FY 2005 MDUFMA FINANCIAL REPORT

REQUIRED BY THE

MEDICAL DEVICE USER FEE AND MODERNIZATION ACT OF 2002

FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

JULY 2006

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

August 8, 2006

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

Dear Mr. President:

Enclosed is the third annual financial report to Congress required by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA). This report covers fiscal year (FY) 2005, documenting how the conditions specified in MDUFMA for the continued collection of medical device user fees were met.

The report also presents the user fee revenues and related expenses for FY 2005, and details the amount carried over at the end of the year that remains available. For FY 2005, net MDUFMA user fee collections totaled $31.1 million, and fees obligated totaled $27.2 million. In addition, FDA received a significant increase in appropriations for its device program in FY 2005. Over 65 percent of the funds spent for device review went for staff salaries and benefits, and the remainder went toward increased support and infrastructure for the device review program. .

Sincerely,

/s/

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. This is FDA's report for fiscal year (FY) 2005.

MDUFMA, as amended by the Medical Device User Fee Stabilization Act of 2005 (MDUFSA), 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 and adjusted for inflation).
2. Fee revenues collected must be specified in 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.

This report describes how these specific statutory conditions or "triggers" were met in FY 2005. The report also provides information on the user fee revenues and expenditures in FY 2005, and on the carryover balance.

In FY 2005, FDA net collections totaled $31.1 million in fees—including $3.4 million of fees paid in advance for applications that had not been received. Cumulative collections since the beginning of the program were $6.1 million less than the adjusted revenue amounts set in statute through FY 2005. The shortfall is due to fewer applications that paid the highest fees, fewer supplements that paid the higher supplement fee, and to a larger number of applications than expected that qualified for exemption from fees.

In FY 2005, FDA obligated $27.2 million from MDUFMA revenues to support FDA's medical device review program, and carried forward into FY 2006 a balance of $13.9 million (including $3.4 million in fees for applications not yet submitted). Over 65 percent of the total amount spent for the device review program in FY 2005 went for personnel salary and benefit costs. The balance was primarily operating costs and infrastructure necessary to support the staff. The MDUFMA fees, and significantly increased appropriations for the medical device program, enabled FDA to dedicate 205 more staff years to device review in FY 2005 than it did in FY 2002, before MDUFMA was enacted. An additional 70 contract years were also dedicated to device review in FY 2005, compared with FY 2002 before MDUFMA was enacted. These resources have enabled FDA to achieve almost all of the performance goals associated with the enactment of MDUFMA, and to substantially strengthen FDA's medical device review program.

The Agency looks forward to continued strengthening of the device program over the two remaining years that MDUFMA is authorized.

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BACKGROUND

MDUFMA authorized FDA to collect fees from the medical device industry to augment appropriations spent on the device review process, and also required additional funding from appropriations. These funds are to be used for additional resources to support the "process for the review of device applications" as defined in MDUFMA, so that safe and effective devices reach the American public more quickly.

Under MDUFMA, an application fee must be paid when certain device applications are submitted. Fee-paying applications include premarket applications (PMAs), product development protocols (PDPs), premarket reports (PMRs), modular PMAs, biologics license applications (BLAs), and certain supplements to all of them, as well as premarket notification submissions (510(k)s). The aggregate application fee revenue amount for FY 2005 was specified by MDUFMA, with a provision for adjustment for cumulative inflation since FY 2003. The individual fees for various types of applications are fixed in statute as a percent of the fee for a PMA. Fees for FY 2005 were set in August 2004 after the inflation, workload, and shortfall adjustments to the statutory fee amount have been determined.

MDUFMA requires FDA to submit two reports to Congress each fiscal year. A performance report is to be sent within 60 days of the end of the fiscal year, and a financial report is to be sent within 120 days. The FY 2005 MDUFMA Performance Report, which discusses FDA's progress in meeting the goals referred to in MDUFMA, is being separately transmitted to Congress. This is FDA's FY 2005 MDUFMA Financial Report, covering the period October 1, 2004, through September 30, 2005.

As required by statute, this report presents the legal conditions or "triggers" that must be satisfied before FDA can collect and spend the fees, and FDA's calculations showing the extent to which those conditions were met in FY 2005 (Appendix A). This report also describes in some detail (Appendix D) the process for the review of devices as defined in MDUFMA—a process that includes portions of activities in FDA's device and radiological health program, biologics program, field activities, and Office of the Commissioner. The total costs of the process for the review of medical device applications, as defined in MDUFMA, are presented—both the costs paid from fee revenues and the costs paid from appropriations. This report presents FY 2005 revenues and obligations from user fees and a summary statement of user fees collected.

