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United States Government Accountability Office
Washington, DC 20548

June 25, 2007

The Honorable Joe Barton
Ranking Member
Committee on Energy and Commerce
House of Representatives

Subject: *Food and Drug Administration: Methodologies for Identifying and Allocating Costs of Reviewing Medical Device Applications Are Consistent with Federal Cost Accounting Standards, and Staffing Levels for Reviews Have Generally Increased in Recent Years*

Dear Mr. Barton:

The Food and Drug Administration (FDA) is the agency responsible for ensuring the safety and effectiveness of medical devices—such as catheters and artificial hearts—marketed in the United States. As part of its regulatory responsibilities, FDA reviews applications submitted by medical device companies for devices they wish to market, including devices that are new or those that include modifications to already approved devices. The Medical Device User Fee and Modernization Act of 2002 (MDUFMA)¹ authorized FDA, beginning in fiscal year 2003, to charge user fees for various types of device applications. User fees were intended to provide resources to FDA, to increase staffing for medical device reviews and speed the timeliness of reviews, in addition to resources otherwise provided through the annual appropriations process.

Under MDUFMA, FDA is required to report to the congressional committees of jurisdiction annually on the implementation of the user fee program. FDA submitted financial reports that include information such as amounts collected from user fees, the costs of reviewing device applications, and staffing levels FDA dedicated to the review of medical device applications for each fiscal year from 2003 through 2005.² In response to industry concerns about the need for more cost information, FDA supplemented these MDUFMA financial reports by reporting

¹Pub. L. No. 107-250, 116 Stat. 1588.

²Department of Health and Human Services, Food and Drug Administration, *FY 2003 MDUFMA Financial Report: Required by the Medical Device User Fee and Modernization Act of 2002* (Washington, D.C., March 2004); *FY 2004 MDUFMA Financial Report: Required by the Medical Device User Fee and Modernization Act of 2002* (Washington, D.C., March 2005); *FY 2005 MDUFMA Financial Report: Required by the Medical Device User Fee and Modernization Act of 2002* (Washington, D.C., July 2006).

more detailed information on the estimated average cost of reviewing medical device applications in those 3 years.³

Industry has challenged the appropriateness of the methodologies FDA used to identify the total cost of the process for reviewing medical device applications and the average costs of reviewing various types of applications. Industry has also questioned the degree to which staffing of the device review process has increased since the enactment of MDUFMA.

MDUFMA will expire on October 1, 2007, and Congress is currently deliberating its reauthorization. You asked us to review FDA's methodology for determining costs of the process of reviewing device applications, as well as changes in the staff levels dedicated to that process since MDUFMA was implemented. We previously provided you with revenue information on certain companies participating in the medical device user fee program.⁴ In this report, we evaluate (1) whether FDA's methodologies for identifying its annual costs⁵ of reviewing device applications and its method for allocating these costs among various application types are consistent with federal cost accounting standards, and (2) the extent to which staffing levels for the process of reviewing device applications have changed since fiscal year 2002, the baseline year before MDUFMA went into effect, and how these changes in staffing levels have been distributed within FDA.

To evaluate whether the methodologies used by FDA to identify its annual costs of reviewing device applications and to allocate the costs used to calculate the average cost of reviewing various application types are consistent with federal cost accounting standards, we interviewed staff from FDA's Office of Management and Systems who are responsible for preparing the annual MDUFMA financial reports to Congress. We reviewed the Statement of Federal Financial Accounting Standards No. 4 (SFFAS 4): Managerial Cost Accounting Concepts and Standards for the Federal Government. We also reviewed the annual MDUFMA financial reports to Congress for fiscal years 2003 through 2005 and the detailed supporting financial data used to prepare the fiscal year 2005 report. Using SFFAS 4, we analyzed the cost accounting methodology used by FDA to calculate the costs of reviewing device applications and the methodology to estimate the average cost of reviewing various types of device applications. We limited our analysis to the appropriateness of the methodologies in relation to federal cost accounting standards. We did not verify the reliability of the data FDA used in either methodology. We also did not determine whether the amounts of the user fees for medical device applications are appropriate.

³Dr. Dale R. Geiger, *FY 2003 and FY 2004 Unit Costs for the Process of Medical Device Review*, prepared for the Food and Drug Administration (September 2005). Dr. Dale R. Geiger, *Extension of Analysis of Unit Costs for the Process for the Review of Medical Devices for Fiscal Year 2005* (July 2006).

