FY 2003 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

MARCH 2004

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

March 10, 2004

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

Dear Mr. President:

Enclosed for your consideration is the first annual financial report to Congress required by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA). This report covers fiscal year (FY) 2003, documenting how each of the conditions specified in MDUFMA for the continued collection of medical device user fees was met.

The report also presents the user fee revenues and related expenses for FY 2003, baseline data for FY 2002, and details the amounts carried over at the end of the year that remain available. For FY 2003, FDA collected $21.9 million in user fees, and spent $14.8 million. About 23 percent of the fees were spent for salaries and benefits for additional staff, and the remainder went toward increased support and infrastructure for the entire device review program. This enhanced infrastructure and the infusion of human resources are critical in enabling FDA to meet the performance goals associated with MDUFMA—goals that become increasingly more stringent each year.

We are pleased that Congress enacted MDUFMA, which will provide increasing levels of user fees, along with increased appropriations, through FY 2007. These additional resources will enable FDA to substantially strengthen and speed its medical device review process, while assuring that only safe and effective devices are available to the public.

Sincerely,

/s/

Tommy G. Thompson

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 law requires the Food and Drug Administration (FDA) to report annually on the financial aspects of its implementation of the Medical Device User Fee and Modernization Act of 2002 (MDUFMA). This is FDA's first financial report required under this act, and it covers fiscal year (FY) 2003.

The MDUFMA specifies that the following three conditions must be satisfied each year 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 products must be at least $205,720,000 (excluding fees and adjusted for inflation), and any shortfalls must be made up by October 1, 2005.
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 the extent to which these specific statutory conditions or "triggers" were met in FY 2003. The statements and tables included in this report also provide information on the user fee revenues and expenditures in FY 2003, and on the carryover balance. Baseline data for FY 2002 is also provided.

For FY 2003, FDA collected $21.9 million in fees--$3.2 million less than the revenue amount set in statute for FY 2003. The shortfall is due primarily to fewer applications that paid the highest fees and to a larger number of applications than expected that qualified for exemption from fees. Under MDUFMA, revenue shortfalls are made up in subsequent years by the compensating adjustment mechanism of the statute. Most or all of this shortfall is expected to be made up in FY 2004.

In FY 2003, FDA spent $14.8 million from MDUFMA revenues, and carried the balance of $7.1 million forward for use in FY 2004. The funds spent in FY 2003 went to support FDA's medical device review program, including information technology support, and to add additional staff to the review process. While $3.4 million went to pay 22 additional staff years in FY 2003, most of the additional staff was hired toward the end of the fiscal year, and FDA utilized only a small fraction of a staff year for each person hired. During FY 2004, FDA expects to spend user fees to pay for over 100 additional staff to conduct and support medical device reviews, positioning the agency to be able to meet the challenging performance goals associated with this program in FY 2004 and FY 2005. Hiring to accomplish the substantial increase in review staff necessary to meet the MDUFMA goals was well underway by the end of FY 2003.

Contents

Appendices

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 resources are to be used to hire and support additional staff for the "process for the review of device applications" as defined in MDUFMA, so that safe and effective devices reach the American public more quickly. MDUFMA was patterned in part after the very successful Prescription Drug User Fee Act (PDUFA).

Under MDUFMA, an application fee must be paid when certain device applications are submitted. Fee-paying applications include premarket applications (PMA's), product development protocols (PDP's), premarket reports (PMR's), modular PMA's, biologics license applications (BLA's), and certain supplements to all of them, as well as premarket notification submissions (510(k)s). The aggregate application fee revenue amount is set in statute, but is adjusted each year for cumulative inflation since FY 2003, and may be further adjusted for increases in workload and for revenue shortfalls from previous years. The individual fees for various types of applications are fixed in statute as a percent of the fee for a PMA. Fees are set in August of each year after the inflation, workload, and shortfall adjustments to the statutory fee amount have been determined. Unlike PDUFA, there are no product or establishment fees under MDUFMA.

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 2003 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 2003 MDUFMA Financial Report, covering the period October 1, 2002 through September 30, 2003.

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 2003 (Appendix A). This report also for the first time describes in some detail (Appendix D) the process for the review of devices as newly 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 2003 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 2003. This is the most favorable category of audit opinion.