In keeping with the requirements of the Chief Financial Officers Act of 1990, the Office of the Inspector General (OIG), Department of Health and Human Services, audits FDA's annual financial statements. The audit covers FDA's financial systems and funds, including MDUFMA revenues and expenses. The OIG issued unqualified audit opinions on FDA's financial statements for fiscal years 1998 through 2004. This is the most favorable category of audit opinion. Auditors did not render an opinion on FDA's financial statements for FY 2005, primarily due to the mid-year conversion to the new HHS Unified Financial Management System, the need to draw financial data from 2 different systems, and the fact that UFMS financial reporting capabilities were still evolving in FY 2005.

MEETING THE LEGAL CONDITIONS FOR USER FEES IN FY 2005

MDUFMA contains legal conditions or "triggers" that must be satisfied for FDA to collect and spend user fees. FDA's calculations showing the extent to which those conditions were met for FY 2003 and FY 2004 are summarized below and presented in more detail in Appendix A.

The **first condition** is a funding trigger which affects the collection of fees in FY 2006. MDUFMA, as amended by MDUFSA, sets funding targets for FY 2005-FY 2006 equaling $205,720,000 multiplied by the adjustment factors applicable for each of those years. The appropriation of this specific funding level was not required to collect fees in FY 2005. Instead, MDUFMA, as amended by MDUFSA, sets a trigger that must be met before fees can be collected for FY 2006.

To collect fees in FY 2006, the sum of appropriations for FY 2005-FY 2006 for the Devices and Radiological Health budget line must equal no more than one percent less than the sum of the funding targets set by MDUFMA, as amended by MDUFSA, for those years. The Agriculture, Rural Development and Food and Drug Administration Appropriation Acts for FY 2005 and FY 2006 are both no less than one percent less than the triggers for these respective years and FDA will therefore be able to collect and spend medical device user fees in FY 2006.

The **second condition** is that the amount of user fees collected each year must be specifically included in Appropriation Acts. The President signed the Appropriation Act (Public Law 108-447) specifying amounts collectable from fees during FY 2005, on December 8, 2004. It provided $33,938,000 to come from fees collected. Thus, the second condition was met.

The **third condition** is that user fees may be collected and used only in years when FDA also spends a specified minimum amount of appropriated funds for the review of device applications. The specified minimum is the amount FDA spent on the process for the review of device applications from appropriations in FY 2002, adjusted for inflation. That adjusted amount is $125,131,313 for FY 2005. FDA's actual obligations from appropriations in FY 2005 were $146,984,432. Since this is greater than the adjusted FY 2002 amount ($125,131,313), the third condition was met.

MDUFMA also contains a provision that must be met if FDA is to be able to continue to have accredited third parties conduct device establishment inspections in FY 2005 and beyond. Under this provision, FDA obligations for inspections of device establishments may not fall below the amount FDA obligated for this purpose in FY 2002, increased by 5 percent each year, for at least one of the two immediately preceding fiscal years. The amount obligated for this purpose in FY 2002 was $19,425,000. With 5 percent increases each year, the MDUFMA targets (rounded to the nearest thousand dollars) for FYs 2004 and 2005 are $21,416,000 and $22,487,000, respectively. FDA's actual obligations for conducting device establishment inspections in FY 2004 and 2005 were $21,522,000 and $21,515,000 respectively. Spending in FY 2004 met the required spending level, but in FY 2005 the amount spent fell short of the requirement by $972,000. Since FDA spending met the

required level for both of the two fiscal years immediately preceding FY 2005 and for one of the two fiscal years immediately preceding FY 2006, FDA has met the MDUFMA financial requirement necessary to permit the Agency to continue to allow accredited third parties to conduct some inspections in FY 2005 and in FY 2006.

Appendix A provides more detail on the calculations that show the extent to which each of these statutory conditions were met.

USER FEE REVENUES

MDUFMA specifies that fee revenues are to be collected only from application fees. The statute specifies annual application fee revenue total amounts and how they are adjusted each year for inflation, workload, and fee shortfalls or surpluses from previous years. FDA then establishes fees each year in an effort to assure that the total revenue collected matches the adjusted statutory total fee amount.

Under MDUFMA, any fees collected and appropriated but not spent by the end of a fiscal year continue to remain available to FDA to spend in future fiscal years. The balance carried to the next year is covered in the section on Carryover Balances beginning on page 9.

The following table shows user fees collected since MDUFMA began.

