

**GAO**

Report to the Committee on Oversight  
and Government Reform, House of  
Representatives

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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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## 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.](#)

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# 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.

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## Abbreviations

CDC	Centers for Disease Control and Prevention
CDSCO	Central Drugs and Standard Control Organization
DHS	Department of Homeland Security
DOJ	Department of Justice
FDA	Food and Drug Administration
HHS	Department of Health and Human Services
OIP	Office of International Programs
ORA	Office of Regulatory Affairs
USDA	U.S. Department of Agriculture

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United States Government Accountability Office  
Washington, DC 20548

September 30, 2010

The Honorable Edolphus Towns  
Chairman  
The Honorable Darrell Issa  
Ranking Member  
Committee on Oversight and Government Reform  
House of Representatives

The globalization of food production and medical product manufacture has presented the Food and Drug Administration (FDA) with challenges. FDA is charged with ensuring the safety of imported products, including food<sup>1</sup> and medical products (drugs, biologics, and medical devices). FDA's oversight of imported products includes inspecting foreign manufacturing establishments and examining imported products at the U.S. border. Demands on the agency have soared, due in part to the globalization of the industries that FDA regulates, according to an FDA advisory board.<sup>2</sup> FDA-regulated imported products arrive from more than 200 countries and territories, and the volume of these imports more than tripled from 1998 to 2008.

A series of recent incidents of illness and death caused by contaminated food and medical products highlight FDA's challenges in ensuring the safety of these imported goods. In 2007, FDA learned that certain pet foods were sickening and killing cats and dogs and contained ingredients imported from China that were contaminated with melamine, an industrial chemical that has no approved use as an ingredient in animal or human food in the United States. In 2008, more than 50 people became ill with *Salmonella* from Honduran cantaloupes, and more than 1,400 people

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<sup>1</sup>FDA, an agency within the Department of Health and Human Services (HHS), shares responsibility for the oversight of food with the U.S. Department of Agriculture's Food Safety and Inspection Service, which oversees the safety of meat, poultry, and processed egg products, both domestic and imported, and verifies that shipments of these products meet its requirements. FDA is responsible for the safety of virtually all other foods, including milk, seafood, fruits, and vegetables.

<sup>2</sup>FDA Science Board, Subcommittee on Science and Technology, *FDA Science and Mission at Risk* (November 2007), [www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4329b\\_02\\_01\\_FDA%20Report%20on%20Science%20and%20Technology.pdf](http://www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4329b_02_01_FDA%20Report%20on%20Science%20and%20Technology.pdf) (accessed May 18, 2010). The Science Board, which is an advisory board to the commissioner of FDA, provides advice on, among other things, specific complex and technical issues as well as emerging issues within the scientific community.

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became ill with *Salmonella* from Mexican peppers. Also in 2008, FDA began an investigation after receiving reports of serious adverse events in people receiving heparin sodium, a commonly used blood thinner. The agency later learned that an active pharmaceutical ingredient found in this drug contained a contaminant and had been manufactured at a Chinese establishment never inspected by FDA.

In recent reports, we highlighted weaknesses in FDA's oversight of these imported products. For example, in 2008, we identified weaknesses involving both FDA's inspection of foreign establishments and its oversight of products at the U.S. border.<sup>3</sup> In addition, we included federal oversight of both food and medical products in our High-Risk Series in 2009 due, in part, to increased globalization of the production of regulated products.<sup>4</sup> In November 2007, the President's Interagency Working Group on Import Safety made several recommendations to improve federal oversight of imported products, including that FDA establish a field presence in key foreign locations.<sup>5</sup> FDA subsequently launched an initiative to establish five overseas offices covering particular countries or regions—China, Europe, India, Latin America, and the Middle East.

You expressed interest in FDA's new overseas offices and whether the agency is taking the steps necessary to ensure the safety of imported products. In particular, you asked us to gather information on the plans, goals, and activities of the overseas offices and the challenges they face. We examined:

1. the steps the 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.

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<sup>3</sup>GAO, *Food Safety: Agencies Need to Address Gaps in Enforcement and Collaboration to Enhance Safety of Imported Food*, [GAO-09-873](#) (Washington, D.C.: Sept. 15, 2009) and GAO, *Drug Safety: Better Data Management and More Inspections Are Needed to Strengthen FDA's Foreign Drug Inspection Program*, [GAO-08-970](#) (Washington, D.C.: Sept. 22, 2008).

<sup>4</sup>GAO, *High-Risk Series: An Update*, [GAO-09-271](#) (Washington, D.C.: January 2009).

<sup>5</sup>*Action Plan for Import Safety: A roadmap for continual improvement* (November 2007), <http://www.importsafety.gov/report/actionplan.pdf> (accessed Dec. 30, 2009). The President's Interagency Working Group on Import Safety was created by President Bush in 2007, is chaired by the Secretary of HHS, and is composed of officials from several different federal agencies.

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To examine steps the overseas offices have taken to help ensure the safety of imported products, we reviewed the offices' fiscal year 2009 accomplishment reports and other documentation of their activities. We also interviewed FDA officials from each of FDA's five overseas offices to learn about their activities, challenges, and accomplishments. For three of the overseas offices—China, India, and Latin America—we interviewed office staff during on-site visits in February and March 2010. During these visits, we also interviewed officials from U.S. agencies with overseas offices and foreign stakeholders, such as officials from FDA's foreign regulatory counterparts, trade associations, and operators of food and medical product establishments. (See app. I for a list of U.S. agencies and other stakeholders we interviewed during the site visits.) We also interviewed domestically based FDA officials responsible for regulating products, conducting foreign inspections, and overseeing the importation of foreign products to learn about their interactions with the overseas offices. To determine the number of inspections that were conducted by FDA officials overseas, we obtained information from FDA's Field Accomplishments and Compliance Tracking System.<sup>6</sup> To assess the reliability of these data we reviewed related documentation, interviewed knowledgeable agency officials, performed electronic data testing, and compared inspection counts to published data. We found counts of inspections sufficiently reliable for the purposes of our report.