⁴GAO, *Food and Drug Administration: Revenue Information on Certain Companies Participating in the Medical Device User Fee Program*, [GAO-07-571R](#) (Washington, D.C.: Mar. 30, 2007).

⁵In this report, costs represent obligations recorded at the end of the fiscal years—regardless of whether related expenditures have been made—because the cost information in FDA's annual MDUFMA financial reports is based on obligations. FDA believes obligations represent a reasonable estimate of cost because FDA's financial records have historically shown that over 81 percent of obligated amounts are expended within 1 year, and 96 percent within 2 years.

To evaluate the extent to which FDA staffing for the process of reviewing device applications has changed since MDUFMA went into effect in fiscal year 2003, and how these changes in staffing levels were distributed within FDA, we interviewed FDA officials involved in the process of reviewing device applications and obtained information from FDA on annual staffing for the process of reviewing device applications. Our analysis reflects data for fiscal year 2002, the baseline year before MDUFMA went into effect, and data for fiscal years 2003 through 2006, the first 4 years MDUFMA was implemented. We measure staffing for this analysis as full-time equivalent (FTE) employees.⁶ A measure of one FTE represents 40 hours of work per week over the course of a year.⁷ We assessed the reliability of FDA data by conducting interviews with FDA staff to better understand how FDA collects and uses these data and by examining FDA documents. We determined that the data are adequate for our purposes. We conducted our work from November 2006 through June 2007 in accordance with generally accepted government auditing standards.

Results in Brief

FDA's methodologies for identifying its annual costs of reviewing device applications and for allocating the costs used in calculating the average cost of reviewing the various application types are consistent with federal cost accounting standards. In this regard, FDA took four steps to identify its annual costs. First, it identified which of its components were responsible for carrying out the activities related to medical device application reviews. Second, it developed a methodology to determine the full costs of reviewing device applications within each of the responsible components. Third, it used an economically feasible, appropriate method to measure the costs by identifying direct costs and allocating a reasonable portion of indirect costs to the process. Finally, it reported its costs regularly and publicly in annual MDUFMA financial reports to the congressional committees of jurisdiction. To allocate the annual costs of reviewing applications to the various application types, FDA allocated the annual MDUFMA costs to different application types, and divided the amount for each application type by the number of medical device application reviews completed during the year. FDA directly assigned a cost category to a particular application type if all of the costs in that category related directly to that type of application. For those cost categories related to more than one application type, FDA management used its judgment appropriately to allocate the costs, consistent with federal cost accounting standards.

From fiscal year 2002, the baseline year before MDUFMA went into effect, through fiscal year 2005, staffing for the process of reviewing device applications increased. However, staffing decreased slightly in fiscal year 2006. From fiscal year 2002 through fiscal year 2005, staffing associated with the process of reviewing device applications increased from 917 to 1,192 FTEs, or about 30 percent. These increases were spread among four components of the agency involved in the process of reviewing device applications: the Center for Devices and Radiological Health (CDRH), the Center for Biologics Evaluation and Research (CBER), the

⁶Federal government employee FTEs for all FDA activities from fiscal year 2002 through 2006 were 9,468, 10,257, 10,141, 9,910, and 9,698, respectively.

⁷This could measure the time one full-time employee works on a regular basis, or it may measure the time more than one employee works on a part time basis. For example, if two employees each work 20 hours per week on a regular basis, the time they work equals one FTE employee. For our analysis of MDUFMA FTE levels, we included both federal government employees and contract employees involved in device review activities based on the results of a time-reporting survey of MDUFMA-related activities that FDA conducted on a quarterly basis.

Office of Regulatory Affairs (ORA), and the Office of the Commissioner (OC). In fiscal year 2006, FTEs associated with the process of reviewing device applications declined to 1,181; FDA attributed this slight decrease to a hiring freeze during the prior year.

HHS reviewed a draft of this report and stated the report fairly and accurately describes FDA's accounting for the costs of medical device reviews and the resources FDA added to the medical device review program.

Background

MDUFMA authorizes FDA to assess and collect fees for the review of medical device applications and identifies the costs that those fees may be used to help recover. These include the costs of activities such as

- reviewing specific types of device applications, such as a premarket application;⁸
- monitoring research conducted in connection with the review of device applications;
- providing technical assistance to device manufacturers in connection with the submission of device applications; and
- developing guidance, policy documents, or regulations to improve the process for the review of device applications.

