September 2005

FOOD AND DRUG ADMINISTRATION

Limited Available Data Indicate That FDA Has Been Meeting Some Goals for Review of Medical Device Applications

GAO Accountability · Integrity · Reliability

Highlights

Highlights of GAO-05-1042, a report to congressional committees

Why GAO Did This Study

The Food and Drug Administration (FDA) reviews applications from manufacturers that wish to market medical devices in the United States. To facilitate 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 from manufacturers and, in return, requires FDA to meet performance goals tied to the agency's review process. These goals are linked to certain actions FDA may take during the application review process. The goals specify lengths of time for taking these actions and the percentage of actions the agency is to take within specified time frames.

MDUFMA requires GAO to report on whether FDA is meeting performance goals established by the Secretary of Health and Human Services for fiscal year 2005 and whether FDA is likely to meet the goals established for fiscal year 2006.

GAO analyzed data provided by FDA that are based on actions taken on applications FDA received from October 1, 2002, through March 31, 2005. GAO used FDA's performance on applications received in fiscal years 2003 and 2004 as an indicator of the agency's likely performance.

www.gao.gov/cgi-bin/getrpt?GAO-05-1042.

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 or crossem@gao.gov.

What GAO Found

Limited available data indicate that FDA has been meeting some MDUFMA performance goals established for fiscal year 2005. It is uncertain, however, whether FDA will meet all of the goals. FDA met most of the MDUFMA 2005 performance goals for which data were sufficiently complete to measure the agency's performance. As of March 31, 2005, FDA had sufficiently complete data from applications received in fiscal year 2003 to measure performance against 11 of the 20 goals established for fiscal year 2005. FDA met 9 of those 11 goals. For applications received in fiscal year 2004, FDA had sufficiently complete data to measure performance against 10 goals and met 9 of them. When FDA did not have sufficiently complete data to evaluate performance, GAO reviewed preliminary data from applications received in fiscal years 2003, 2004, and 2005. These data suggest that FDA has taken actions tied to many of the fiscal year 2005 goals within specified time frames. These data are preliminary because some applications from each year were pending within the review process and FDA could receive and act on additional applications or amendments to applications. For example, as of March 31, 2005, about half of the applications FDA had received in fiscal year 2005 were pending 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 on applications within required time frames, FDA's performance results could change as the agency completes actions on all applications and amendments for which the performance goals apply.

The limited data available on FDA's performance suggest that FDA is likely to meet some fiscal year 2006 performance goals. GAO's analysis of FDA's past performance shows that FDA met most of the MDUFMA 2006 performance goals for which it had sufficiently complete data to evaluate its performance. As of March 31, 2005, FDA has sufficiently complete data from applications received in fiscal year 2003 to measure performance against 14 of 26 goals established for fiscal year 2006. FDA met 12 of those 14 goals. FDA also had sufficiently complete data from applications received in fiscal year 2004 to measure performance against 12 performance goals and met 9 of those 12 goals. GAO also reviewed preliminary data from applications FDA received in fiscal years 2003, 2004, and 2005 and found that FDA took actions tied to many of the fiscal year 2006 goals within specified time frames. Most of these results are preliminary, however, and FDA's performance could change as the agency completes actions for applications received in fiscal years 2003, 2004, and 2005 and receives applications in fiscal year 2006.

FDA concurred with GAO's findings.