To examine the extent to which FDA engaged in long-term strategic planning for the overseas offices, we reviewed FDA's strategic planning documents. These included draft strategic plans developed by each overseas office and documents related to FDA's plans for evaluating the performance of the offices. Through the review of these documents and interviews with overseas and domestic officials, we examined the integration of strategic planning for the overseas offices with planning by other agency components. To examine the extent to which FDA engaged in long-term workforce planning, we reviewed FDA staffing requirements for the overseas offices and interviewed current overseas staff to learn about their experiences and challenges. We examined the status of FDA's workforce planning for the overseas offices, including planning for staff reintegration into FDA's domestic operations. To learn about how other agencies have approached the staffing of their overseas offices, we also

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<sup>6</sup>FDA later indicated that it inadvertently excluded a few inspections from the Field Accomplishments and Compliance Tracking System data that the agency originally provided. We subsequently included these inspections in our analysis.

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interviewed officials from other federal agencies that have had overseas staff for several years, including the Centers for Disease Control and Prevention (CDC) and the Foreign Agricultural Service. We also considered information in our previous reports on strategic planning, workforce planning, and the creation of overseas offices by other federal agencies to examine issues for FDA to consider in future planning.<sup>7</sup>

We conducted this performance audit from January 2010 to September 2010, in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

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## Background

FDA is responsible for ensuring the safety of food and medical products marketed in the United States. FDA has opened overseas offices to assist it in the oversight of products manufactured overseas. While FDA's overseas offices have only recently opened, other federal agencies have long-standing overseas offices and, in previous work, we have identified strategic and workforce planning as important in managing these offices.

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## FDA Oversight of Imported Products

FDA is responsible for ensuring that products marketed in the United States meet the same statutory and regulatory requirements, whether they are produced in the United States or a foreign country. FDA also works with representatives of other countries to reduce the burden of regulation, harmonize regulatory requirements, and achieve appropriate reciprocal arrangements.<sup>8</sup>

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<sup>7</sup>For a list of these and other related reports, see Related GAO Products later in this publication.

<sup>8</sup>See 21 U.S.C. § 393(b)(3).



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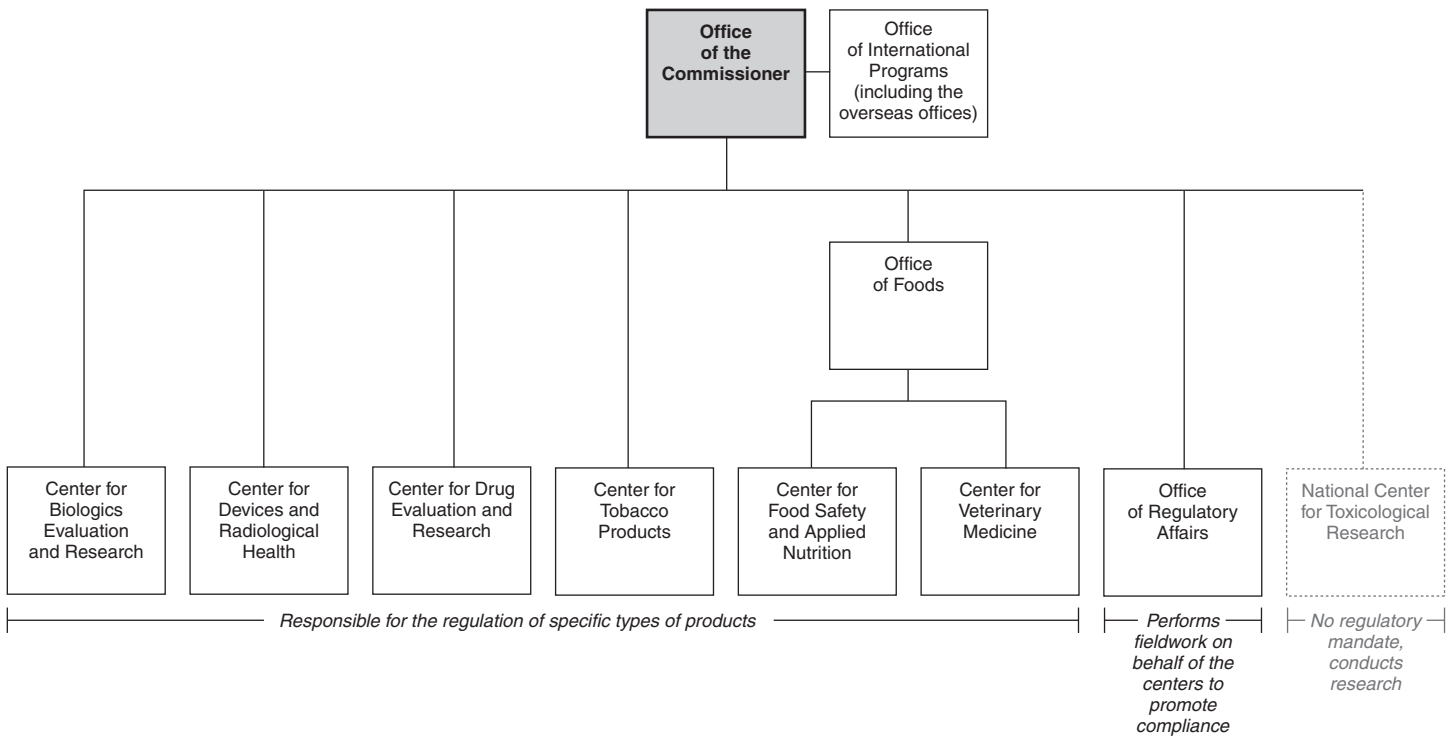
FDA's responsibilities for overseeing the safety of imported products are divided among its centers and offices. FDA's six regulatory centers are each responsible for the regulation of specific types of products.<sup>9</sup> In addition, the Office of Regulatory Affairs (ORA) performs fieldwork, such as inspecting foreign establishments and examining products at the U.S. border, on behalf of all the product centers to promote compliance with FDA requirements and the applicable laws. To enhance FDA's activities in this regard, the centers and ORA also engage with foreign regulators and industry through a variety of activities, such as conducting and attending training workshops. In addition, each center and ORA has staff dedicated to managing these international activities.