Under MDUFMA, FDA must report annually to the Committee on Energy and Commerce of the U.S. House of Representatives and the Committee on Health, Education, Labor and Pensions of the U.S. Senate on how it is implementing the user fee program, among other things. FDA has published annual MDUFMA financial reports since fiscal year 2003 that elaborate on the amount collected from user fees, the annual cost of the process of reviewing device applications, and staff levels involved.

In response to industry concerns about the need for more information about the costs FDA incurred to review medical device applications, FDA hired a private contractor to develop a methodology to calculate the average cost of different application types for fiscal years 2003 through 2005.

In calculating the costs associated with reviewing device applications, FDA needed to consider not only MDUFMA requirements, but also federal financial management requirements and accounting standards. SFFAS 4, which became effective in fiscal year 1998, sets forth the fundamental elements for managerial cost accounting in government agencies.

⁸A premarket application is a medical device application, for example, that is submitted to obtain premarket approval for a Class III device, that is, one that supports or sustains human life, is of substantial importance in preventing impairment of human health, or presents a potential unreasonable risk of illness or injury.

There are five standards in SFFAS 4, four of which are applicable to FDA's process for reviewing device applications.⁹ These standards require FDA to do the following:

- **Accumulate and report the costs of activities on a regular basis for management information purposes.** An agency should report costs in a timely manner, on a regular basis, consistently, so that costs can be compared over time. This reporting should meet the needs of management and the requirements of budgetary and financial reporting.
- **Establish responsibility segments to match costs with outputs.** This involves identifying the responsibility segments, or components of an agency involved in carrying out the activity or program, and collecting and reporting cost information for these segments. For example, if an office within an agency has the responsibility for inspecting facilities or collecting user fees, that office would be considered the relevant responsibility segment for those activities. Therefore, the agency should collect and report cost information from that office for the activities associated with those outputs.
- **Determine and report the full costs of government goods and services, including direct and indirect costs.** Full costs include direct and indirect costs. Direct costs are costs that can be specifically identified with an output; they may include salaries and benefits for employees working directly on the output, and costs for materials, supplies, and facilities used exclusively to produce the output. Indirect costs are costs that are not specifically identifiable with any output; they may include costs for general administration, research and technical support, and operations and maintenance for all an agency's buildings and equipment.
- **Use and consistently follow costing methodologies or cost-finding techniques most appropriate to the segment's operating environment to accumulate and assign costs to outputs.** When it is feasible and economically practical, the standards state, the best results may be obtained by directly measuring costs. For example, an agency could use the detailed time-reporting system for its employees to directly measure the time employees spend on activities related to the program versus activities unrelated to the program. In certain cases, measuring costs directly may not be feasible or economically practical. For example, it may not be economically feasible or even possible for an agency to directly measure the portion of staff or management salaries associated with a program. In such circumstances, the standards state that costs should be estimated on a reasonable and consistent basis. For instance, an agency can calculate the ratio of direct costs for an activity to the total direct costs for a program as a basis for estimating the applicable indirect costs.

While each entity's managerial cost accounting should meet SFFAS 4, the standards do not specify the degree of complexity or sophistication of any managerial cost accounting process. SFFAS 4 gives management the flexibility to determine the appropriate detail for its cost accounting processes and procedures based on several factors, including (1) the nature of the entity's operations, (2) precision desired and needed in cost information, (3) practicality of data collection and processing, (4) availability of electronic data-handling

⁹The fifth standard states that federal agencies should recognize the costs of goods and services provided among federal entities, also known as the standard for Inter-Entity Costs. According to FDA officials, through an interagency service agreement the Department of Energy provides some services to FDA related to the process for reviewing device applications. Because of the limited nature of this agreement, we did not consider it material to FDA's process. Thus we did not consider the standard for Inter-Entity Costs to be relevant to our evaluation.

facilities, (5) cost of installing, operating, and maintaining the cost accounting processes, and (6) any specific information needs of management. Therefore, agencies' cost accounting processes and results may vary and still be acceptable under the standards.

FDA's Methodologies for Identifying Costs of Reviewing Device Applications and Allocating Them to Various Application Types Are Consistent with Federal Cost Accounting Standards

In providing financial information to Congress in its annual MDUFMA financial reports, FDA used a methodology to identify the annual cost of reviewing device applications that was consistent with federal cost accounting standards as set forth in SFFAS 4. In response to industry requests for more detailed cost information, FDA developed a methodology for allocating the costs it had identified to various types of device applications to meet the annual reporting requirements of MDUFMA. This allocation was also consistent with SFFAS 4.

