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MEDICAL DEVICES

FDA Faces Challenges in Conducting Inspections of Foreign Manufacturing Establishments

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Highlights

Highlights of GAO-08-780T, a testimony before the Subcommittee on Health, 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 certain foreign and domestic 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 voluntary programs for that purpose.

This statement is based primarily on GAO testimonies from January 2008 (GAO-08-428T) and April 2008 (GAO-08-701T). In this statement, GAO assesses (1) FDA's program for inspecting foreign establishments that manufacture medical devices for the U.S. market and (2) FDA's programs for third-party inspections of those establishments. For GAO's January and April 2008 testimonies, GAO interviewed FDA officials, analyzed information from FDA, and updated GAO's previous work on FDA's programs for inspections by accredited third parties. GAO updated selected information for this statement in early May 2008.

To view the full product, including the scope and methodology, click on GAO-08-780T. For more information, contact Marcia Crosse at (202) 512-7114 or crossem@gao.gov.

What GAO Found

FDA faces challenges managing its program to inspect foreign establishments that manufacture medical devices. GAO testified in January 2008 that two databases that provide FDA with information about foreign medical device establishments and the products they manufacture for the U.S. market contained inaccurate information about establishments subject to FDA inspection. In addition, comparisons between these databases—which could help produce a more accurate count—had to be done manually. Recent changes FDA made to its registration database could improve the accuracy of the count of establishments, but it is too soon to tell whether these and other changes will improve FDA's management of its foreign inspection program. Another challenge is that FDA conducts relatively few inspections of foreign establishments; officials estimated that the agency inspects foreign manufacturers of high-risk devices (such as pacemakers) every 6 years and foreign manufacturers of medium-risk devices (such as hearing aids) every 27 years. Finally, inspections of foreign manufacturers pose unique challenges to FDA, such as difficulties in recruiting investigators to travel to certain countries and in extending trips if the inspections uncovered problems. FDA is pursuing initiatives that could address some of these unique challenges, but it is unclear whether FDA's proposals will increase the frequency with which the agency inspects foreign establishments.

Few inspections of foreign 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). Under FDA's Accredited Persons Inspection Program, from March 11, 2004—the date when FDA first cleared an accredited organization to conduct independent inspections—through May 7, 2008, four inspections of foreign establishments had been conducted by accredited organizations. An incentive to participation in the program is the opportunity to reduce the number of inspections conducted to meet FDA's 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, as a partnership between FDA and Canada's medical device regulatory agency and allows accredited organizations to conduct a single inspection to meet the regulatory requirements of both countries. As of May 7, 2008, two inspections of foreign establishments had been conducted by accredited organizations through this program. The small number of inspections completed to date by accredited third-party organizations raises questions about the practicality and effectiveness of these programs to quickly help FDA increase the number of foreign establishments inspected.