Responsibility for leading, managing, and coordinating all of FDA's international activities and its overseas offices lies with the Office of International Programs (OIP), within the Office of the Commissioner. (See fig. 1) FDA, including OIP, has historically had staff based only in the United States. OIP engages with international health and regulatory partners on a variety of issues, including holding bilateral meetings, establishing confidentiality agreements with regulatory counterparts for sharing information on regulated products, and holding meetings to harmonize FDA and international regulatory requirements.

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<sup>9</sup>FDA's seventh center, the National Center for Toxicological Research, does not have a regulatory mandate. Instead, it conducts research that supports FDA's regulatory and public health mission by focusing, for example, on the detection and prevention of toxicity and adverse events associated with FDA-regulated products.

**Figure 1: FDA's Main Organizational Structure, as of June 2010**



Source: FDA.

## Development and Structure of FDA's Overseas Offices

FDA developed a proposal to establish the overseas offices in May 2008. The stated mission of the offices is to engage with foreign stakeholders to develop information that FDA officials can use to make better decisions about products manufactured in foreign countries for the U.S. market. FDA stated that establishing relationships with foreign stakeholders and gathering information are important responses to globalization, in part because the agency is not able to inspect all of the foreign establishments that manufacture products for the U.S. market. During this planning, FDA identified several broad categories of activities that would serve as the initial focus for the offices, with the expectation that they would evolve as OIP and the offices gained experience. These activities included (1) establishing relationships with U.S. agencies located overseas and foreign stakeholders, including regulatory counterparts and industry; (2) gathering better information locally on product manufacturing and transport to U.S. ports; (3) improving FDA's capacity to conduct foreign inspections; and (4) providing assistance to build the capacity of

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counterpart agencies to better assure the safety of the products manufactured and exported from their countries.<sup>10</sup>

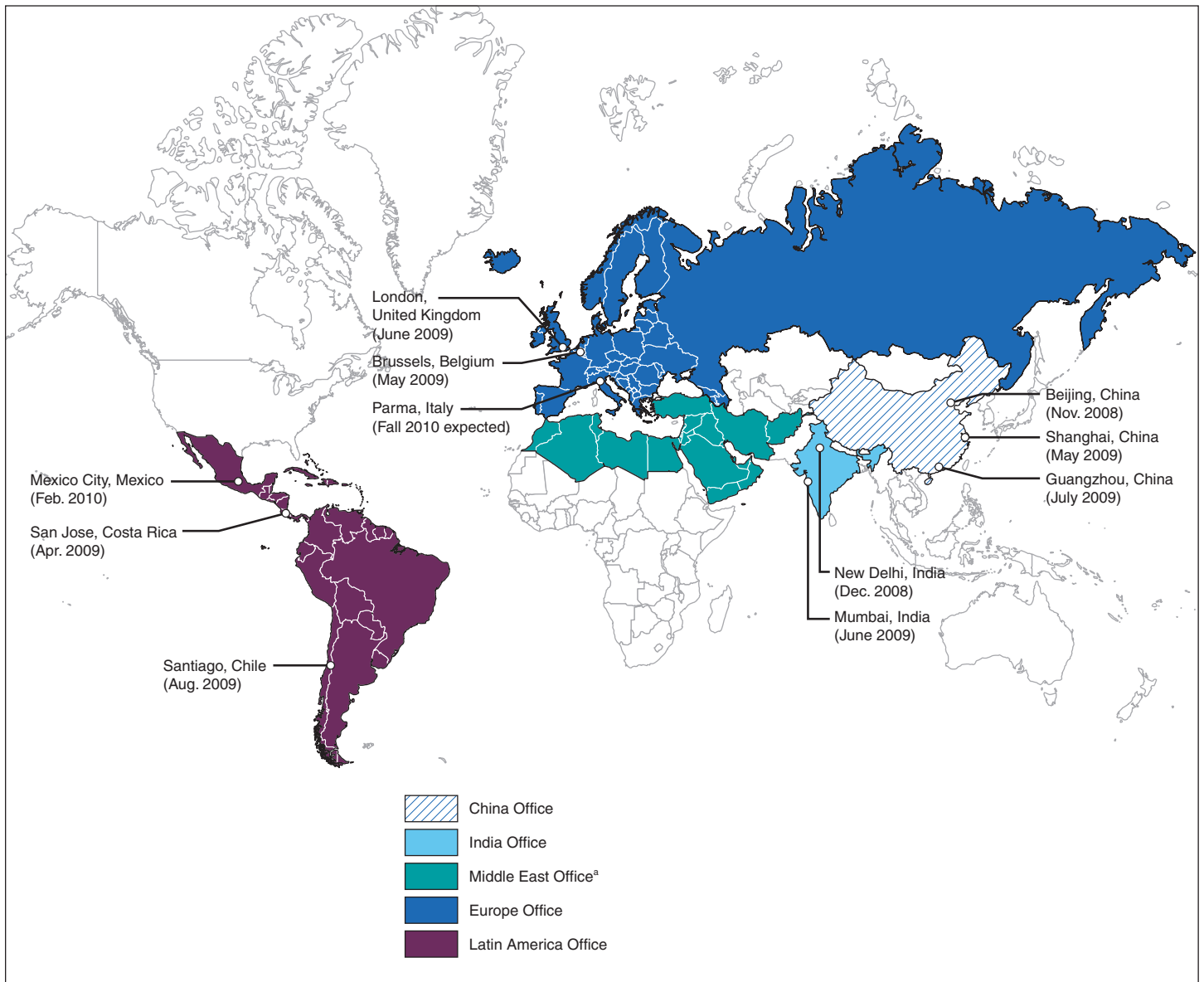
As of July 2010, most of the offices had opened overseas, and each of these had posts in multiple locations.<sup>11</sup> (See fig. 2.) However, the Middle East Office staff continued to work in the United States while FDA was in the process of finalizing plans to locate the office overseas. Also, as of July 2010, the Europe Office was planning to open its post in Parma, Italy, by late fall 2010. The first FDA staff member was deployed overseas in November 2008, to the China Office, and most staff arrived overseas in the middle of 2009. FDA budgeted \$29.9 million for the overseas offices in fiscal year 2009. For fiscal year 2010, the agency increased its budget for the overseas offices by \$1 million, bringing the year's total to \$30.9 million. All staffing and administrative costs associated with the offices are included in these budgeted amounts. In addition to the regions covered by the overseas offices, OIP has domestic offices that cover other regions of the world, such as its Africa and Asia Office.