FDA's Methodology for Identifying the Cost of Reviewing Device Applications Is Consistent with SFFAS 4

FDA complied with SFFAS 4 in the following ways.

- Consistent with the SFFAS 4 standard for timely, regular cost reporting, FDA has reported the costs of the device review program in annual MDUFMA financial reports to the congressional committees of jurisdiction in fiscal years 2003 through 2005 and made the reports available to the public on its Web site. This provided FDA, Congress, and the public with the ability to compare the costs of reviewing applications for these years. In addition, FDA responded to industry requests for more cost information by reporting the estimated average cost of device application reviews in fiscal years 2003 through 2005.
- FDA's methodology for identifying the cost of the process of reviewing device applications is consistent with the SFFAS 4 standard for identifying responsibility segments. Under MDUFMA, the annual cost reported by FDA must include the cost of specific activities associated with the process of reviewing device applications. To be consistent with SFFAS 4, FDA identified the four components of the agency responsible for carrying out these activities. These components are CDRH and CBER, which evaluated device applications submitted to FDA; ORA, which inspects facilities where devices under review are manufactured; and the OC,¹⁰ which provides general management and oversight of all FDA activities, including the review of medical device applications.
- FDA's methodology is consistent with the SFFAS 4 standard for capturing the full costs of the review process—both direct and indirect costs—within each of the four components, or responsibility segments, involved in the process for reviewing device applications

¹⁰The Office of the Commissioner (OC) includes the following offices: (1) Immediate Office of the Commissioner, (2) Office of the Chief Counsel, (3) Office of Equal Employment Opportunity and Diversity Management, (4) Office of Administrative Law Judge, (5) Office of Science and Health Coordination, (6) Office of International Activities and Strategic Initiatives, (7) Office of Crisis Management, (8) Office of Legislation, (9) Office of External Relations, (10) Office of Policy and Planning, and (11) Office of Management.

under MDUFMA.¹¹ Using this methodology, FDA identified the direct and indirect costs in several ways.

1. Within CDRH, FDA analyzed time charges to identify the direct salaries and benefit costs incurred by staff involved in reviewing device applications. FDA used a similar procedure to measure these costs for CBER's direct review and laboratory components. To identify the portion of salaries and benefits incurred by management and administrative support personnel to assign to the process for the review of device applications, FDA used the average percentage of time charged to the process compared to total costs incurred by these units for all programs.
 2. FDA also identified a portion of the indirect review and support costs¹² incurred by CDRH and CBER that are associated with reviewing device applications. The portion of these costs that are assigned to the process equaled the average percentage of allowable costs for the direct review and laboratory components compared to the total costs incurred by CDRH and CBER. FDA also allocated certain expenses incurred by CDRH and CBER that it paid for centrally, such as rent, utilities, and facilities repair and maintenance, based on the level of user fee-related costs to total costs of the two centers.
 3. Within ORA, FDA used a time-reporting system to identify the number of direct hours devoted to the application review process by its inspection, investigations, administrative, and management staff. FDA multiplied the total number of staff hours devoted to the process by the average salary and benefit cost to arrive at the costs ORA incurred for the process. FDA also allocated a portion of ORA's operating and rent expenses based on the ratio of total staff years devoted to the process compared to total ORA staff years.
 4. FDA determined that the costs incurred by its Office of the Commissioner (OC) represent the agency's general and administrative costs. FDA calculated the OC's percentage of total costs by dividing the total OC costs by the total salary obligations of FDA, excluding the OC. FDA then multiplied this percentage by the total salaries (not including benefits) applicable to the process in CDRH, CBER, and ORA to arrive at the total OC costs, or general and administrative costs applicable to the process.
- Consistent with the SFFAS 4 standard for selecting a methodology that is economically feasible and practical, FDA adapted a methodology developed by a national accounting firm for a similar FDA program.¹³ The methodology had already been used successfully and it allowed FDA to obtain the cost information it needed from the financial data produced by its accounting and budgeting system, which it uses to prepare its annual

¹¹FDA's methodology did not capture certain costs related to Civil Service Retirement System pension and postretirement health benefits that are paid for by the Office of Personnel Management on behalf of current and retired federal employees.