FOOD AND DRUG ADMINISTRATION
STATEMENT OF MDUFMA FEE REVENUES
As of September 30, 2005

Fees Collected:	FY 2003	FY 2004	FY 2005	Cumulative Total
TOTAL FEES COLLECTED:	**$21,622,000**	**$25,464,961**	**$32,781,347**	**$79,868,308**
UNEARNED FEES INCLUDED: [1]	($0)	($109,911)	($3,395,225)	($3,505,136)
FEES RECEIVABLE:	$87,911	$0	$187,838	$275,749

[1] Unearned income represents fees received for applications not received as of September 30, 2005

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 $27,169,321 of fees collected in FY 2004, of which $1,499,940 was shown as "unearned income" since the application for which the fee was paid had not been received by the end of FY 2004. The FY 2004 total fees collected line is reduced to $25,464,961 in this report, since most of the unearned income reported last year has now been credited to FY 2005—the year the application was actually received. In addition, the FY 2004 total fees collected line has also been reduced to reflect refunds that have been made over the last 12 months as well. The total fees collected line for FY 2005, when seen in next year's FY 2006 report, will also be substantially less than the figure shown here—reflecting both the reassignment of most of the unearned income to FY 2006, and the refunds that will be made over the next 12 months. Totals reported for each year are net of any refunds for that year, as of September 30th, but do not take into account any refunds that may be made after September 30th. Information on the number of each type of fee received in FY 2005 is contained in Appendix B.

In addition to the revenue shown in the table above, a total of $87,911 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 are over 120 days old, have been turned over to a collection agency, and by now are unlikely to be collected. After April 1, 2003, FDA no longer accepted applications for review unless a fee for the application had been received.

Accounts receivable FY 2005 represent additional amounts owed because the wrong fee amount was initially submitted.

A summary of FY 2005 waivers, reductions, and exemptions is provided in Appendix C.

OBLIGATION OF USER FEE REVENUES

User fee revenues are expended only for costs necessary to support the process for the review of device applications, as defined in MDUFMA. Allowable and excludable costs for the process for the review of device applications are defined in Appendix D. In FY 2005, FDA obligated $27,171,400 from medical device user fee revenues and $150,547,256 from appropriations.

FOOD AND DRUG ADMINISTRATION
FY 2005 DEVICE REVIEW OBLIGATIONS BY EXPENSE CATEGORY AND REVENUE SOURCE
As of September 30, 2005

Expense Category	From Appropriations	From Fees	Total
Personnel Compensation and Benefits	$97,720,160	$19,137,884	$116,858,044
Travel and Transportation	2,554,958	227,219	$2,782,177
Rent	10,301,690	2,236,700	$12,538,390
Communications	2,279,489	553,577	$2,833,066
Contract Services	28,526,535	4,499,724	$33,026,259
Equipment and Supplies	6,397,348	378,127	$6,775,475
Other	2,767,076	138,169	$2,905,245
Total Obligations	**$150,547,256**	**$27,171,400**	**$177,718,656**

FDA uses data from time reporting studies to determine the percentage of time each organizational component devoted to activities that are included in the process for the review of device applications, as defined in MDUFMA. This allowed for the calculation of costs. The development of the costs associated with the process for the review of device applications is described in more detail in Appendix E. The time percentages will be recalculated regularly in future years based on the results of regularly conducted time-reporting surveys. The table below shows the FTE spent on the process for the review of device applications by major organizational component beginning in FY 2002. In FY 2005, over 65 percent of all funds obligated went for salaries and benefits of employees.

FOOD AND DRUG ADMINISTRATION
PROCESS FOR THE REVIEW OF DEVICE APPLICATIONS—TOTAL FTE
As of September 30, 2002, 2003, 2004, and 2005

	FY 2002	FY 2003	FY 2004	FY 2005
Center for Devices and Radiological Health (CDRH)	650	662	713	794
Center for Biologics Evaluation and Research (CBER)	45	59	70	87
Office of Regulatory Affairs (ORA)	54	59	60	64
Office of the Commissioner (OC)	80	77	72	89
Total FTE	**829**	**857**	**915**	**1,034**

FTE numbers for FY 2004 and FY 2005 show CDRH, CBER, and ORA staff transferred to the consolidated shared services organization in the Office of the Commissioner as if they are

still in CDRH, CBER, and ORA, to make the numbers comparable to the FY 2002 and FY 2003 numbers. In addition to the FTE numbers shown in the table above, the Center for Devices and Radiological Health also expended about 70 more contractor staff-years on the device review process in FY 2005 than it did in FY 2002.