MEETING THE LEGAL CONDITIONS FOR USER FEES IN FY 2003

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

The **first condition** requires that appropriations for FDA's device and radiological products activities total $205,720,000 in FY 2003, and increase annually for inflation by an adjustment factor thereafter. For FY 2003, FDA's Salaries and Expenses appropriation, excluding user fees and after rescission, included $193,455,000 for the devices and radiological health program. Thus the FY 2003 appropriation amount is $12,265,000 less than the amount specified in MDUFMA ($205,720,000). FDA may continue to collect user fees and strive to meet the MDUFMA performance goals, but the appropriation shortfall of $12,265,000 must be made up by October 1, 2005 (the first day of FY 2006), or the MDUFMA authority to collect and spend device user fees will terminate on that day.

In a letter from the Director of the Office of Management and Budget dated October 29, 2003, the Administration has proposed that the statutory requirement to make up appropriation shortfalls for FY 2003 and FY 2004 be eliminated. The Administration's FY 2005 budget authority request for the Medical Devices program is $216,699,000. It and subsequent fiscal year requests will each meet the MDUFMA specified level. FDA has committed to achieving the original MDUFMA performance goals with the levels enacted in FY 2003 and subsequent fiscal years. MDUFMA stakeholders and Congress were consulted during the development of this plan and are supportive of the revised strategy. Congressional action on this Administration proposal will be required after submission of the President's FY 2005 Budget.

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 108-7) specifying amounts collectable from fees during FY 2003 on February 20, 2003. It provided $25,125,000 to be derived from fees collected. Thus, the second condition was met, and fees may be collected.

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 amount was $119,673,026. FDA actually spent $125,597,098 from appropriations for the process for the review of device applications for FY 2003. Since this is greater than the FY 2002 amount ($119,673,026), adjusted for inflation, the third condition was met.

Appendix A provides more detail on the calculations that show how these three 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 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 6.

The following table provides a breakout of user fees by fee source during the two fiscal years, 2003 and 2004, and also reflects estimates of receivables.

FOOD AND DRUG ADMINISTRATION
STATEMENT OF MDUFMA FEE REVENUES
As of September 30, 2003

	FY 2003	FY 2004
Fees Collected:		
TOTAL FEES COLLECTED:	**$21,889,582**	**$47,328**
Fees Receivable:		
TOTAL FEES RECEIVABLE:	**$779,724**	
Total:	**$22,669,306**	**$47,328**

Note that user fee revenues are reported in the year the fee was originally due—referred to as the cohort year. For example, a fee due in FY 2004, even if it is received in FY 2003, is attributed to FY 2004 revenues. 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 2003 is contained in Appendix B.

The FY 2003 accounts receivable are due to unpaid invoices for fees for applications that were submitted between October 1, 2002 and March 30, 2003. After April 1, 2003, FDA no longer accepted applications for review unless a fee for the application had been received. Fees receivable for FY 2003 are, for the most part, over 120 days old, and most have been turned over to a collection agency. A summary of FY 2003 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 2003, FDA obligated $14,837,600 from medical device user fee revenues.

FOOD AND DRUG ADMINISTRATION
STATEMENT OF MDUFMA USER FEE OBLIGATIONS BY EXPENSE CATEGORY
As of September 30, 2003

Expense Category	FY 2003
Personnel Compensation and Benefits	$3,412,405
Travel and Transportation	$386,740
Rent	$400,000
Communications	$85,930
Contract Services	$8,623,067
Equipment and Supplies	$1,886,317
Other	$43,141
TOTAL OBLIGATIONS:	$14,837,600

FDA dedicated 854 staff-years to the review of device applications in FY 2002, before MDUFMA was enacted. A time reporting study was undertaken in 2003 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 methodology used closely tracked the methodology used in 1993 when human drug review process costs were initially developed under PDUFA. 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.

In FY 2003, MDUFMA fees and appropriations paid for about 22 more staff-years than were used in FY 2002 for the process for the review of device applications. FDA is working to strengthen and expand our capacity to conduct efficient and timely reviews to ensure the safety and effectiveness of new medical devices.

For FY 2003, the Center for Devices and Radiological Health (CDRH) expended approximately 681 staff years on the process for the review of device applications. Most of the additional staff (about 67 of them) were hired very late in the fiscal year, and the impact of their full-year cost will not be incurred until FY 2004. In FY 2004, FDA expects to utilize over 100 more staff years than in FY 2002, as the Agency ramps up its staffing to levels necessary to meet the MDUFMA performance goals.