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<sup>10</sup>FDA's capacity building, also known as technical assistance or technical cooperation, includes the provision of scientific, technical, regulatory, or inspection assistance, and education and training to help strengthen public health regulatory infrastructures abroad, especially for countries where exports to the United States are significant or increasing. FDA also engages with foreign industry to help assure their understanding of U.S. standards.

<sup>11</sup>The offices in China, India, and Latin America are located in either U.S. embassies or consulates managed by the Department of State. The office in Europe has an official at the U.S. mission to the European Union, in Brussels, an official in London embedded within the European Medicines Agency, and plans to assign an official in Parma, Italy to be embedded within the European Food Safety Authority.

**Figure 2: Geographic Responsibilities of FDA's Overseas Offices, Including Their Locations and Opening Dates**



Sources: GAO analysis of FDA information; Map Resources (map).

Notes: OIP also has domestic offices that cover other regions of the world. For example, it has an Africa and Asia Office and a Quadrilateral and Trilateral Office, which is responsible for agency interactions with Canada, Australia, and New Zealand.

<sup>a</sup>As of July 2010, FDA had not opened the Middle East Office overseas.

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FDA officials said it was important to staff the overseas offices with experienced personnel who could represent the agency and speak on its behalf in foreign countries. As of July 2010, FDA had a total of 42 staff assigned to the overseas offices. Of these, FDA had posted 24 staff overseas; planned to assign 1 person to Parma, Italy by fall 2010; had 3 staff for the Middle East Office, who were still working in the United States; and had 14 locally employed staff in India, China, and Latin America, some of whom have technical expertise, while others focus on administrative issues.<sup>12</sup> Each office has a director in that country or region to whom all staff members report. The offices also all have technical experts responsible for engaging with foreign stakeholders and gathering information on food or medical products. In China and India, FDA also placed investigators, who conduct inspections. Like other overseas staff, the investigators are part of OIP for administrative purposes, but decisions regarding which establishments to inspect are made by ORA, which receives input on this from the centers. FDA officials stated that they did not assign investigators to Latin America because U.S.-based investigators can gain access to establishments in that region more quickly than in China or India. OIP staff in the United States also assist the overseas offices.

FDA staff agreed to be posted overseas for an initial 2-year rotation. The Department of Health and Human Services (HHS) requires that its overseas staff commit to rotations of no more than 2 years per tour. However, they have the option to renew up to two times, for a total of 6 years in one country. In addition, HHS requires that staff spend a total of no more than 8 years overseas before returning to the United States for at least 1 year.

(See app. II for more information on the development and structure of FDA's overseas offices.)

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## Federal Strategic and Workforce Planning

Strategic planning is utilized by agencies to manage their programs more effectively by clearly establishing goals and objectives and describing how program activities can serve those goals. Strategic planning can help agencies develop strategies to address current and future management challenges. In our prior work, we have identified a variety of leading

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<sup>12</sup>Locally employed staff, also known as Foreign Service Nationals, are non-U.S. citizens who are generally employed at U.S. missions.

