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FOOD AND DRUG ADMINISTRATION

Data to Measure the Timeliness of Reviews of Medical Device Applications Are Limited

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Highlights

Highlights of GAO-04-1022, a report to congressional committees

Why GAO Did This Study

FDA reviews applications from manufacturers that wish to market medical devices in the United States. To ensure prompt approval of new devices and clearance of devices that are substantially equivalent to those legally on the market, the Congress passed the Medical Device User Fee and Modernization Act of 2002 (MDUFMA). The act authorizes FDA to collect user fees and, in return, requires FDA to meet performance goals that are tied to the agency's review process. The goals set actions FDA may take on applications and specify the time that FDA should take in certain phases of the review process.

MDUFMA requires GAO to report on FDA's performance against the MDUFMA performance goals established for fiscal years 2003 and 2004 and to determine whether FDA is likely to meet the fiscal year 2005 performance goals. MDUFMA also requires GAO to report on the amounts FDA obligated in fiscal year 2002 for medical device compliance activities and inspections of manufacturers after their devices are marketed.

GAO analyzed data provided by FDA that are based on actions taken on applications FDA received from October 1, 2002, through March 31, 2004. GAO also analyzed data on the amounts FDA obligated for medical device compliance and inspection activities for fiscal year 2002.

www.gao.gov/cgi-bin/getrpt?GAO-04-1022.

To view the full product, including the scope and methodology, click on the link above. For more information, contact Marcia Crosse at (202) 512-7119.

What GAO Found

FDA had limited data that could be used to measure the agency's performance against most of the MDUFMA performance goals. Thus, it is uncertain whether FDA will meet the MDUFMA performance goals for fiscal years 2003, 2004, and 2005. For fiscal years 2003 and 2004, there were two performance goals in effect for each year. As of March 31, 2004, only one application was subject to the action tied to one of the two MDUFMA performance goals. On this application, FDA completed its review and made the decision to approve the application within the goal's established time frame. To determine the likelihood of meeting the 20 MDUFMA performance goals for fiscal year 2005, FDA is collecting data on its performance against these goals. GAO found that FDA had performance data for some, but not all, of the MDUFMA performance goals. From fiscal year 2003 applications, data were available to compare FDA's performance against 17 of the 20 fiscal year 2005 performance goals. FDA took actions tied to 14 of the 17 goals within the goals' established time frames. From fiscal year 2004 applications, data were available to compare FDA's performance against 11 of the 20 performance goals. FDA took actions tied to the 11 goals within the goals' established time frames. The results of FDA's performance against MDUFMA performance goals are preliminary, however, because 8 percent and 49 percent, respectively, of the applications FDA accepted in fiscal year 2003 and the first 6 months of fiscal year 2004 were awaiting action by FDA or responses from manufacturers. Because FDA's performance against the MDUFMA performance goals is based on the percentages of actions the agency takes within required review times, FDA's results could change as the agency completes its actions on all applications for which the goals apply.

FDA obligated about $128 million for postmarket medical device compliance activities and inspections in fiscal year 2002. FDA obligated about $109 million for compliance activities for outreach coordination, such as guidance to field staff on reporting problems with medical devices, laboratory analyses, and research, such as the development of domestic and international standards to provide reasonable assurance that medical device products are safe and effective. FDA obligated about $19 million for inspections of device manufacturers' establishments, including routine surveillance inspections to determine compliance with medical device regulations and inspections resulting from device problem reporting or product recalls.

In commenting on a draft of this report, FDA generally agreed with its findings.