As can be seen from the table on the previous page, the remaining funds were spent on restoring support needs for the device review program, including enhanced information technology (IT) resources. FDA has modified device review tracking systems to monitor device review performance on new MDUFMA performance goals. CDRH has accelerated the training of staff using new guidance required to implement MDUFMA and has also developed training plans to significantly increase clinical and technical training in the coming year.

CDRH has also expanded the use of contractors, providing additional flexibility to meet nonrecurring workloads, to augment FDA resources in highly specialized areas, and to achieve particular tasks at a lower cost than would otherwise be possible.

CDRH contracts that improve IT Infrastructure included:

- Electronic 510(k) Review/Submission Template Development
- Support for the Document Scanning Contract
- Development of IT Security Documentation
- Design of a Statement of Work (SOW) to migrate files from Platter to Disk

Additionally, CDRH entered into contracts designed to improve specialized areas having a premarket impact including:

- Global Medical Device Nomenclature
- Institute of Medicine Study of the Adequacy of Postmarket Surveillance
- Standards Utilization in Ophthalmic Premarket Application Study

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 2003 resulted in a net carryover balance of $7,051,982.

The table below captures the carryover balance, and will be updated each year in the future.

FOOD AND DRUG ADMINISTRATION
STATEMENT OF COLLECTIONS, OBLIGATIONS, AND CARRYOVER BALANCES BY FISCAL YEAR
As of September 30, 2003

Fiscal Year	Beginning Carryover	Net Collections	Obligations	Year-End Carryover
2003	-	$21,889,582	$14,837,600	$7,051,982
2004	$7,051,982			

The balances above reflect cumulative cash at the beginning/end of each fiscal year, and net cash collected during each fiscal year for all cohort years. The figures do not include accounts receivable.

COLLECTION CEILINGS, SHORTFALLS AND SURPLUSES

Under MDUFMA, shortages below the cumulative statutory revenue amounts for previous years, after adjustment for inflation and workload, may be recouped by increasing fees in future years by means of the 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 net collections, collection ceilings, and amounts that may be either refunded or used to offset future collections.

FOOD AND DRUG ADMINISTRATION
STATEMENT OF FEES COLLECTED, COLLECTION CEILINGS, SHORTFALLS AND SURPLUSES
As of September 30, 2003

Fiscal Year	Net Collections Realized	Collection Ceiling (Adjusted Cumulative Statutory Revenue Amount)	Shortfall (To be made up by increased future collections)	Surplus (To be offset by reduced future collections)
2003	$21,889,582	$25,125,000	$3,235,418	
2004		$31,654,207		
		Total:		

When fees for FY 2004 were set on August 1, 2003, FDA anticipated a revenue shortfall of $5,478,000, based on actual collections through the end of June 2003. As a result, when fees for

FY 2004 were established, a compensating adjustment of $5,478,000 was added to the inflation adjusted statutory revenue target of $28,418,789, setting the FY 2004 final revenue target at $33,896,789. Collections at the end of FY 2003, especially in the month of September, came in at a much higher level than anticipated, reducing the final shortfall in FY 2003 to $3,235,418.

The actual compensating adjustment for FY 2004 should have been $3,235,418. Had this amount been added to the inflation adjusted statutory revenue target of $28,418,789, the revised revenue target after compensating adjustment would have been $31,654,207. This later amount will be regarded as the Collection Ceiling for FY 2004, and should revenues be collected in excess of this amount, then revenues for future years will be offset by such surplus collections. Given the shortfall in FY 2003, and the fact that FDA did not lower the estimated number of fee-paying submissions when fees were set for FY 2004, the Agency regards it as unlikely that collections in FY 2004 will exceed this Collection Ceiling.

RESERVE FOR FUTURE OPERATIONS

FDA should have at least a 1-month reserve for future operations at the end of each fiscal year—at least until FY 2007, when it is expected to have at least a three-month carryover balance before the statute sunsets. The carryover amount shown as available for allocation in the table below is enough to fund estimated FY 2004 operations for approximately 2.5 months. (Revised FY 2004 Collection Ceiling of $31,654,207 divided by 12 yields an estimated monthly fee amount of $2,637,851.)