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practices for successful strategic planning.<sup>13</sup> One of these practices is the development of a set of results-oriented performance measures. Agencies use performance measures to help evaluate program performance, demonstrate progress in achieving results, balance competing priorities, and inform decision making. Such results-oriented performance measures should, whenever possible, demonstrate a program's contributions toward the long-term outcomes, or the results the agency expects a program to achieve. Given FDA's mission to ensure the safety of food and medical products, we have previously noted that the agency's long-term outcomes should focus on public health.<sup>14</sup> Agencies can show their interim progress and contributions toward long-term outcomes using short-term and intermediate goals and measures. When long-term outcomes may be influenced by multiple agency programs and external factors, short-term and intermediate measures can also demonstrate a program's specific contribution to a long-term outcome.<sup>15</sup>

In addition, workforce planning is utilized by agencies to align their workforce with current and future program needs and develop long-term strategies for recruiting, training, and retaining staff.<sup>16</sup> Approaches to such planning can vary with each agency's particular needs and mission, but should share certain principles, such as the identification of skills and competencies to fill critical workforce gaps and the strategies needed to recruit them. Workforce planning, in essence, helps agencies think strategically about how to put the right people in the right jobs at the right time.

In a February 2010 report, we noted that FDA was not fully utilizing practices for effective strategic and workforce planning.<sup>17</sup> We stated that most of FDA's established performance measures were not results-oriented as they did not focus on the actual public health outcomes of

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<sup>13</sup>See, for example, GAO, *Managing for Results: Critical Issues for Improving Federal Agencies' Strategic Plans*, [GAO/GGD-97-180](#) (Washington, D.C.: Sept. 16, 1997).

<sup>14</sup>GAO, *Food and Drug Administration: Opportunities Exist to Better Address Management Challenges*, [GAO-10-279](#) (Washington, D.C.: Feb. 19, 2010).

<sup>15</sup>GAO, *Agency Performance Plans: Examples of Practices That Can Improve Usefulness to Decisionmakers*, [GAO/GGD/AIMD-99-69](#) (Washington, D.C.: Feb. 26, 1999).

<sup>16</sup>GAO, *Human Capital: Key Principles for Effective Strategic Workforce Planning*, [GAO-04-39](#) (Washington, D.C.: Dec. 11, 2003).

<sup>17</sup>[GAO-10-279](#).

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FDA's work. We also stated that FDA's internal coordination between its centers and offices was one of the major management challenges facing the agency. We recommended, and FDA agreed, that the agency issue an up-to-date strategic workforce plan, make its performance measures more results-oriented, and more clearly align center and office program activities to FDA's strategic goals.

We have also previously reported on the importance of strategic and workforce planning for other federal agencies managing offices overseas. For example, in 2002, the U.S. Customs Service posted officials at foreign ports to screen cargo containers. We noted that long-term program success would require strategic plans that clearly establish the program's goals and objectives, results-oriented performance measures, and a workforce plan.<sup>18</sup> We have also noted challenges faced by other federal agencies with long-standing offices overseas. In our review of workforce planning by CDC, an agency within HHS that has 270 U.S. and 1,400 locally employed staff overseas, we noted that the agency has faced difficulties hiring and retaining staff posted overseas due, in part, to a lengthy hiring process and limited opportunities for promotion.<sup>19</sup> In addition, we have previously reported on the Department of State's challenges staffing qualified personnel to hardship locations overseas, which the agency defines as locations where differential pay incentives are provided to compensate staff for the severity or difficulty of the local conditions.<sup>20</sup>

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<sup>18</sup>GAO, *Container Security: Expansion of Key Customs Programs Will Require Greater Attention to Critical Success Factors*, [GAO-03-770](#) (Washington, D.C.: July 25, 2003).

<sup>19</sup>GAO, *Centers for Disease Control and Prevention: Human Capital Planning Has Improved, but Strategic View of Contractor Workforce Is Needed*, [GAO-08-582](#) (Washington, D.C.: May 28, 2008).

<sup>20</sup>GAO, *Department of State: Additional Steps Needed to Address Continuing Staffing and Experience Gaps at Hardship Posts*, [GAO-09-874](#) (Washington, D.C.: Sept. 17, 2009).

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## FDA's Overseas Offices Have Taken Steps to Assist Regulatory Oversight, but Challenges Could Limit Their Effectiveness

FDA's overseas offices are establishing relationships with foreign stakeholders and U.S. federal agencies located overseas, gathering information to assist regulatory decision making, conducting establishment inspections, and providing capacity building to foreign stakeholders in an effort to help ensure the safety of imported products. Though FDA officials cite specific benefits associated with the overseas offices, overseas officials report facing a variety of challenges that may limit their ability to enhance agency oversight.

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## Overseas Offices Have Begun to Establish Relationships with Foreign Stakeholders and U.S. Federal Agencies Located Overseas, but the Process Takes Time

One of the primary activities for the newly established offices, after their initial set-up,<sup>21</sup> has been to develop relationships with foreign stakeholders and other U.S. federal agencies located overseas. FDA has identified building relationships as a key step towards better understanding foreign regulatory processes, identifying possible collaborative activities, sharing information, and building capacity. FDA officials said that prior to the opening of the overseas offices, the agency had little knowledge of the regulatory structures in some countries with which the overseas offices interact or lacked points of contact with some of their regulatory counterparts. For example, FDA's overseas officials said that prior to the opening of the overseas offices it took the agency a month to identify their Chinese regulatory counterparts during the melamine crisis.<sup>22</sup> Similarly, prior to the opening of the India Office, FDA had a limited understanding of its regulatory counterparts. For example, it was unclear which Indian regulatory agency is responsible for overseeing food products exported to the United States.<sup>23</sup> FDA's overseas officials in that office are still working to clarify their regulatory counterparts in certain areas.

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<sup>21</sup>FDA officials stated that the first priority of the overseas offices was to locate staff overseas and conduct activities to set up the offices, which took a substantial effort.