In FY 2005, FDA made steady progress in implementing MDUFMA. FDA continued to focus on consulting with its stakeholders, developing guidance documents, and building the new review processes and process improvements required to meet MDUFMA's progressively challenging performance goals. Among the key activities and accomplishments during FY 2005 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, and FY 2005 receipt cohorts.
- **Guidance documents.** FDA issued six MDUFMA guidance documents during FY 2005; four provided new guidance and two provided updated editions of earlier guidance. These include guidances related to the Inspection by Accredited Persons Program authorized by section 201 of MDUFMA.
- **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 2004, FDA held its Annual Stakeholder Meeting to report on the implementation of MDUFMA and to hear directly from stakeholders.
- **Public notification.** FDA published 13 *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.

During the last FY, CDRH also began its evaluation of the post-market surveillance program to assess the need for improvement and additional funding, as required by MDUFMA. CDRH continued its contract with Georgetown University and Virginia Polytechnic Institute to provide continuing scientific education for its staff. Finally, to better enable reviewers and managers to monitor different types of marketing applications, such as those for combination products and pediatric indications, CDRH greatly expanded the capabilities of its tracking system. This effort is part of a larger initiative to move towards electronic submission and review of applications.

During Fiscal Year (FY) 2005, CBER has met or exceeded all of the MDUFMA performance goals; review of all of CBER FY 2004 MDUFMA submissions have been completed. CBER continued emphasis on review process oversight, e.g., focusing on communication with sponsors during the first review cycle and updating 510(k) standard operating procedures and policies (SOPPs) to implement process improvements. CBER continues to harmonize with CDRH on revisions/updates of common device review processes and policies to improve

review efficiency, e.g., review of the Quality System Record (QSR) section of a PMA, when to file supplements to PMAs and review of PMA annual reports. In FY 2005, CBER made a number of information technology system modifications including; new packages, views, tables, reports, and maintenance screens to facilitate the transfer of data between the CBER Blood Logging and Tracking System (BLT) and the Office of Financial Management (OFM) coversheet application which manages the receipt of MDUFMA payments.

CARRYOVER BALANCES

Under MDUFMA, any fees appropriated and collected but not obligated by the end of a fiscal year continue to remain available to FDA in future fiscal years. These revenues are referred to as carryover balances. Operations in FY 2005 resulted in a net carryover balance of $13,984,108.

The table below captures the carryover balance at the beginning and end of each fiscal year.

FOOD AND DRUG ADMINISTRATION
STATEMENT OF COLLECTIONS, OBLIGATIONS, AND CARRYOVER BALANCES BY FISCAL YEAR
As of September 30, 2005

Fiscal Year	Beginning Carryover	Net Collection	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			

The balances above reflect cumulative cash at the beginning/end of each fiscal year, and net cash collected during each fiscal year. The net collection amount for FY 2005 is less than the fees credited to FY 2005, shown on page 4. Some of the fees credited to 2005 were actually collected in FY 2004, and reflected as FY 2004 collections that were unearned income in last year's report. In this report they are now credited to FY 2005, since the application for which the fee was submitted was received in FY 2005. The net collection in FY 2005 also reflects refunds in FY 2005 of some fees that were collected in FY 2004.

COLLECTION CEILINGS, SHORTFALLS AND SURPLUSES

Under MDUFMA, amounts below the adjusted cumulative statutory revenue amounts for previous years may be collected in future years by increasing fees using the MDUFMA compensating adjustment. Similarly, collections in excess of amounts stated in appropriations may be kept and used to reduce fees that would otherwise be assessed in a later fiscal year. The following table depicts cumulative net collections, collection ceilings, and cumulative shortfalls through the end of FY 2005.

FOOD AND DRUG ADMINISTRATION
STATEMENT OF FEES COLLECTED, COLLECTION CEILINGS, AND SHORTFALLS
As of September 30, 2005

Fiscal Year	Cumulative Net Collections	Adjusted Cumulative Statutory Revenue Amount	Cumulative Shortfall
2003	$21,936,910	$25,125,000	$3,188,090
2004	$48,765,444	$53,543,789	$4,778,345
2005	$79,868,308	$85,973,697	$6,105,389

The cumulative collection ceiling for FY 2005, in the table above, is the FY 2003 amount of $25,125,000 plus the FY 2004 inflation adjusted amount of $28,418,789, plus the FY 2005 inflation adjusted amount of $32,429,908, with no compensating adjustment, for a total of $85,973,697. Cumulative fees collected through the end of FY 2005 fell short of this cumulative collection ceiling by $6,105,389, as the table above shows.

The MDUFSA amendments to MDUFMA, enacted in August 2005, eliminated revenue targets for MDUFMA, and established a new financial structure with fees for FY 2006 and FY 2007 set in statute rather than based on revenue targets. When fees for FY 2006 were set in August 2005, they were based on the new MDUFSA financial structure.