FOOD AND DRUG ADMINISTRATION
SUMMARY STATEMENT OF MDUMFA FEE REVENUE CARRYOVER BALANCE
As of September 30, 2003

Status of Carryover Funds	Amount
Reserve for Refunds of Excess Collections	$500,000
Available for Allocation	$6,551,982
TOTAL Carryover Balance	$7,051,982

TOTAL COSTS OF THE PROCESS FOR THE REVIEW OF DEVICE APPLICATIONS

The following table presents the costs for the review of device applications for FY's 2002 and 2003 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 in FY 2003. 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
As of September 30, 2002 and 2003

FDA Component	FY 2002	FY 2003
Center for Devices and Radiological Health (CDRH)	$95,973,640	$111,499,009
Center for Biologics Evaluation and Research (CBER)	$6,665,132	$10,970,557
Field Inspection and Investigation Costs (ORA)	$6,778,594	$7,671,835
Agency General and Administrative Costs (OC)	$10,255,659	$10,293,297
Total Process Costs	**$119,673,026**	**$140,434,698**
Amount from Appropriations	$119,673,026	$125,597,098
Amount from Fees	0	$14,837,600

The costs for all components rose in FY 2003. This increase primarily reflects enhanced spending made possible by the additional resources in FY 2003 and increases in pay rates for federal employees.

The Agency General and Administrative Costs, though up slightly from FY 2002 levels, declined 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 only 7.3 percent in FY 2003.

MANAGEMENT CHALLENGES FOR FY 2004

With the passage of MDUFMA, great expectations have been created for substantially reducing the time it takes to evaluate new device applications, while maintaining rigorous standards for device safety and effectiveness. In FY 2004, FDA must continue to increase personnel to support the review of device applications, and continue to restore the infrastructure of the device program, in order to assure that MDUFMA performance goals, which become quite challenging in FY 2005 and beyond, will be met.

The Agency is assuring the viability of MDUFMA in FY 2005 and beyond requesting appropriations of approximately $217 million in FY 2005 for FDA's device and radiological health program. This will assure that the key appropriations trigger for FY 2005 will be satisfied, assuming elimination of the requirement that appropriation shortfalls in FY 2003 and FY 2004 must be made up.

The challenge for the Agency in FY 2004 is to manage a combination of decreased appropriations and increased fee revenues in such a way that increases the most essential review staff and infrastructure needs of the program, and positions the Agency to hire the additional staff needed to meet performance goals at the end of FY 2004 and at the beginning of FY 2005.

FDA will continue to be challenged by the need to hire, train, and retain qualified reviewers and support staff in FY 2004, and to gear up for substantial staff increases near the end of FY 2004 and the beginning of FY 2005. CDRH, which does the largest portion of the device review activities, lost over 70 employees in FY 2002. FY 2003 recruiting efforts hired replacements for these employees, and added about 67 additional employees in the last few months of FY 2003. Retaining review staff and recruiting and training new review staff is a constant challenge. Yet, the Agency's ability to attract and retain outstanding review staff is critical to maintaining the FDA's commitment to meeting the MDUFMA performance goals. Recruiting and retaining top rate professional staff is among the Commissioner's highest priorities.

Appendix A

CONDITIONS FOR ASSESSMENT AND USE OF FEES

The Federal Food, Drug, and Cosmetic Act (the Act), as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), Public Law 107-250, specifies three major conditions that must be met to some extent each year before medical device user fees may be collected and spent. A summary of these conditions and the extent to which they were met was provided earlier on page 2. Each of these conditions is described in more detail below, with an explanation of how the condition was met in FY 2003.

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 each year. It states:

> The term 'adjustment factor' applicable to a fiscal year is the Consumer Price Index for all urban consumers (all items; United States city average) for April of the preceding fiscal year divided by such Index for April 2002.

April preceding FY 2003, which began on October 1, 2002, was April 2002. Dividing the consumer price index (CPI) of April 2002 into itself yields an adjustment factor of 1.

The **first condition** relates to the amount of appropriation required annually for the device and radiological health program line in FDA's annual appropriation. (Note that this not the same as the process for the review of device applications as defined in MDUFMA—the third condition deals with spending on this process). This first condition is in section 738(g)(1) of the Act. It requires that appropriations for FDA's devices and radiological health program activities total $205,720,000 in FY 2003, and increase annually by an adjustment factor thereafter. In addition, MDUFMA specifies that any shortfall in appropriations below the amount specified above must be made up by October 1, 2005, or the MDUFMA program, fee revenues and performance goals, ends then.

For FY 2003, FDA's Salaries and Expenses appropriation, excluding user fees and after rescission, included $193,455,000 for devices and radiological health program. Thus the FY 2003 appropriation amount is $12,265,000 less than the amount specified in MDUFMA ($205,720,000). FDA may continue to collect user fees and strive to meet the MDUFMA performance goals, but the appropriation shortfall of $12,265,000 must be made up by October 1, 2005 (the first day of FY 2006) or the MDUFMA authority to collect and spend device user fees will terminate on that day.

