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MEDICAL DEVICES

Status of FDA's Program for Inspections by Accredited Organizations

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Highlights

Highlights of GAO-07-157, a report to congressional committees

Why GAO Did This Study

The Food and Drug Administration (FDA) inspects domestic and foreign establishments where U.S.-marketed medical devices are manufactured to assess compliance with FDA's quality system requirements for ensuring good manufacturing practices and other applicable requirements. The Medical Device User Fee and Modernization Act of 2002 (MDUFMA) required FDA to accredit organizations to inspect certain establishments where devices that are marketed in both the United States and other countries are manufactured.

This report includes information that MDUFMA requires GAO to provide on (1) the number of organizations that sought accreditation, the number that were accredited, and reasons for denial of accreditation and (2) the number of inspections conducted by accredited organizations. It also includes information about factors that could influence manufacturers' interest in voluntarily requesting and paying for an inspection by an accredited organization.

GAO examined FDA documents, interviewed FDA officials, and obtained information from FDA on the number of inspections conducted from March 11, 2004—when FDA first cleared an accredited organization to conduct independent inspections—through October 31, 2006. GAO also interviewed affected entities, including accredited organizations and medical device manufacturers.

www.gao.gov/cgi-bin/getrpt?GAO-07-157.

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

FDA granted accreditation to 17 of 23 organizations that applied to conduct inspections of establishments where medical devices are manufactured. FDA denied accreditation to applicants that did not meet minimum criteria because their applications were not correctly completed or did not demonstrate the applicants' technical competence. During the first accreditation year, which started in April 2003, FDA received 23 applications. Of the 23 applications, 2 were not correctly completed and 2 did not demonstrate that the applicants had adequate technical competence. Although the remaining 19 applicants met the minimum criteria, MDUFMA limited the number of organizations that could be accredited to 15 during the first year after FDA issued criteria for accreditation. FDA scored the 19 applications against these criteria and rank-ordered them. It accredited the 15 organizations with the highest ranking applications, but 1 organization later withdrew. After the initial accreditation year, FDA received 2 more applications for accreditation and it accredited both organizations. These 16 organizations remained accredited as of October 31, 2006.

Between March 11, 2004, and October 31, 2006, two accredited organizations conducted independent inspections—one inspection of a domestic establishment and one inspection of a foreign establishment. During that same period, 36 inspections of domestic establishments and 1 inspection of a foreign establishment were conducted by accredited organizations jointly with FDA officials as part of training that FDA requires of accredited organizations. As of October 31, 2006, individuals from 7 of the 16 accredited organizations had completed all training requirements and were cleared to conduct independent inspections.

Several factors may influence manufacturers' interest in voluntarily requesting an inspection by an accredited organization. According to FDA and representatives of affected entities, there are potential incentives and disincentives to requesting an inspection, as well as reasons for deferring participation in the program. Potential incentives include the opportunity to reduce the number of inspections conducted to meet FDA and other countries' requirements and to control the scheduling of the inspection. Potential disincentives include bearing the cost for the inspection and uncertainty about the potential consequences of making a commitment to having an inspection to assess compliance with FDA requirements in the near future. Some manufacturers might be deferring participation. For example, manufacturers that already contract with a specific accredited organization to conduct inspections to meet the requirements of other countries might defer participation until FDA has cleared that organization to conduct independent inspections.

The Department of Health and Human Services provided technical comments on a draft of this report, which GAO incorporated as appropriate.