AVAILABILITY OF CARRYOVER BALANCES

Of the total carryover balance of $13,984,108, $3,505,136 is unearned income from applications not yet received, and must be held in reserve. In addition, $1,000,000 is held in reserve for potential refunds. The MDUFSA amendments to MDUFMA require FDA to have at least a 1-month reserve for future operations at the end of FY 2007, when the statute sunsets—about $3 million. The amount shown as available for allocation in FY 2006 and FY 2007, in the table below, is subject to the requirement for Congressional notification as required under 21 U.S.C. 379j(c)(3).

FOOD AND DRUG ADMINISTRATION
SUMMARY STATEMENT OF MDUFMA FEE REVENUE CARRYOVER BALANCE
As of September 30, 2005

Status of Carryover Funds	Amount
Unearned Income	$3,505,136
Reserve for Refunds	$1,000,000
Reserve for Operations at the end of FY 2007	$3,000,000
Available for allocation in FY 2006 and FY 2007	$6,478,972
Total Carryover Balance	**$13,984,108**

TOTAL COSTS OF THE PROCESS FOR THE REVIEW OF DEVICE APPLICATIONS

The following table presents the costs for the review of device applications for FYs 2003, 2004, and 2005 by organizational component. This presents the full cost of the process for the review of device applications, including costs paid both from appropriations and from user fee revenues. The amounts are based upon obligations recorded as of the end of each fiscal year. In the past, over 81 percent of obligated amounts are expended within one year, and 96 percent within two years. Thus, obligations represent an accurate measure of costs.

FOOD AND DRUG ADMINISTRATION
PROCESS FOR THE REVIEW OF DEVICE APPLICATIONS—TOTAL COST BY COMPONENT AND SOURCE
As of September 30, 2003, 2004 and 2005[1]

FDA Component	FY 2003	FY 2004	FY 2005
Center for Devices and Radiological Health (CDRH)	$111,499,009	$115,537,033	$140,704,264
Center for Biologics Evaluation and Research (CBER)	$10,970,557	$13,161,145	$15,534,783
Field Inspection and Investigation Costs (ORA)	$7,671,835	$8,027,300	$9,674,368
Agency General and Administrative Costs (OC)	$10,293,297	$10,671,593	$11,805,241
Total Process Costs	**$140,434,698**	**$147,397,071**	$177,718,656
Amount from Appropriations	$125,597,098	$123,521,871	$150,547,256
Amount from Fees	$14,837,600	$23,875,200	$27,171,400

[1]For comparability purposes, costs for FY 2004 and FY 2005 for the Office of Shared Services are shown prorated back to the components where they were obligated in FY 2003—CDRH, CBER, ORA, and OC.

The costs for all components other than OC rose in FY 2005. This increase primarily reflects enhanced spending made possible by the additional resources, both from fees and from appropriations, for device review in FY 2005.

The Agency General and Administrative Costs continued to decline as a percent of total spending on the device review process. The percent of device review process costs devoted to Agency 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 6.1 percent in FY 2005.

MANAGEMENT CHALLENGES FOR FY 2006

With the passage of MDUFMA, expectations have been created for significantly reducing the time it takes to evaluate new device applications, while maintaining rigorous standards for device safety and effectiveness. The enactment of the MDUFSA amendments to MDUFMA in August 2005, and appropriations for FY 2005 and FY 2006 sufficient to meet the requirements of MDUFMA, as amended by MDUFSA, provides reasonable assurance of the continuation of this innovative program through the end of FY 2007.

FDA faces a number of 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 provide for more timely and efficient device reviews. Additionally, FDA will work with stakeholders, the Administration, and Congress to ensure continued success of the device user fee program.

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 Office of the Commissioner, 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

CONDITIONS FOR COLLECTION AND USE OF FEES

The Federal Food, Drug, and Cosmetic Act (the Act), as amended by MDUFMA, Public Law 107-250, and by the Medical Device and User Fee Stabilization Act of 2005 (MDUFSA), specifies three major conditions that must be met to some extent for medical device user fees to be collected and spent. A summary of these conditions and the extent to which they were met was provided earlier on pages 2 and 3. Each of these conditions is described in more detail below, with an explanation of the extent to which the condition was met in FY 2005.

For making the comparisons to determine if statutory conditions are met, an adjustment factor, which is defined in section 737(7) of the Act, must be calculated and applied each year. The statute 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 2005, which began on October 1, 2004, was April 2004. The consumer price index (CPI) for April 2004 was 188.0. The CPI for April 2002 was 179.8. Dividing the CPI of April 2003 by the CPI of April 2002 yields a MDUFMA adjustment factor of **1.04561** for FY 2005.

