
Full Fees Waived	6	$259,600	$1,557,600
Full Fees Reduced	5	$160,952	$804,760
Panel Track Supplements Reduced	2	$160,952	$321,904
180-Day Supplements Reduced	27	$34,605	$934,335
Real-Time Supplements Reduced	16	$11,588	$185,408
510(k)s Fees Reduced	613	$767	$470,171
Total	**669**		**$4,274,178**

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

FDA collected $34,325,120 fees or net cash in fiscal year 2006. Had there been no small business waivers and reductions, FDA would have collected an additional $4,274,178, or an additional 12.5 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 5 HDE applications and 53 supplements in FY 2006. 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.

FDA received 5 exemption requests in FY 2006 for applications submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only.

FDA received and granted 4 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 2006 was $15,332.

FDA granted 38 510(k)s and 1 panel track supplement for pediatric exemptions in FY 2006. Total value of these exemptions was $405,254.

The Third Party Review Program for 510(k) submissions increased by 18 percent in FY 2006 over FY 2005. In FY 2006, FDA received 287 510(k) submissions subject to third party review. Out of 287 submissions, FDA made final decisions on 268 – 18 more than 250 in FY 2005. FDA exempted fees for the 268 submissions. Total value of these exemptions in FY 2006 was $996,411 – assuming that 15 percent of the third party submissions paid the reduced small business fees.

FOOD AND DRUG ADMINISTRATION
SUMMARY AND TOTAL VALUE OF ALL FEE WAIVERS, REDUCTIONS, AND EXEMPTIONS GRANTED
As of September 30, 2006

Reason	FY 2005	FY 2006
Small Business	$5,108,227	$4,274,178
Govt. Sponsored Application not for Commercial Distribution	$7,004	$15,332
Pediatric Indications	$394,639	$405,254
510(k)s Reviewed by 3rd Party Review	$825,786	$996,411
Total Value	**$6,335,656**	**$5,691,175**

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 one year, and 96 percent within two 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 Good Manufacturing Practice (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
- 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
- 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
- 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
- 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"
- 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
- 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, radiation safety authorities of the Federal Food, Drug, and Cosmetic 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.

CDRH had a time reporting system that has been used to gather information about how employees spend their time for a 2-week period one or two times each year for the past 10 years. 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 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 will be followed in future years. In addition, further modifications were made in FY 2005 to be able to break out time for various specific

types of application review, and training in the use of the time reporting system and its importance was also provided in the first half of FY 2005.

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. This means that some of the difference from FY 2005 to FY 2006 is explained by a change in methodology.

A similar procedure was used in CBER's direct review and laboratory components to measure costs for the device review process. CBER was able to use the time-reporting system it has had in place for over 10 years, and which was validated by studies done just after PDUFA was initiated. 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 time of the management and administrative support personnel is assumed to follow the same pattern between process and non-process costs as the average time of those employees who reported their time. The results from each 2-week period of time reported is extrapolated for the quarter being reported. The extrapolated results for each quarter are totaled to represent the entire year.

This 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 measured 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 user fee related staff years to the average salary cost in ORA to arrive at the ORA user fee related salary costs. 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 2005 and FY 2006, respectively.

FOOD AND DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS
COSTS OF THE PROCESS FOR THE REVIEW OF MEDICAL DEVICE APPLICATIONS
As of September 30, 2006

Cost Component	FY 2005	FY 2006
Staff Years Utilized	62	64
ORA Average Salary and Benefits	$93,594	$99,675
Total Salary and Benefits	$5,802,816	$6,379,211
Operating and Other Costs[1]	$3,871,551	$4,120,047
Total	**$9,674,368**	**$10,499,258**

[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. During FY 2006, OC was comprised of the following offices:

- Immediate Office of the Commissioner
- Office of the Chief Counsel
- Office of Equal Employment Opportunity and Diversity Management
- Office of the Administrative Law Judge
- Office of Science and Health Coordination
- Office of International Activities and Strategic Initiatives
- Office of Crisis Management
- Office of Legislation
- Office of External Relations
- Office of Policy and Planning
- Office of Management

The OC costs applicable to the process for the review of medical device applications were calculated using a method prescribed by the Division of Cost Determination Management, Office of Finance, Office of the Secretary, Department of Health and Human Services. The method uses the percentage derived by dividing total 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 $11,805,241 and $12,313,468 in general and administrative expenses to the medical device review process in FYs 2005 and 2006, respectively. The FY 2006 general and administrative obligations are from appropriations and user fees, and accounted for 6.2 percent of the total cost of the process for the review of medical device applications. Comparing to FY 2005 (6.6 percent), FDA managed to operate under a lower cost for the review process of the medical 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 2006 supporting the medical 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 2006 comparable with figures prior to FY 2004.