September 2010

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Highlights

Highlights of GAO-10-961, a report to the Committee on Oversight and Government Reform, House of Representatives

DRUG SAFETY

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

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.

View GAO-10-961 or key components. For more information, contact Marcia Crosse at (202) 512-7114 or crossem@gao.gov.

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.

September 2010

FOOD AND DRUG ADMINISTRATION

Overseas Offices Have Taken Steps to Help Ensure Import Safety, but More Long-Term Planning Is Needed

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Highlights

Highlights of GAO-10-960, a report to the Committee on Oversight and Government Reform, House of Representatives

Why GAO Did This Study

An increasing volume of food and medical products marketed in the United States are produced in foreign countries. This globalization has challenged the Food and Drug Administration (FDA), which is responsible for ensuring the safety of these products. In late 2008 and early 2009, FDA established overseas offices comprised of 42 total staff covering particular countries or regions—China, Europe, India, Latin America, and the Middle East. The offices are to engage with foreign stakeholders to develop information that FDA officials can use to make better decisions about products manufactured in foreign countries, among other activities. GAO examined (1) the steps overseas offices have taken to help ensure the safety of imported products and (2) the extent to which FDA has engaged in long-term strategic and workforce planning for the overseas offices. GAO reviewed documentation of overseas office activities and planning. GAO also visited offices in China, India, and Latin America to interview FDA officials, officials from other U.S. agencies overseas, and foreign regulators and other stakeholders.

What GAO Recommends

GAO recommends that the Commissioner of FDA take steps to enhance strategic planning to ensure coordination between overseas and domestic activities and develop a workforce plan to help recruit and retain overseas staff. FDA agreed with GAO's recommendations.

View GAO-10-960 or key components. For more information, contact Marcia Crosse at (202) 512-7114 or crossem@gao.gov or Lisa Shames at (202) 512-3841 or shamesl@gao.gov.

What GAO Found

FDA's overseas offices have engaged in a variety of activities to help ensure the safety of imported products, but officials report challenges that could limit their effectiveness, due to an increasing workload and other factors. A primary activity for the offices has been establishing relationships with foreign stakeholders (such as foreign regulators and industry) and U.S. agencies overseas. FDA officials and foreign stakeholders said they had limited contact prior to the opening of the offices, and each noted that the overseas offices are beneficial for relationship building, although relationship building can be time consuming. FDA overseas officials have also gathered information about regulated products and shared it with U.S. officials to assist with decision making. Although FDA has used some of this information to take regulatory actions, some FDA overseas officials told us that they lack feedback regarding the utility of much of the information that they submit to the agency. FDA's offices in China and India include investigators who inspect foreign establishments. In these two countries, as of June 2010, the overseas investigators conducted 48 inspections since they were posted overseas. The FDA overseas officials have also started to provide training, responses to queries, and other assistance to foreign stakeholders to help them improve their regulatory systems and better understand FDA regulations. These officials said, however, that an increasing interest in this type of assistance from foreign stakeholders, while important, could lead to an unmanageable workload. Although FDA staff and others have pointed to several immediate benefits of the offices, it is early and their impact on the safety of imported products is not yet clear.

FDA is in the process of long-term strategic planning for the overseas offices and has not developed a long-term workforce plan. FDA expects to complete a 5-year strategic plan to manage office activities by October 2010. Officials said that they intend to include performance goals and measures for the offices in the strategic plan, but that it will be difficult to quantify office contributions toward long-term outcomes. Also, coordination of the overseas offices with other parts of FDA has been a challenge, and strategic planning efforts can help ensure this coordination. FDA has not yet developed a long-term workforce plan to help ensure that it is prepared to address potential overseas office staffing challenges. Overseas staff agree to 2-year rotations, and workforce planning has focused on preparing to fill any 2011 vacancies. FDA has experienced challenges staffing some office locations and officials from FDA and other agencies with overseas staff have identified potential recruitment and retention challenges that could affect FDA's mission. They said that recruiting staff with language skills and reintegrating returning staff into domestic operations may be difficult. Certain FDA staff experienced a reduction in their pay when they went overseas. Workforce planning could help FDA prepare for potential staffing challenges.