The **first condition** is a funding trigger which affects the collection of fees in FY 2006. MDUFMA, as amended by MDUFSA, sets funding targets for FY 2005-FY 2006 equaling $205,720,000 multiplied by the adjustment factors applicable for each of those years. The appropriation of this specific funding level was not required to collect fees in FY 2005. Instead, MDUFMA, as amended by MDUFSA, sets a trigger that must be met before fees can be collected for FY 2006.

To collect fees in FY 2006, the sum of appropriations for FY 2005-FY 2006 for the Devices and Radiological Health budget line must equal no more than one percent less than the sum of the funding targets set by MDUFMA, as amended by MDUFSA, for those years. The Agriculture, Rural Development and Food and Drug Administration Appropriation Acts for FY 2005 and FY 2006 are both no less than one percent less than the triggers for these respective years and FDA will therefore be able to collect and spend medical device user fees in FY 2006.

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…." Without an appropriation, no fees may be collected.

On December 8, 2004, the President signed the Appropriation Act (Public Law 108-447) specifying amounts collectable from fees during FY 2005. It provided $33,938,000 to come from fees collected. Thus, the second condition was met.

The **third condition** of MDUFMA requires an annual minimum amount of spending from appropriations, exclusive of user fees, on the process for 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 actual obligations for the process for the review of device applications totaled $119,673,026. The adjustment factor for FY 2005 is 1.04561, as stated above. Multiplying by this adjustment factor, the minimum amount of spending from appropriations for the device review process in FY 2005 is $125,131,313.

The amount FDA obligated from appropriations for the process for the review of device applications for FY 2005 was $150,547,256. Since this is greater than the adjusted FY 2002 amount ($125,131,313) the third condition was met.

The table below shows amounts FDA spent on the process for the review of device applications in FY 2004 and FY 2005. It also shows the amount of these costs that was charged to appropriations and the amount spent from user fee revenues.

FOOD AND DRUG ADMINISTRATION
OBLIGATIONS FOR THE PROCESS FOR THE REVIEW OF DEVICE APPLICATIONS
As of September 30, 2005

	FY 2004	FY 2005
From Appropriations	$123,521,871	$150,547,256
From User Fee Revenues	$23,875,200	$27,171,400
Total Obligations	**$147,397,071**	**$177,718,656**

In addition to the above conditions, MDUFMA imposes a **fourth condition** that must be met if FDA is to be able to continue to have accredited third parties conduct device establishment inspections in FY 2005 and beyond. Under this provision, FDA obligations for inspections

of device establishments may not fall below the amount FDA obligated for this purpose in FY 2002, increased by 5 percent each year, for at least one of the two immediately preceding fiscal years. Should obligations for device establishment inspections fall below this minimum spending level for two consecutive years, FDA would be prohibited from allowing accredited third parties to conduct such inspections. This fourth condition is in section 704(g)(10) of the Act. As the table below shows, the amount FDA obligated for device establishment inspections in both FY 2003 and FY 2004 exceeded the minimum specified. Since FDA spending met the required level for both of the two fiscal years immediately preceding FY 2005 and for one of the two fiscal years immediately preceding FY 2006, FDA has met the MDUFMA financial requirement necessary to permit the Agency to continue to allow accredited third parties to conduct some inspections in FY 2005 and in FY 2006.

FOOD AND DRUG ADMINISTRATION
OBLIGATIONS FOR THE INSPECTION OF DEVICE ESTABLISHMENTS
As of September 30, 2005, Rounded to the Nearest Thousand Dollars

	2002 Base	2003	2004	2005
2002 Obligations increased by 5% each year	$19,425,000	$20,396,000	$20,416,000	$22,487,000
Actual Obligations	$19,425,000	$22,576,000	$21,522,000	$21,515,000
Excess (Shortfall)	*NA*	$2,180,000	$106,000	($972,000)

Appendix B

SUMMARY OF APPLICATION FEES PAID IN FY 2005

MDUFMA sets fees for a number of different categories of applications. The highest fees are paid by premarket applications, premarket reports, panel track supplements, and efficacy supplements, all of which were required to pay $239,237 each in FY 2005. These are referred to collectively as full fee applications, even though those that were submitted by qualifying small businesses paid only 38 percent of the full fee rate, or $90,910, in FY 2005. There are two kinds of fee-paying supplements to these applications under MDUFMA, 180-day supplements and Real Time supplements. The 180-day supplements were assessed a fee of $51,436 each in FY 2005, except that those from qualifying small businesses paid only $19,546. The Real Time supplements were assessed a fee of $17,225 in FY 2005, except that those from qualifying small businesses paid $6,546. 510(k) notifications submitted in FY 2005 were assessed a fee of $3,502, except that those from qualifying small businesses paid a fee of $2,802.