In a letter from the Director of the Office of Management and Budget dated October 29, 2003, the Administration has proposed that the statutory requirement to make up appropriation shortfalls for FY 2003 and FY 2004 be eliminated. The Administration's FY 2005 budget authority request for the Medical Devices program is $216,699,000. It and subsequent fiscal year requests will each meet the MDUFMA specified level. FDA has

committed to achieving the original MDUFMA performance goals with the levels enacted in FY 2003 and subsequent fiscal years. MDUFMA stakeholders and Congress were consulted during the development of this plan and are supportive of the revised strategy. Congressional action on this Administration proposal will be required after submission of the President's FY 2005 Budget.

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 a specific appropriation, no fees may be collected.

The President signed the Appropriation Act (Public Law 108-7) specifying amounts collectable from fees during FY 2003 on February 20, 2003. It provided $25,125,000 to come from fees collected. Thus, the second condition was met, and fees were collected.

The **third condition** of MDUFMA requires a minimum amount of spending from appropriations, exclusive of user fees, each year on the process for device review as newly 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 2003 was 1, as stated above.

The FDA costs (obligations) from appropriations for the process for the review of device applications for FY 2003 was $125,597,098. Since this is greater than the FY 2002 amount ($119,673,026) the third condition was met.

The table below shows amounts FDA spent on the process for the review of device applications in FY 2002 and FY 2003. 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, 2003

	FY 2002	FY 2003
From Appropriations	$119,673,026	$125,597,098
From User Fee Revenues	$0	$14,837,600
Total Obligations	$119,673,026	$140,434,698

Appendix B

SUMMARY OF APPLICATION FEES PAID IN FY 2003

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 $154,000 each in FY 2003. 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 $58,520 in FY 2003. 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 $33,110 each in FY 2003, except that those from qualifying small businesses paid only $12,582. The real time supplements were assessed a fee of $11,088 in FY 2003, except that those from qualifying small businesses paid only $4,213. All 510(k) notifications submitted in FY 2003 were assessed the same fee—$2,187—regardless of whether or not they came from a small business. They are all shown in the small business fee rate column below, since there was no two-tier fee rate for 510(k)s in FY 2003, and the number for all was kept low this year. (The two-tier fee rate for 510(k) notifications does not go into effect until FY 2004.)

The Table below summarizes the number and type of application fees received in FY 2003.

Application Type	Number Paying Full Fee	Number Paying Reduced Small Business Fee
Full Fee Applications	46	6
180-Day Supplements	118	22
Real-Time Supplements	136	19
510(k)s		4001 [1]

The Table below summarizes the number and type of application fees that FDA assumed it would receive in FY 2003 when MDUFMA was enacted.

Application Type	Number Paying Full Fee	Number Paying Reduced Small Business Fee
Full Fee Applications	58	10
180-Day Supplements	171	24
Real-Time Supplements	86	14
510(k)s		4000 [1]

[1] All 510(k) paid the same fee in FY 2003, so all are shown in the small business fee column.

Appendix C

WAIVERS, REDUCTIONS, AND EXEMPTIONS

MDUFMA directs FDA to waive the first premarket application fee from a qualified small business, and to reduce premarket application and supplement fees for subsequent applications from qualified small businesses. Beginning in FY 2004, FDA will also charge 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 and notifications for humanitarian devices 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 which are not intended for commercial distribution;
- applications for products solely for use in pediatric populations; and,
- 510(k)s submitted to certified 3rd party reviewers, rather than to FDA, are not subject to an application fee.

This appendix provides a summary of the MDUFMA fee waivers, reductions, and exemptions allowed in FY 2003.

FDA responded to a large number of e-mails and phone calls from firms wanting to know how to qualify as a small business for purposes of MDUFMA fees. Most firms which learned from these phone calls and e-mails that they would not qualify as a small business did not send in a formal request for a small business determination. Likewise, most firms which learned that they would qualify as a small business did send in written requests. FDA granted 125 of the 135 written requests for small business status received in FY 2003. Of the 125 firms granted small business certification, 40 went on to submit applications in FY 2003 for which fees were either waived (if the application was their first PMA) or reduced. The following table summarizes the value of the small business reductions or waivers granted to these 40 firms for applications submitted to FDA in FY 2003. Some qualifying small businesses submitted more than one application that had a fee reduced.

