November 1, 2007

DRUG SAFETY

Preliminary Findings Suggest Weaknesses in FDA's Program for Inspecting Foreign Drug Manufacturers

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Highlights

Highlights of GAO-08-224T, a testimony before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives

Why GAO Did This Study

Many drugs marketed in the United States are manufactured in foreign countries and the value of such products entering the country is increasing. The Food and Drug Administration (FDA) is responsible for overseeing the safety and effectiveness of human drugs that are marketed in the United States, whether they are manufactured in foreign or domestic establishments. Foreign establishments that market their drugs in the United States must register with FDA and FDA inspects foreign establishments to ensure that they meet the same standards that are required of domestic ones. GAO reported 9 years ago that FDA needed to improve its foreign drug inspection program (GAO/HEHS-98-21). Questions remain as to whether FDA has improved its management of the foreign drug inspection program.

This statement discusses preliminary information on (1) the extent to which FDA has accurate data to manage the foreign drug inspection program, (2) the frequency of foreign inspections and factors influencing the selection of establishments to inspect, and (3) issues unique to conducting foreign inspections. To address these issues GAO interviewed FDA officials; reviewed pertinent statutes, regulations, and guidance; and analyzed information from FDA databases. Because of the preliminary nature of our work, we are not making recommendations at this time.

To view the full product, including the scope and methodology, click on GAO-08-224T. For more information, contact Marcia Crosse at (202) 512-7114 or crossem@gao.gov.

What GAO Found

FDA's effectiveness in managing the foreign drug inspection program continues to be hindered by weaknesses in its databases. FDA does not know how many foreign establishments are subject to inspection. Instead, FDA relies on databases that were not designed for this purpose. Further, these databases contain inaccuracies that FDA cannot easily reconcile. One database indicates there were about 3,000 foreign establishments registered to market drugs in the United States in fiscal year 2007, while another indicates that about 6,800 foreign establishments actually imported drugs in that year. FDA recognizes these flaws. Further, because the databases cannot exchange information, any comparisons of the data are performed manually, on a case-by-case basis. FDA officials told GAO that they have not generated an accurate count of foreign establishments whose drugs are imported into the United States.

FDA inspects relatively few foreign establishments. Data from FDA suggest that the agency may inspect about 7 percent of foreign establishments in a given year. At this rate, it would take FDA more than 13 years to inspect each foreign establishment once, assuming that no additional establishments require inspection. However, FDA cannot provide an exact number of foreign establishments that have never been inspected. Most of the foreign inspections performed are conducted as part of a review associated with processing an application to market a new drug, rather than inspections for monitoring the quality of marketed drugs. Although FDA uses a risk-based process to develop a prioritized list of foreign establishments for inspections to monitor the quality of marketed drugs, few are completed in a given year. This prioritized list was used to select foreign establishments for inspection in fiscal year 2007. According to FDA, about 30 such inspections were completed in that year and at least 50 are targeted for inspection in fiscal year 2008.

The foreign inspection process involves unique circumstances that are not encountered domestically. For example, FDA relies on staff that inspect domestic establishments to volunteer for foreign inspections. Unlike domestic inspections to monitor the quality of a marketed drug, FDA does not arrive unannounced at a foreign establishment. It also lacks the flexibility to easily extend foreign inspections if problems are encountered, due to the need to adhere to an itinerary that typically involves multiple inspections in the same country. Finally, language barriers can make foreign inspections more difficult than domestic ones. FDA does not generally provide translators to its inspection teams. Instead, they may have to rely on an English-speaking representative of the foreign establishment being inspected, rather than an independent translator.