The Table below summarizes the number and type of application fees originally expected before MDUFMA was enacted, the revised plan published in August 2004 when FY 2005 fees were set, and the actual number of fees received in FY 2004 and FY 2005.

FOOD AND DRUG ADMINISTRATION
NUMBERS OF FEE PLANNED/ACTUALLY RECEIVED
As of September 30, 2005

Application Type	Original Plan	Rev 2005 Plan	FY 2004 Actual	FY 2005 Actual
Full Fee Applications	58	51	40.5	45
Small Business Rate	10	6	4	7
180-Day Supplements	171	86	93	81
Small Business Rate	24	9	13	9
Real-Time Supplements	86	160	157	140
Small Business Rate	14	15	20	16
510(k)s	4000	3060	2,874	3026
Small Business Rate		540	517	537

It should be noted that the numbers of fees received should in no way be used as a surrogate for device review workload. There are many applications that for a variety of reasons pay no fee at all. The reasons that no fee is paid include first applications submitted by small businesses, applications that are bundled under one fee because of similarity of review issues, applications that are exempt from fees such as those for pediatric indications, and applications for which no fee is charged such as those 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 any fees for applications 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 premarket notifications (510(k)s) from qualified small businesses. In addition, MDUFMA fees are not to be collected for the following:

- applications for humanitarian device exemptions 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.

This appendix provides a summary of the MDUFMA fee waivers, reductions, and exemptions allowed in FY 2005.

FDA responded to thousands of e-mails and phone calls from firms asking for information regarding the small business waiver for MDUFMA fees. FDA granted 644 of the 674 written requests for small business status received in FY 2005. A total of 555 applications received in FY 2005 had fees either waived (if the application was their first PMA) or reduced because the submitter was a qualified small business. The following table summarizes the value of the small business reductions or waivers granted for applications that were received in FY 2005. Some qualifying small businesses submitted more than one application that had a fee reduced, and some did not submit an application in FY 2005.

FOOD AND DRUG ADMINISTRATION
FY 2005 SMALL BUSINESS FEE WAIVERS AND REDUCTIONS GRANTED
As of September 30, 2005

	Number	Value for Each	Total Value
Full Fees Waived	14	$239,237	$3,349,318
Full Fees Reduced	7	$148,327	$1,038,289
180-Day Supplements Reduced	6	$31,890	$191,340
Real-Time Supplements Reduced	16	$10,680	$170,880
510(k) Fees Reduced	512	$700	$358,400
Total Value of Small Business Waivers and Reductions:			**$5,108,227**

FDA received fees totaling $32,551,970 in FY 2005. Had there been no small business waivers and reductions, FDA would have collected an additional $4,749,827. (The value of the 510(k) waivers is not included in this amount, since under MDUFMA the fees for 510(k)s from large firms is increased slightly to offset the reduction in 510(k) fees charged to

qualifying small businesses.) The total with no small business waivers or reductions would have been $37,301,797. The small business waivers and reductions resulted in FDA's collecting about 12.7 percent less revenue than would have otherwise been the case.

FDA received 5 Humanitarian Device Exemption (HDE) applications and 24 supplements in FY 2005. None of these are subject to MDUFMA fees. We do not know if any of them would have been submitted had they been subject to a fee. Therefore we do not know the extent to which this exemption resulted in any loss of revenue.

FDA received no exemption requests in FY 2005 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 2 requests from a State or Federal government entity for exemptions for an application (in this case a 510(k)) or a device that was not intended for commercial distribution. Total cost of this exemption in FY 2005 was $7,004.

Pediatric Exemptions were granted in FY 2005 for 1 full fee application, 2 180-day supplement, no real-time supplements, and 15 510(k)s. Total value of these exemptions for applications received in FY 2005 was $394,639.

In FY 2005, FDA received 243 510(k)s that were subject to third party review and therefore did not pay MDUFMA fees. This is 12 less than the 255 510(k)s that were submitted for third party review in FY 2004. Total value of these exemptions in FY 2005 was $825,786—assuming that 15 % of those submitted to 3rd parties would have paid the reduced small business fee.

FOOD AND DRUG ADMINISTRATION
SUMMARY OF VALUE OF ALL FEE WAIVERS AND REDUCTIONS GRANTED
As of September 30, 2003, 2004, and 2005

Reasons for Waiver	FY 2003	FY 2004	FY 2005
Small Business	$3,297,371	$5,345,157	$5,108,227
Govt. sponsored application not for commercial distribution	$2,187	$3,480	$7,004
Pediatric indications	$136,662	$339,245	$394,639
510(k)s reviewed by 3rd parties	$415,530	$887,400	$825,786
Total	**$3,851,750**	**$6,575,282**	**$6,335,656**

Appendix D

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

The Federal Food, Drug, and Cosmetic Act (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."