FY 2003 Small Business Fee Waivers and Reductions Granted

	Number	Value for Each	Total Value
Full Fees Waived	14	$154,000	$2,156,000
Full Fees Reduced	6	$95,480	$572,880
180-Day Supplements Reduced	22	$20,528	$451,616
Real-Time Supplements Reduced	17	$6,875	$116,875
Total Value of Small Business Waivers and Reductions:			**$3,297,371**

FDA received fees totaling $21,889,582 in FY 2003. Had there been no small business waivers and reductions, FDA would have collected an additional $3,297,371, for a total of

$25,186,953. The small business waivers and reductions resulted in FDA's collecting about 13.1 percent less revenue than would have otherwise been the case.

FDA received 10 Exempted Humanitarian Device applications and 29 supplements in FY 2003. None of these were subject to MDUFMA fees in FY 2003. It is assumed that none of them would have been submitted had they been subject to a fee, so this exemption probably did not result in any loss of revenue.

FDA received no exemption requests in FY 2003 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 only one request from a State or Federal government entity for exemptions for an application (in this case a 510(k)) that was not intended for commercial distribution. Total cost of this exemption in FY 2003 was $2,187.

Pediatric Exemptions were granted in FY 2003 for three 180-day supplements, one real-time supplement, and 12 510(k)s. Total value of these exemptions in FY 2003 was $136,662.

In FY 2003, FDA received 190 510(k)s that were subject to third party review and therefore did not pay MDUFMA fees. This is a 50% increase over the 127 510(k)s that were submitted for third party review in FY 2002. Total value of these exemptions in FY 2003 was $415,530.

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 the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), Public Law 107-250, 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, amendment, supplements, and annual reports)
- PDPs (including amendments, supplements, and annual reports)
- Premarket Reports (amendments, supplements, annual reports)
- Reclassification Petitions
- Class II Exemption Petitions
- 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 Aagreeement 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) and 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 (PMA's), Product Develompent Protocols (PDP's), Premarket Reports (PMR's), Modular PMA's and Supplements, and 510(k)s	CDRH
Costs for the Review of Biologic License Applications (BLA's) 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, 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 are 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—60 percent of all FDA funds go to pay for employee salaries and benefits, and almost all other costs are directly supporting 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 percents of allowable costs had never been collected for earlier periods, the percents of allowable costs reported in this eight-week period were likewise applied to each cost centers direct costs (obligations) incurred in FY 2002, to get the baseline FY 2002 device review process cost data required under MDUFMA.

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. The results from the eight weeks of time reporting data were then averaged and extrapolated to 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 Systems and Management. 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 was 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.

Center Time Reporting Results for FY 2003

The time reporting systems operated by CDRH indicated that 681 (or over 66 percent) of the 1025 staff years expended by CDRH in FY 2003 were expended on the process for the review of device applications. The time reporting system operated by CBER indicated that 59 (or 6 percent) of the 978 staff years expended by CBER in FY 2003 were expended on the process for the review of device applications as defined in MDUFMA.

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 FY's 2002 and 2003, respectively.

FOOD AND DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS
COSTS OF THE PROCESS FOR THE REVIEW OF DEVICE APPLICATIONS
As of September 30, 2002 and 2003

Cost Component	FY 2002	FY 2003
Staff Years Utilized	54	59
ORA Average Salary & Benefits	$77,987	$79,696
Salary and Benefits	$4,211,289	$4,702,043
Operations and Rent	$2,567,305	$2,969,792
Total	**$6,778,594**	**$7,671,835**

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 most of FY 2002 and FY 2003, OC was comprised of the following offices:

- Immediate Office of the Commissioner
- Office of the Chief Counsel
- Office of Equal Opportunity
- Office of the Administrative Law Judge
- Office of Science Coordination and Communication
- Office of Communications and Constituent Relations
- Office of International Affairs
- Office of Policy, Planning and Legislation
- Office of Management and Systems

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.

Using this process, $10,255,659 and $10,293,297 in general and administrative obligations were dedicated to the device review process in FY's 2002 and 2003, respectively. These are total costs, including funds obligated both from appropriations and from fees. The Agency general and administrative obligations in FY 2003 accounted for about 7.3 percent of the total FY 2003 cost of the process for the review of device applications. This is down significantly from 8.6 percent in FY 2002.