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# DRUG SAFETY

## Preliminary Findings Suggest Recent FDA Initiatives Have Potential, but Do Not Fully Address Weaknesses in Its Foreign Drug Inspection Program

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Highlights

Highlights of GAO-08-701T, a testimony before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives

### Why GAO Did This Study

The Food and Drug Administration (FDA) is responsible for overseeing the safety and effectiveness of human drugs that are marketed in the United States, whether they are manufactured in foreign or domestic establishments. FDA inspects foreign establishments to ensure that they meet the same standards required of domestic establishments. Ongoing concerns regarding FDA's foreign drug inspection program recently were heightened when FDA learned that contaminated doses of a common blood thinner had been manufactured at a Chinese establishment that the agency had never inspected. FDA has announced initiatives to improve its foreign drug inspection program.

In November 2007, GAO testified on weaknesses in FDA's foreign drug inspection program (GAO-08-224T). This statement presents preliminary findings on how FDA's initiatives address the weaknesses GAO identified. GAO interviewed FDA officials and analyzed FDA's initiatives. GAO examined reports and proposals prepared by the agency, as well as its plans to improve databases it uses to manage its foreign drug inspection program.

To view the full product, including the scope and methodology, click on GAO-08-701T. For more information, contact Marcia Crosse at (202) 512-7114 or crossem@gao.gov.

### What GAO Found

Recent FDA initiatives—some of which have been implemented and others proposed—could strengthen FDA's foreign drug inspection program, but these initiatives do not fully address the weaknesses that GAO previously identified.

- GAO testified in November 2007 that FDA's databases do not provide an accurate count of foreign establishments subject to inspection and do provide widely divergent counts. Through one recent initiative, FDA has taken steps to improve its database intended to include foreign establishments registered to market drugs in the United States. This initiative may reduce inaccuracies in FDA's count of foreign establishments. However, these steps will not prevent foreign establishments that do not manufacture drugs for the U.S. market from erroneously registering with FDA. Further, to reduce duplication in its import database, FDA has supported a proposal that would change the data it receives on products entering the United States. However, the implementation of this proposal is not certain and would require action from multiple federal agencies, in addition to FDA. Efforts to integrate these databases have the potential to provide FDA with a more accurate count of establishments subject to inspection, but it is too early to tell.

- GAO testified that gaps in information weaken FDA's processes for prioritizing the inspection of foreign establishments that pose the greatest risk to public health. While FDA recently expressed interest in obtaining useful information from foreign regulatory bodies that could help it prioritize foreign establishments for inspections, the agency has faced difficulties fully utilizing these arrangements in the past. For example, FDA had difficulties in determining whether the scope of other countries' inspection reports met its needs and these reports were not always readily available in English.

- GAO also testified that FDA inspected relatively few foreign establishments each year. FDA made progress in inspecting more foreign establishments in fiscal year 2007, but the agency still inspects far fewer of them than domestic establishments. FDA dedicated about $10 million to foreign drug inspections in fiscal year 2007 and plans to dedicate about $11 million to such inspections in fiscal year 2008.

- Finally, GAO testified that FDA faced certain logistical and staffing challenges unique to conducting foreign inspections. FDA is pursuing initiatives that could address some of the challenges that we identified as being unique to foreign inspections, such as volunteer inspection staff and lack of translators. FDA has proposed establishing a dedicated cadre of staff to conduct foreign inspections, but the timeframe associated with this initiative is unclear. FDA plans to open an office in China and is considering establishing offices in other countries, but the impact that this will have on the foreign drug inspection program is unknown.