¹²Within CDRH these costs relate to the Office of the Center Director, and Office of Management and Operations. Within CBER, these costs relate to the Office of the Center Director, Office of Management, Office of Information Management, and Office of Communications, Training, and Manufacturers Assistance.

¹³The national accounting firm originally developed the methodology for FDA's prescription drug user fee program.

financial statements. Using this methodology, FDA directly measured costs when doing so was economically feasible and met management's needs. For example, FDA used quarterly time-reporting data to directly measure the percentage of time device reviewers in CDRH and CBER spent on activities related to the review of device applications over the course of a fiscal year. FDA then applied this percentage of time to the total cost of salaries and benefits for device reviewers in CDRH and CBER—the two device review centers. FDA also used appropriate and consistent methods to estimate costs when direct measurement was not economically feasible. For example, within CDRH and CBER, a number of expenses such as rent, equipment, and maintenance are paid for from central funds. FDA allocated costs that could not be traced to a specific activity, based on the ratio of direct costs of device application reviews to total costs each center incurred.

FDA's Methodology for Allocating the Costs Used in Calculating the Average Costs of Reviewing the Various Application Types Is Consistent with SFFAS 4

FDA allocated the annual costs incurred by CDRH and CBER—organized by cost categories—to 13 types of applications.¹⁴ In addition, FDA added an amount to each application type for costs incurred by ORA for field inspections and investigations conducted on behalf of the review process, and OC for administrative and general support costs. For example, in allocating CDRH and CBER costs, FDA directly assigned cost categories to a particular application type if all of the costs in the categories pertained to that type of application. For those categories that pertained to more than one application type, FDA management used its knowledge of the device application process to allocate costs. This allocation process is consistent with SFFAS 4 standards for capturing full costs and using a reasonable methodology.

To calculate the average cost of reviewing various application types, FDA divided the annual costs by the number of reviews completed during the year for each application type. For example, in fiscal year 2005, FDA estimated that of the \$177 million costs to review applications, \$46.1 million, or 26 percent, pertained to premarket approval applications (PMA)¹⁵. FDA then divided \$46.1 million by the 53 completed PMAs in fiscal year 2005, which resulted in a calculated average cost of \$870,400 per PMA. FDA used completed applications because the agency wanted to reflect actual performance achieved with program dollars. Because FDA's resources and workloads fluctuate from year to year, which directly affects unit cost estimates, FDA's management suggested that the annual unit cost estimates be viewed as benchmarks for future comparisons.

FDA Staffing for the Process of Reviewing Device Applications Increased from Fiscal Years 2002 through 2005, but Decreased Slightly in Fiscal Year 2006

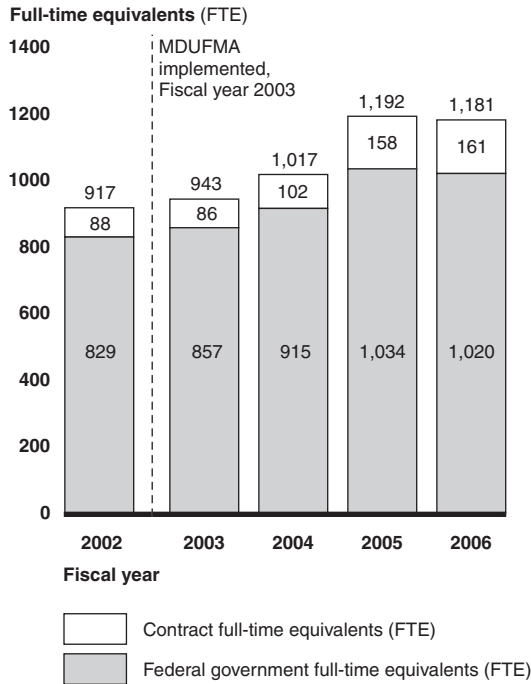
From fiscal year 2002, the baseline year before MDUFMA went into effect, through fiscal year 2005, staffing for the process of reviewing device applications increased. However, staffing

¹⁴FDA's original plan was to develop cost information for 15 different types of application reviews. However, according to FDA officials, data quality concerns and limitations in the time-reporting process within CDRH limited the scope of cost estimation to 8 application types in fiscal years 2003 and 2004. As a result of CDRH expanding the categories in its time-reporting system and retraining reviewers in the methods and importance of time reporting, FDA expanded the number of unit cost estimates in fiscal year 2005 to 13 application types. FDA has indicated that it is committed to continuing to enhance its time-reporting system and increasing the number of future cost estimates.