<sup>22</sup>Several regulatory agencies in China share responsibility for overseeing food and FDA officials said there was confusion about which agency oversaw the contaminated products. These agencies include the Ministry of Agriculture, the State Food and Drug Administration, and the General Administration of Quality Supervision, Inspection and Quarantine, which regulates products bound for export.

<sup>23</sup>Indian regulation of food products is also split between several agencies. The Food Safety and Standards Authority of India oversees the regulation of food manufactured for consumption in India, while food exported to other countries, including the United States, is overseen by various bodies, including the Export Inspection Council and the Agricultural and Processed Food Products Export Development Authority.



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Both foreign stakeholders and other federal agency officials located overseas report that FDA's presence overseas is beneficial for relationship building. Some of the foreign stakeholders that we spoke with said that they either had not interacted with FDA prior to the opening of the overseas offices or had only limited contact. Officials from both FDA and its foreign regulatory counterparts told us that having a local FDA presence has enabled them to start building a personal connection and trust that would be hard to develop otherwise. FDA officials said, for example, that being located overseas allows them to attend local conferences and better reach out to industry stakeholders. In comparison, officials from FDA's Middle East Office and Africa and Asia Office—both FDA offices without overseas locations—said that it is challenging to develop relationships with foreign stakeholders from the United States and on-going, real-time communication is difficult. Some of these officials also told us that they have not been able to develop relationships with foreign stakeholders to the same extent as their colleagues in the overseas offices. FDA overseas officials have also begun collaborating with other federal agencies collocated at overseas embassies, through both formal and informal interactions, such as embassy workgroups on health. Federal agency officials we spoke with said that having FDA located overseas will be important for FDA and helpful for the other federal agencies located overseas. For example, some of these officials said that FDA's overseas presence allows their agencies to spend less time on issues related to FDA-regulated products.

Although FDA's relationship with foreign stakeholders has grown, FDA's overseas officials have identified continued challenges to forming these relationships. Officials in some of FDA's overseas offices told us that relationships with foreign regulators are taking longer to develop than FDA originally anticipated. For example, FDA officials in India said that it has been both difficult and time consuming to schedule meetings with their counterparts because Indian regulators must obtain permission from senior levels of their government before participating in meetings with FDA. In comparison, FDA officials said that memorandums of agreement with Chinese regulatory agencies have greatly facilitated relationship building.<sup>24</sup> Though some foreign stakeholders suggested that such

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<sup>24</sup>In 2007, FDA, through HHS, signed memorandums of agreement with Chinese agencies—specifically, the State Food and Drug Administration and the General Administration of Quality Supervision, Inspection and Quarantine—that regulate food and medical products for export to the United States. As part of these agreements, the agencies agreed to collaborate on activities intended to ensure the safety of imported products, such as providing technical assistance, and meet annually to discuss the progress of the agreement.

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agreements could benefit FDA's relationship with Indian regulators, FDA officials said that these agreements are time consuming to create and they did not yet know if this type of agreement was needed in India. Additionally, officials located in overseas offices that focus on a geographic region, such as Latin America or the Middle East, said they are challenged by the number of different regulators with whom they must establish relationships. In contrast to the single-country focus of the China and India Offices, the Latin America and Middle East Offices cover 37 and 21 countries, respectively. Also, the regulatory structure of some countries can make relationship building difficult. In China and India, regulations are developed at the national level, but are generally enforced at the local level to varying degrees, according to officials from foreign regulatory agencies. Because of this, officials from other U.S. agencies located in these countries said that FDA will probably have to establish relationships with multiple layers of government officials.

FDA's overseas officials also face pressure to spend time contributing to trade discussions involving U.S. industries and other U.S. federal agencies located abroad. Industry officials said that it would be helpful for the overseas offices to intervene in situations where they believe a misunderstanding of FDA's regulations by foreign regulators inhibits trade. For example, an industry official cited one instance where a U.S. product was allowed entry into China only after FDA's China Office provided documentation to the Chinese government showing equivalency between Chinese and U.S. standards. Industry officials with concerns may also contact federal agencies that promote U.S. products, such as the Department of Commerce, which may then solicit FDA to provide technical assistance to their trade discussions. Federal agency officials said that it is beneficial to have FDA's overseas staff participate in such discussions because FDA is highly regarded by foreign stakeholders due to its scientific and regulatory expertise. FDA's overseas officials said that they provide technical expertise, rather than advocate for specific companies, during these discussions. Although the overseas officials said they participate as technical advisors in these discussions to a limited extent—as trade promotion is not directly related to FDA's mission and it may take time away from the offices' other activities—they generally acknowledge that participating in such activities is a necessary part of collaborating with other federal agencies located in the embassies overseas.

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## Overseas Offices Gathered Information to Assist Regulatory Decision Making, but Lacked Feedback on Its Effectiveness

FDA's overseas officials are also gathering firsthand information about regulated products and sharing it with domestic FDA components with the intention that it will help the agency make better decisions about the regulation of imported products. FDA officials report that being located overseas provides the agency with better access to firsthand information about regulated products from local media, other federal agencies, and other sources. For example, an official from the Department of State said that the department routinely provides information on food and medical products to other federal agency officials located in the Beijing embassy, including FDA's China Office. In contrast, officials in the Middle East Office said that their information-gathering efforts suffer because they are not located overseas. They are limited to reading media available in the United States and do not have easy access to industry or other government agencies located overseas. FDA officials report that the information collected by the overseas offices is something the agency would not have had timely access to prior to the opening of the overseas offices. For example, FDA officials said that the use of melamine in products had been widely known in certain sectors of the Chinese dairy industry prior to the melamine crisis. However, FDA did not learn about its use until after it learned of pets sickened by the ingredient. ORA officials speculate that if the agency had staff stationed locally at the time, they would have known about the information in a timelier manner.

