

Why GAO Did This Study

Globalization has placed increasing demands on the Food and Drug Administration (FDA), an agency within the Department of Health and Human Services (HHS), in ensuring the safety and effectiveness of drugs marketed in the United States. Drugs manufactured in more than 100 countries were offered for entry into the United States in fiscal year 2009. FDA inspects drug manufacturing establishments in order to ensure that the safety and quality of drugs are not jeopardized by poor manufacturing practices.

In 1998 GAO identified weaknesses in FDA's foreign drug inspection program. In 2008 GAO found, among other things, that from fiscal years 2002 through 2007, FDA inspected relatively few foreign establishments each year. GAO also determined that, because of inaccurate information in its databases, FDA did not know how many foreign drug establishments were subject to inspection.

In 2008 GAO recommended that FDA increase inspections of foreign drug establishments and improve information it receives to manage the foreign drug inspection program. This report examines FDA's progress since 2008 in (1) conducting more foreign drug inspections, and (2) improving its information on foreign drug establishments. GAO analyzed information from FDA databases, reviewed documents related to FDA's efforts to both improve these databases and supplement its existing information on foreign drug establishments, examined staffing and funding information, and interviewed FDA officials.

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DRUG SAFETY

FDA Has Conducted More Foreign Inspections and Begun to Improve Its Information on Foreign Establishments, but More Progress Is Needed

What GAO Found

FDA increased the number of foreign drug inspections it conducted from fiscal year 2007 to 2009, but still conducts relatively fewer foreign drug inspections each year than it conducts domestically. In fiscal year 2009, FDA conducted 424 foreign inspections, compared to 333 and 324 inspections conducted in fiscal years 2007 and 2008, respectively. Using a list FDA developed to prioritize foreign establishments for inspection, GAO estimated that FDA inspected 11 percent of foreign establishments on this list in fiscal year 2009. At this rate, GAO estimated it would take FDA about 9 years to inspect all establishments on this list once. In contrast, in that same year, FDA conducted 1,015 domestic inspections, inspecting approximately 40 percent of domestic establishments. GAO estimated that at this rate FDA inspects domestic establishments approximately once every 2.5 years. Further, FDA's approach in selecting establishments for inspection is inconsistent with GAO's 2008 recommendation that FDA inspect, at a comparable frequency, those establishments that are identified as having the greatest public health risk potential if they experience a manufacturing defect, regardless of whether they are a foreign or domestic establishment. Instead, its foreign inspections continue to be driven by the establishments listed on an application for a new drug, instead of those already producing drugs for the U.S. market.

FDA is taking steps to improve the information it receives from the drug establishment registration and import databases the agency uses to manage its foreign drug inspection program. For example, FDA is working to obtain more accurate information for its database that contains information about foreign establishments registered to market their drugs in the United States. In addition, FDA has an initiative underway to eliminate duplicate information from its database containing information about foreign establishments whose drugs are offered for import into the United States. However, these efforts are in the early stages. In addition, FDA is exploring other options for obtaining better information about foreign drug establishments, such as by collaborating with foreign regulatory authorities to exchange information about planned inspections and the results of completed inspections.

In 1998, and again in 2008, GAO reported that FDA needed to conduct more inspections of foreign establishments and that it was vital that the agency strengthen the data it uses to manage its foreign drug inspection program. FDA has begun to respond to GAO's recommendations; however, it has not yet fully addressed these weaknesses at a time when the volume of imported drugs and the number of foreign establishments producing these drugs have been increasing. Given the long-standing nature of these challenges and the nation's reliance on drugs manufactured overseas, it is urgent that FDA implement GAO's prior recommendations to better protect public health. HHS reviewed a draft of this report and agreed that more progress is needed in order to meet the challenge of safeguarding the nation's drug supply in today's global marketplace.