¹⁵A premarket approval application is an application to market a class III medical device.

decreased slightly in fiscal year 2006. Specifically, total FTEs for government and contract employees combined increased from 917 to 1,192 FTEs, or about 30 percent, from fiscal year 2002 through fiscal year 2005. (See fig. 1.) In fiscal year 2006, total FTEs declined to 1,181.

Figure 1: FDA Staffing for the Process of Reviewing Medical Device Applications from Fiscal Years 2002 through 2006



Source: GAO analysis of FDA data.

According to FDA officials, the lower staffing levels in fiscal year 2006 are attributed to a hiring freeze.¹⁶ In fiscal year 2005, FDA imposed a hiring freeze on CDRH, the component that reviews the largest number of device applications. This freeze led to a delay in the hiring process in fiscal year 2006. FDA officials told us that the agency froze hiring in CDRH because of uncertainty over FDA’s authority to assess and collect user fees in fiscal years 2006 and 2007 due to a provision in MDUFMA.¹⁷ In 2005, Congress passed the Medical Device User Fee and Stabilization Act of 2005 (MDUFSA),¹⁸ which amended the law, allowing FDA to retain its authority to assess and collect user fees in fiscal years 2006 and 2007. According to

¹⁶In addition, according to FDA officials, efforts to improve time reporting may have contributed to reduced fiscal year 2006 FTE numbers. FDA officials stated that the agency improved its measurement of FTEs in fiscal year 2006 by using more precise measures that, in some cases, eliminated some activities not related to medical device reviews that had been included in less precise measures used to calculate FTEs in prior years.

¹⁷Under MDUFMA, FDA would not have had the authority to continue assessing and collecting user fees if total appropriations for fiscal years 2003 through 2006, excluding user fees, did not meet specified amounts. FDA officials told us that the agency imposed a hiring freeze on CDRH on March 3, 2005, because the required total appropriation level had not yet been met and the agency did not know if it would have the authority to continue to assess and collect user fees.

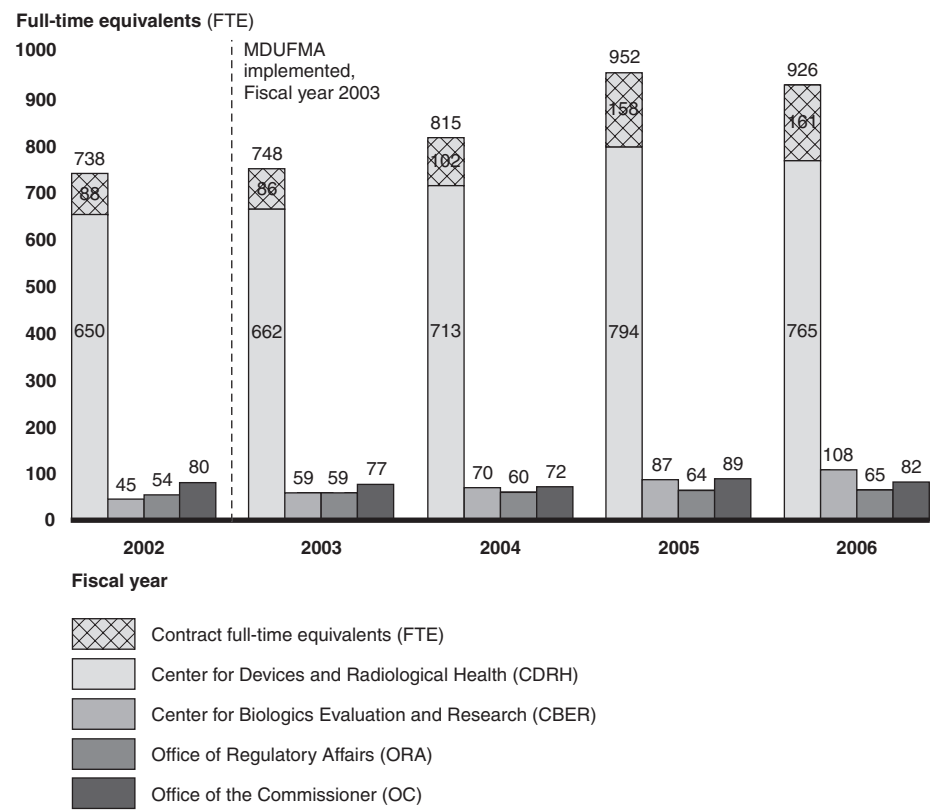
¹⁸Pub. L. No. 109-43, 119 Stat. 439.