FDA officials identified specific cases in which the agency took actions based on information gathered by the overseas offices, although some overseas officials also reported a lack of feedback on the usefulness of this information from the centers and ORA. FDA officials said that much of the information collected by the overseas offices does not necessitate action by the agency, although they said that four import bulletins have been issued based on information gathered from the overseas offices.<sup>25</sup> Specifically, between October 2009 and May 2010, FDA issued import bulletins on garlic powder suspected of heavy metal contamination from any country, food products from China suspected of toxic pesticide contamination, food products from India suspected of using water contaminated with pesticides, and flour products from China suspected of being bleached with limestone. In these cases, FDA officials in the United

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<sup>25</sup>FDA may issue an import bulletin, which may advise FDA staff to sample products when they are offered for import, in an effort to collect information about possible contamination. Import bulletins are generally valid for 90 days after issuance, and FDA will review the information developed from the import bulletin to see if there is a need for further action.

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States reported that they would not have known about this information in such a timely manner without being informed by the overseas offices. However, overseas officials submit information to OIP on a weekly basis, but said they often have not received feedback on whether center and ORA officials find the information they gather to be useful or generally did not know who this information was shared with within the agency.

FDA's overseas officials have also been collecting information on foreign regulatory agencies. Officials in some of the overseas offices—such as the India, Latin America, and Middle East Offices—have begun to develop summaries of foreign regulatory agencies and other documents that analyze key regulatory issues. For example, the India Office is comparing regulations from the United States and India, and also developing summaries and points of contact for Indian regulatory agencies. Officials in this office said that they want to use this type of information to better understand the responsibilities and limitations of their local counterparts. However, OIP officials acknowledged a general lack of coordination with the centers and ORA regarding the development of these types of documents. The overseas officials said that they are conducting work that they consider to be valuable to the centers and ORA but do not yet know if this is the case. FDA officials said that they plan to obtain feedback on these documents from centers and offices once they are complete.

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### Overseas Investigators Have Conducted Inspections, Although Most Foreign Inspections Were Conducted by Domestic-Based Investigators

FDA's overseas investigators have conducted inspections of establishments producing products for the U.S. market since arriving in the overseas offices, although most inspections are still conducted by domestic investigators. The overseas investigators we spoke with estimate that they spend between 30 and 80 percent of their time on inspections. From June 16, 2009, the first date on which investigators in the China or India Office conducted an inspection,<sup>26</sup> through June 10, 2010, FDA's overseas officials—including seven investigators and a technical expert who can perform inspections—conducted a total of 48 inspections in China and India.<sup>27</sup> In comparison, during that same time period, FDA's

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<sup>26</sup>Investigators are located in the China and India Offices, but not the other overseas offices. FDA officials said the agency did not post investigators in the Latin America Office, for example, because it determined that it would make more economic and logistical sense for inspections in Latin America to be conducted by domestic-based investigators.

<sup>27</sup>FDA officials said that there may be a delay in entering inspection information in the Field Accomplishments and Compliance Tracking System. We analyzed data that were up-to-date as of June 10, 2010, and these data may not include all inspections conducted by the agency during this time period.

domestic investigators conducted a total of 132 inspections in these two countries. There is variation across product areas in the portion of inspections conducted by overseas officials. For example, the overseas investigators conducted all 13 of the inspections of food establishments in these countries, while domestic investigators conducted 120 of the 144 inspections of drug establishments. (See table 1.) FDA officials said the agency does not have a goal for how many inspections it would like the overseas investigators to conduct, but it would like to see overall increases in the number of inspections conducted in both China and India. However, we found that FDA conducted about 8 percent fewer inspections (a decrease from 196 inspections) in China and India during this time period than during the previous 12-month period—June 16, 2008, through June 15, 2009.

**Table 1: Number of Inspections Conducted by FDA and Its Overseas Offices in China and India, through June 10, 2010**

Type of inspection		China	India	Total
Food	Overseas staff	13	0	13
	Domestic staff	0	0	0
	<b>Total</b>	<b>13</b>	<b>0</b>	<b>13</b>
Drugs (human and animal)	Overseas staff	9	15	24
	Domestic staff	38	82	120
	<b>Total</b>	<b>47</b>	<b>97</b>	<b>144</b>
Medical devices and radiological health	Overseas staff	10	1	11
	Domestic staff	10	2	12
	<b>Total</b>	<b>20</b>	<b>3</b>	<b>23</b>
<b>Total</b>	<b>Overseas staff</b>	<b>32</b>	<b>16</b>	<b>48</b>
	<b>Domestic staff</b>	<b>48</b>	<b>84</b>	<b>132</b>
	<b>Total</b>	<b>80</b>	<b>100</b>	<b>180</b>

Source: GAO analysis of FDA data.

FDA officials report that having investigators located overseas allows the agency to conduct more timely inspections with greater flexibility. For example, some of these officials indicated that for domestic-based investigators, visa and other delays can result in an inspection being conducted several months after an establishment is notified of FDA's intent to conduct an inspection. For the investigators located overseas, however, inspections may be conducted within weeks of notifying an establishment. In one instance, FDA officials said an investigator in India conducted an inspection of a drug establishment on short notice that was

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needed as part of the drug approval process.<sup>28</sup> FDA officials said that establishing relationships with foreign regulatory authorities is also intended to help the agency to schedule inspections more quickly in times of crisis and to more quickly identify information about problematic products. The overseas investigators noted that being local gives them the ability to extend the length of an inspection or reschedule an inspection, which they say is difficult for ORA investigators traveling from the United States to do. Overseas investigators also told us that greater flexibility in scheduling and conducting foreign inspections may improve the quality of inspections conducted overseas.

