

Highlights of [GAO-11-936T](#), a testimony before the Committee on Health, Education, Labor, and Pensions, U.S. Senate

## Why GAO Did This Study

Globalization has placed increasing demands on the Food and Drug Administration (FDA) in ensuring the safety and effectiveness of drugs marketed in the United States. The pharmaceutical industry has increasingly relied on global supply chains in which each manufacturing step may be outsourced to foreign establishments. As part of its efforts, FDA may conduct inspections of foreign drug manufacturing establishments, but there are concerns that the complexity of the drug manufacturing supply chain and the volume of imported drugs has created regulatory challenges for FDA. FDA has begun taking steps to address some of these concerns, such as the establishment of overseas offices.

This statement discusses (1) FDA's inspection of foreign drug manufacturing establishments, (2) the information FDA has on these establishments, and (3) recent FDA initiatives to improve its oversight of the supply chain. The statement presents findings based primarily on GAO reports since 2008 related to FDA's oversight of the supply chain. These reports include *Food and Drug Administration: Overseas Offices Have Taken Steps to Help Ensure Import Safety, but More Long-Term Planning Is Needed* ([GAO-10-960](#), Sept. 30, 2010) and *Drug Safety: FDA Has Conducted More Foreign Inspections and Begun to Improve Its Information on Foreign Establishments, but More Progress Is Needed* ([GAO-10-961](#), Sept. 30, 2010). GAO supplemented this prior work with updated information obtained from FDA in August and September 2011.

View [GAO-11-936T](#). For more information, contact Marcia Crosse at (202) 512-7114 or [crosse@m@gao.gov](mailto:crosse@m@gao.gov).

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## DRUG SAFETY

### FDA Faces Challenges Overseeing the Foreign Drug Manufacturing Supply Chain

## What GAO Found

Inspections of foreign drug manufacturers are an important element of FDA's oversight of the supply chain, but GAO's prior work showed that FDA conducts relatively few such inspections. In 2008, GAO reported that in fiscal year 2007 FDA inspected 8 percent of foreign establishments subject to inspection and estimated that, at that rate, it would take FDA about 13 years to inspect all such establishments. GAO recommended that FDA increase the number of foreign inspections it conducts at a frequency comparable to domestic establishments with similar characteristics. FDA subsequently increased the number of foreign establishment inspections. FDA's inspection efforts in fiscal year 2009 represent a 27 percent increase in the number of inspections it conducted, when compared to fiscal year 2007—424 and 333 inspections, respectively. However, FDA officials acknowledged that FDA is far from achieving foreign drug inspection rates comparable to domestic inspection rates—the agency inspected 1,015 domestic establishments in fiscal year 2009. Also, the types of inspections FDA conducts generally do not include all parts of the drug supply chain. Conducting inspections abroad also continues to pose unique challenges for the agency. For example, FDA faces limits on its ability to require foreign establishments to allow it to inspect their facilities. Furthermore, logistical issues preclude FDA from conducting unannounced inspections, as it does for domestic establishments.

GAO previously reported that FDA lacked complete and accurate information on foreign drug manufacturing establishments—information critical to understanding the supply chain. In 2008, GAO reported that FDA databases contained incorrect information about foreign establishments and did not contain an accurate count of foreign establishments manufacturing drugs for the U.S. market. FDA's lack of information hampers its ability to inspect foreign establishments. GAO recommended that FDA address these deficiencies. FDA has taken steps to do so, but has not yet fully addressed GAO's concerns.

Given the difficulties that FDA has faced in inspecting and obtaining information on foreign drug manufacturers, and recognizing that more inspections alone are not sufficient to meet the challenges posed by globalization, the agency has begun to implement other initiatives to improve its oversight of the drug supply chain. FDA's overseas offices have engaged in a variety of activities to help ensure the safety of imported products, such as training foreign stakeholders to help enhance their understanding of FDA regulations. GAO recommended that FDA enhance its strategic and workforce planning, which FDA agreed it would do. FDA has also taken other positive steps, such as developing initiatives that would assist its oversight of products at the border, although these are not yet fully implemented. Finally, FDA officials identified statutory changes that FDA believes it needs to help improve its oversight of drugs manufactured in foreign establishments. For example, in place of the current requirement that FDA inspect domestic establishments every 2 years, officials indicated the agency would benefit from a risk-based inspection process with flexibility to determine the frequency with which both foreign and domestic establishments are inspected. In light of the growing dependence upon drugs manufactured abroad and the potential for harm, FDA needs to act quickly to implement changes across a range of activities in order to better assure the safety and availability of drugs for the U.S. market.