Over 96 percent of amounts obligated are expended 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 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
- GLP 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 Act.

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 device applications are based on obligations recorded within FDA's Center for Devices and Radiological Health (CDRH) the Center for Biologics Evaluation and Research (CBER), Office of Regulatory Affairs (ORA), and the Office of the Commissioner (OC). These organizations correspond to the cost categories presented on the Statement of Costs for the Process for the Review of Device Applications as follows:

Cost Category	FDA Organization
Costs for the Review of Premarket Applications (PMAs), Product Development Protocols (PDPs), Premarket Reports (PMRs), Modular PMAs and Supplements, and 510(k)s	CDRH
Costs for the Review of Biologic License Applications (BLAs) and Supplements, and 510(k)s	CBER
Field Inspection and Investigation Costs	ORA
Agency General and Administrative Costs	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, a portion of the costs within each of the four organizations listed above was identified as part of the device review process.

CENTER COSTS

Costs are accumulated in CDRH and CBER in cost centers corresponding to the organizational components within the Centers. Most FDA components involved in the device review process perform a mixture of activities--some included in the definition of the process for the review of device applications, and some not included. These components fall into three categories: 1) direct review and laboratory components; 2) indirect review and support components; and 3) center-wide costs. Costs are accumulated by cost centers (usually organization components at the division level). The allocation of costs for the categories is discussed below.

Direct Review and Laboratory Components:

Employees in all components of CDRH and CBER other than those noted below as Center indirect review and support components reported their time in categories 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 two-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 eight consecutive weeks, from June 29 through August 23, 2003. Whether time categories were counted as allowable or excluded was not apparent to employees as they reported their time.

FDA Centers are very payroll-intensive 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 eight-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 fiscal year, FY 2003.

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

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

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 two-week period during each quarter of the fiscal year.

CBER's existing system was also modified to assure that categories against which time was reported could be clearly divided into those 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 then assumed to follow the same pattern between process and non-process costs as the average time of those employees who reported their time. The eight weeks of time reporting data collected by CBER were collected for two weeks at a time for four different two-week periods over FY 2003 and 2004, and a similar process will take place each future fiscal year. The results from each two-week period of time reported is extrapolated to 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 Components

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 Management, 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 Expenses

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 Office of Regulatory Affairs (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 FYs 2003, 2004, and 2005, respectively.

FOOD AND DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS
COSTS OF THE PROCESS FOR THE REVIEW OF DEVICE APPLICATIONS
As of September 30, 2003, 2004 and 2005

Cost Component	FY 2003	FY 2004	FY 2005
Staff Years Utilized	59	60	62
ORA Average Salary & Benefits	$79,696	$86,376	$93,594
Salary and Benefits	$4,702,043	$5,182,556	$5,802,816
Operations and Rent	$2,969,792	$2,844,744	$3,871,551
Total	**$7,671,835**	**$8,027,300**	**$9,674,368**

The ORA costs for the process for the review of device applications described above include total process costs, including costs paid from appropriations and costs paid from fee revenues.

AGENCY GENERAL AND ADMINISTRATIVE COSTS

The Agency general and administrative costs are incurred in the FDA's Office of the Commissioner (OC). During FY 2005, 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 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 salary obligations of the Agency, excluding the Office of the Commissioner. That percentage is then multiplied by the total salaries (excluding benefits) applicable to the process for the review of devices in CDRH, CBER, and ORA to arrive at the total General and Administrative Costs applicable to the process for the review of device applications.

Using this process, $10,671,593 and $11,805,241 in general and administrative obligations were dedicated to the device review process in FYs 2004 and 2005, respectively. These are total costs, including funds obligated both from appropriations and from fees. The Agency general and administrative obligations in FY 2005 accounted for about 6.6 percent of the total FY 2005 cost of the process for the review of device applications. This is down significantly from 7.2 percent in FY 2004, 7.3 percent in FY 2003, and 8.6 percent in FY 2002.

At the beginning of FY 2004, FDA implemented a major reorganization and streamlining of its administrative support activities. Many functions and resources from all FDA Centers, ORA, and from components of the Office of the Commissioner were consolidated into an Office of Shared Services under the Office of Management—a component of the Office of the Commissioner. 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 2005 supporting the device review process are shown as having been incurred by CDRH, CBER, ORA, or OC, in proportion to the resources transferred from each these components to the Office of Shared Services. This makes the figures shown for FY 2005 comparable with figures for FY 2003 and 2004.