

GAO Highlights

Highlights of [GAO-17-143](#), a report to the Committee on Energy and Commerce

Why GAO Did This Study

Globalization has complicated FDA's oversight of drugs marketed in the United States. FDA reports that more than 40 percent of finished drugs and 80 percent of active pharmaceutical ingredients are produced overseas. FDA inspects drug manufacturing establishments to ensure that the safety and quality of drugs are not jeopardized by poor manufacturing practices. Beginning in 2008, FDA established foreign offices to obtain better information on products coming from overseas and perform inspections, among other things.

In 2008 and 2010, GAO examined FDA's foreign drug inspection program and recommended it conduct more foreign inspections. In another 2010 report, GAO recommended the agency develop strategic and workforce plans for its foreign offices. GAO was asked to update its work with a focus on FDA's oversight of foreign drug establishments. This study examines (1) enhancements FDA has made to its foreign drug inspection program; and (2) FDA's assessment of its foreign offices, and the challenges they face in ensuring drug safety. GAO analyzed FDA's inspection data from fiscal year 2007 through June 30, 2016; reviewed agency planning documents; and interviewed FDA officials, including former foreign office employees.

What GAO Recommends

GAO recommends that FDA assess the contributions of the foreign offices, and set a goal that distinguishes between the vacancy rates of staff in its foreign offices and those in its domestic international program office. HHS agreed with GAO's recommendations.

View [GAO-17-143](#). For more information, contact Marcia Crosse at (202) 512-7114 or crossem@gao.gov.

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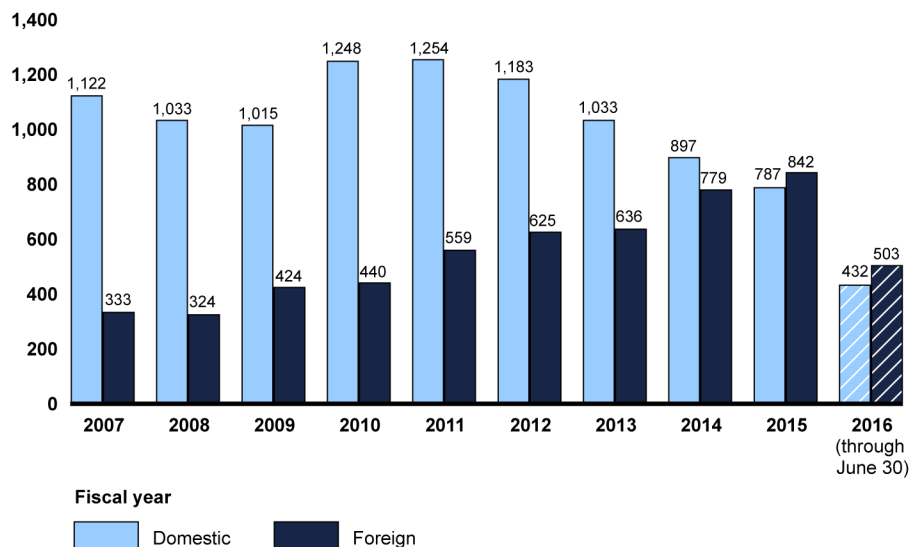
DRUG SAFETY

FDA Has Improved Its Foreign Drug Inspection Program, but Needs to Assess the Effectiveness and Staffing of Its Foreign Offices

What GAO Found

The Food and Drug Administration (FDA), an agency within the Department of Health and Human Services (HHS), has increased its foreign drug inspections and enhanced its ability to prioritize drug establishments for inspection. The number of foreign inspections has consistently increased each year since fiscal year 2009. Beginning in fiscal year 2015, FDA conducted more foreign than domestic inspections. FDA has also improved the accuracy and completeness of information on its catalog of drug establishments subject to inspection. It has also reduced its catalog of drug establishments with no inspection history to 33 percent of foreign establishments, compared to 64 percent in 2010. However, the number of such establishments remains large, at almost 1,000 of the approximately 3,000 foreign establishments. FDA plans to inspect all of these establishments over the next 3 years.

Total Number of Food and Drug Administration (FDA) Inspections of Domestic and Foreign Drug Establishments, Fiscal Year 2007 through June 30, 2016
Number of inspections



Source: GAO analysis of FDA data. | GAO-17-143

FDA has not yet assessed its foreign offices' contributions to drug safety. FDA has made progress in its strategic planning for its offices in China, Europe, India, and Latin America, but the lack of an assessment is inconsistent with federal standards for internal controls. Though FDA uses two performance measures to assess the foreign offices—number of medical product inspections and number of collaborative actions—the collaborative action measure does not capture the offices' unique contributions to drug safety. Moreover, the foreign offices face persistently high vacancy rates. As of July 2016, 46 percent of the foreign offices' authorized positions were vacant. Although FDA recently finalized a workforce plan, GAO identified several weaknesses with it. For example, the plan sets a workforce target that applies to both foreign and domestic international program offices, making it difficult to ascertain whether its goal of reducing foreign office staff vacancies is being met.