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MEDICAL DEVICES

Challenges for FDA in Conducting Manufacturer Inspections

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Highlights

Highlights of GAO-08-428T, a testimony before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives

Why GAO Did This Study

As part of the Food and Drug Administration's (FDA) oversight of the safety and effectiveness of medical devices marketed in the United States, it inspects domestic and foreign establishments where these devices are manufactured. To help FDA address shortcomings in its inspection program, the Medical Device User Fee and Modernization Act of 2002 required FDA to accredit third parties to inspect certain establishments. In response, FDA has implemented two such voluntary programs. GAO previously reported on the status of one of these programs, citing concerns regarding its implementation and factors that may influence manufacturers' participation. (Medical Devices: Status of FDA's Program for Inspections by Accredited Organizations, GAO-07-157, January 2007.)

This statement (1) assesses FDA's management of inspections of establishments—particularly those in foreign countries—manufacturing devices for the U.S. market, and (2) provides the status of FDA's programs for third-party inspections of medical device manufacturing establishments. GAO interviewed FDA officials; reviewed pertinent statutes, regulations, guidance, and reports; and analyzed information from FDA databases. GAO also updated its previous work on FDA's programs for inspections by accredited third parties.

To view the full product, including the scope and methodology, click on GAO-08-428T. For more information, contact Marcia Crosse at (202) 512-7114 or crossem@gao.gov.

What GAO Found

FDA has not met the statutory requirement to inspect certain domestic establishments manufacturing medical devices every 2 years, and the agency faces challenges inspecting foreign establishments. FDA primarily inspected establishments located in the United States. The agency has not met the biennial inspection requirement for domestic establishments manufacturing medical devices that FDA has classified as high risk, such as pacemakers, or medium risk, such as hearing aids. FDA officials estimated that the agency has inspected these establishments every 3 years (for high risk devices) or 5 years (for medium risk devices). There is no comparable requirement to inspect foreign establishments, and agency officials estimate that these establishments have been inspected every 6 years (for high risk devices) or 27 years (for medium risk devices). FDA faces challenges in managing its inspections of foreign medical device establishments. Two databases that provide FDA with information about foreign medical device establishments and the products they manufacture for the U.S. market contain inaccuracies that create disparate estimates of establishments subject to FDA inspection. Although comparing information from these two databases could help FDA determine the number of foreign establishments marketing medical devices in the United States, these databases cannot exchange information and any comparisons must be done manually. Finally, inspections of foreign medical device manufacturing establishments pose unique challenges to FDA in human resources and logistics.

Few inspections of medical device manufacturing establishments have been conducted through FDA's two accredited third-party inspection programs—the Accredited Persons Inspection Program and the Pilot Multi-purpose Audit Program (PMAP). From March 11, 2004—the date when FDA first cleared an accredited organization to conduct independent inspections—through January 11, 2008, five inspections have been conducted by accredited organizations through FDA's Accredited Persons Inspection Program. An incentive to participation in the program is the opportunity to reduce the number of inspections conducted to meet FDA and other countries' requirements. Disincentives include bearing the cost for the inspection, particularly when the consequences of an inspection that otherwise might not occur in the near future could involve regulatory action. The Food and Drug Administration Amendments Act of 2007 made several changes to program eligibility requirements that could result in increased participation by manufacturers. PMAP was established on September 7, 2006, and as of January 11, 2008, two inspections had been conducted by an accredited organization through this program, which is more limited than the Accredited Persons Inspection Program. The small number of inspections completed to date by accredited third-party organizations raises questions about the practicality and effectiveness of establishing similar programs that rely on third parties to quickly help FDA fulfill its responsibilities.