FDA officials, the agency resumed hiring in 2006 following the approval of the fiscal year 2006 federal budget, which reflected the changes in MDUFSA.

The overall increase in staffing for the process of reviewing device applications for fiscal year 2002 through 2006 was primarily due to an increase in government employees. According to FDA officials, this increase was accomplished through the transfer of existing FDA employees from other programs and activities, with the remaining staff increases from new hires such as temporary or special government employees. In addition, FDA used contract employees to increase staffing of the process of reviewing device applications.

Fiscal year 2002 through 2005 increases in FTEs were spread among the four FDA components involved in the process of reviewing device applications: CDRH, CBER, the ORA, and the OC. The largest increase of FTEs occurred in CDRH, with an increase of 188 FTEs. Staffing in the three other offices—CBER, ORA, and OC—increased 63, 11, and 2 FTEs respectively. (See fig. 2.) The overall decline of 11 FTEs in fiscal year 2006 was due primarily to a decline of FTEs in CDRH, which decreased by 26 FTEs. OC decreased by 7 FTEs, while CBER and ORA increased by 21 and 1, respectively.

Figure 2: FDA Staffing, by Component, for the Process of Reviewing Medical Device Applications from Fiscal Years 2002 through 2006



Source: GAO analysis of FDA data.

Agency Comments

HHS reviewed a draft of this report and stated the report fairly and accurately describes FDA's accounting for the costs of medical device reviews and the resources FDA added to the medical device review program (see enc. I).

As agreed with your office, unless you publicly announce the contents of this report earlier, we plan no further distribution of it until 30 days from the date of this report. At that time, we will send copies of this report to the Secretary of Health and Human Services, the Commissioner of FDA, appropriate congressional committees, and other interested parties. We will also make copies available to others on request. In addition, the report will be available at no charge on GAO's Web site at <http://www.gao.gov>. If you or your staff have questions about this report, please contact Randall B. Williamson at (206) 287-4860 or williamsonr@gao.gov or Robert Martin at (202) 512-6131 or martinr@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. Key contributors to this report were James Musselwhite, Assistant Director; Donald Neff, Assistant Director; Lisa Crye; Jessica Morris; and Yorick F. Uzes.

Sincerely yours,



Randall B. Williamson
Acting Director, Health Care



Robert E. Martin
Director, Financial Management and Assurance

Enclosure – I

Agency Comments from the Department of Health and Human Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Assistant Secretary
for Legislation

Washington, D.C. 20201

JUN 18 2007

Randall B. Williamson
Director, Health Care
U.S. Government Accountability Office
Washington, DC 20548

Dear Mr. Williamson:

Enclosed please find the department's comments on the U.S. Government Accountability Office's draft report entitled, "Food and Drug Administration: Methodologies for Identifying and Allocating Costs of Reviewing Medical Device Applications Are Consistent with Federal Cost Accounting Standards, and Staffing Levels for Reviews Have Generally Increased in Recent Years" (GAO-07-882R).

We appreciate the opportunity to review and comment on this draft correspondence before it is published.

Sincerely,

VJ
Rebecca Hernandez
Vincent J. Ventimiglia
Assistant Secretary for Legislation

**COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES
ON THE GOVERNMENT ACCOUNTABILITY OFFICE DRAFT REPORT
ENTITLED, "FOOD AND DRUG ADMINISTRATION: METHODOLOGIES
FOR IDENTIFYING AND ALLOCATING COSTS OF REVIEWING MEDICAL
DEVICE APPLICATIONS ARE CONSISTENT WITH FEDERAL COST
ACCOUNTING STANDARDS, AND STAFFING LEVELS FOR REVIEWS HAVE
GENERALLY INCREASED IN RECENT YEARS (GAO 07-882R)**

HHS COMMENTS:

GAO's draft correspondence fairly and accurately describes FDA's efforts to provide a reasonable accounting of the costs of medical device reviews. The correspondence provides a clear and complete explanation of FDA's methodology and our successful efforts to add resources to the medical device review program. The report does not require any corrections or clarifications.

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