

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.

FOOD AND DRUG ADMINISTRATION

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

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.