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DRUG SAFETY

Better Data Management and More Inspections Are Needed to Strengthen FDA's Foreign Drug Inspection Program

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Highlights

Highlights of GAO-08-970, a report to congressional requesters

Why GAO Did This Study

The Food and Drug Administration (FDA), an agency within the Department of Health and Human Services (HHS), oversees the safety and effectiveness of human drugs marketed in the United States, including those manufactured in foreign establishments. FDA inspects foreign establishments in order to ensure that the quality of drugs is not jeopardized by poor manufacturing processes. This report examines (1) the extent to which FDA has accurate data on the number of foreign establishments subject to inspection, (2) the frequency of foreign inspections, and (3) oversight by FDA to ensure that foreign establishments correct serious problems identified during inspections. GAO analyzed information from FDA databases, reviewed inspection reports which identified serious deficiencies, and interviewed FDA officials.

What GAO Recommends

GAO recommends that FDA improve the data that it uses to manage its foreign inspection program, conduct more inspections of foreign establishments, and ensure more timely inspection of foreign establishments where FDA has identified serious deficiencies. HHS agreed that FDA should conduct more foreign inspections but did not comment on the other recommendations. HHS noted that additional inspections are only one component of FDA's strategy to enhance oversight and elaborated on other initiatives, such as database improvements, discussed in this report.

To view the full product, including the scope and methodology, click on GAO-08-970. For more information, contact Marcia Crosse at (202) 512-7114 or crossem@gao.gov.

What GAO Found

FDA databases contain inaccurate information on foreign establishments subject to inspection. FDA uses information from a database of establishments registered to market drugs in the United States and a database of establishments that shipped drugs to the United States to compile a list of establishments subject to inspection, but these databases contain divergent estimates—about 3,000 and 6,800, respectively. FDA's registration database contains information about establishments not subject to FDA inspection. Although annual reregistration is required, FDA does not deactivate in its database establishments that do not fulfill this requirement. The agency also does not routinely verify that a registered establishment manufactures a drug for the U.S. market. The accuracy of this information is important in FDA's identification of foreign establishments subject to inspection.

FDA inspects relatively few foreign establishments each year to assess the manufacturing of drugs currently marketed in the United States. FDA inspected 1,479 foreign drug manufacturing establishments from fiscal years 2002 through 2007. Because FDA does not know the number of establishments subject to inspection, the percentage of those inspected cannot be calculated with certainty. However, using a list FDA developed to prioritize foreign establishments for inspection in fiscal year 2007, GAO estimated that FDA may inspect about 8 percent of foreign establishments in a given year. At this rate, it would take the agency more than 13 years to inspect these establishments once. In contrast, FDA estimates that it inspects domestic establishments about once every 2.7 years. Unlike domestic establishments, foreign establishments were generally only inspected if they were named in an application for a new drug. While FDA made progress in fiscal year 2007 in conducting more foreign inspections, GAO estimated it still inspected less than 11 percent of such establishments. As FDA plans additional inspections, it is important that it ensure that foreign and domestic establishments with similar characteristics are inspected at a similar frequency.

FDA's identification of serious deficiencies has led foreign establishments to take corrective actions, but inspections to determine continued compliance are not always timely. FDA identified deficiencies during most foreign inspections, but determining how the agency classified the results of a specific inspection is hindered by inconsistencies in its databases, particularly on the classification of inspections with serious deficiencies. From fiscal years 2002 through 2007, FDA issued 15 warning letters to foreign establishments at which it identified serious deficiencies. FDA generally determined the adequacy of actions taken in response to these letters by reviewing information provided by the establishments. FDA's subsequent inspections to determine establishments' continued compliance were not always timely. Of establishments named in the 15 warning letters, FDA subsequently inspected 4 establishments 2 to 5 years later, generally because these establishments were named in a new drug application. At 3 of these 4 inspections, FDA verified that corrective actions had been taken but identified additional deficiencies.