In addition to conducting inspections, FDA's overseas investigators and other staff have been involved in preliminary investigations that may precede establishment inspections. For example, officials from one center said that the China, India, and Latin America Offices have been utilized to contact establishments that were selected by that center for inspection in order to verify certain information, such as their location. Center officials report that the overseas offices staff have been able to more readily obtain responses from the foreign establishments than domestic-based staff and that this activity has helped them improve the quality of the information they have prior to conducting inspections. Overseas officials have suggested that they could also assist other centers in a similar manner by conducting more of these investigations. Furthermore, some FDA officials, including staff stationed overseas, stated that the overseas offices could be better utilized in inspection planning. Specifically, these officials stated that the overseas offices could contribute to the process of assisting the centers in selecting establishments for inspection and provide assistance to domestic-based investigators traveling abroad.

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<sup>28</sup>FDA must approve a new drug application before the drug listed in the application can be marketed in the United States, which may include an inspection of the manufacturing establishment. The agency may also conduct periodic surveillance inspections of products already approved for marketing. In other work, we noted that the majority of foreign establishments manufacturing human drugs that were inspected in fiscal year 2009 were inspected as part of the drug approval process, rather than for ongoing surveillance. See GAO, *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](#) (Washington, D.C.: Sept. 30, 2010). Similarly, we found that 94 percent of drug manufacturing inspections conducted by overseas investigators in China and India from June 16, 2009, through June 10, 2010, were conducted as part of the drug approval process.

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## Overseas Offices Have Provided Assistance to Build the Capacity of Foreign Stakeholders, but Some Officials Raised Concerns about Potential Future Workload

FDA officials said that the agency's foreign capacity building efforts are in their early stages and the agency is planning to increase these efforts in the future. Overseas officials stated that their local presence makes it easier to arrange training on FDA regulations for foreign stakeholders and respond to their follow-up questions. Other federal agencies, such as the Foreign Agricultural Service, have partnered with the overseas offices to conduct training and invited FDA overseas officials to present at their events. FDA has indicated that many of the regulatory agencies with which the overseas offices interact are in various levels of development. For example, India recently created a new food regulatory agency and is in the process of developing regulations for the oversight of medical devices, according to India Office officials. FDA officials said that being overseas allows the agency to assist the countries in building their regulatory infrastructures. Officials from the India, China, Latin America, and Middle East Offices have engaged in activities related to helping countries develop their regulatory systems. For example, FDA's overseas officials said they have been able to provide comments to foreign regulatory counterparts on draft regulations and provide information on the U.S. regulatory system that could inform the development of these foreign systems.

The overseas offices have also helped to identify and translate FDA's policies and regulations into foreign languages, such as Spanish and Chinese. Because FDA did not have an inventory of translated materials, the China, Latin America, and Middle East Offices have been working to identify what documents have already been translated and what needs to be completed. FDA officials report that translating agency policies and regulations is valuable and integral to its overseas efforts, but also an expensive and time-consuming process. Some stakeholders also reported that they have begun to translate such documents because they could not wait for FDA to do so. Due to the resources needed to translate documents and the fact that many people—both internal and external to FDA—are eager to translate the agency's documents, overseas officials suggest that the agency needs to make strategic decisions about which documents it chooses to translate. Foreign stakeholders report that FDA's efforts related to the translation of FDA's policies and regulations have been beneficial, though it would also be useful for the agency to conduct training in conjunction with the translated documents.

FDA's overseas officials have been involved in answering queries from foreign stakeholders about FDA's regulations, and some of these officials anticipate future workload challenges as a result. For example, officials from many of the agency's overseas offices said they have fielded queries from foreign regulators and industry regarding FDA's policies and

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regulations. These queries are then coordinated with the centers to obtain technical expertise, if needed. Foreign stakeholders told us that FDA's overseas staff are more accessible and approachable than staff located in the United States. Though currently manageable, officials from the Latin America Office said they spend a significant portion of their time responding to such queries and believe that it is likely to become unmanageable as more local stakeholders learn about the office and the office's duties expand. FDA officials also said that, if pending food safety legislation is enacted,<sup>29</sup> they expect the overseas offices to receive an overwhelming number of requests for information and training on how the food safety law would impact products imported to the United States. Additionally, some center staff have expressed concerns regarding the workload generated by the overseas offices as queries received by the overseas offices are often forwarded to experts within the centers.

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## FDA Is in the Early Stages of Long-Term Strategic Planning and Has Not Developed a Long-Term Workforce Plan for the Overseas Offices

FDA planning for the overseas offices initially focused on guiding early activities and the agency is now developing a 5-year strategic plan, which it expects to complete by October 2010. FDA has not yet developed a long-term workforce plan to help ensure that it is prepared to address potential recruitment and retention challenges.

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<sup>29</sup>See, for example, Food Safety Enhancement Act of 2009, H.R. 2749, 111th Cong. (2009) and FDA Food Safety Modernization Act, S. 510, 111th Cong. (2009).



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## FDA Has Initiated Long-Term Strategic Planning for the Overseas Offices but Acknowledges Challenges Identifying Outcome-Oriented Goals and Measures and Coordinating across Offices and Centers

FDA engaged in strategic planning to guide the initial activities and priorities of the overseas offices. Prior to opening the offices, FDA developed the broad categories of activities for the overseas offices that it considered important for furthering FDA's mission to ensure the safety of imported products. In the summer and fall of 2009, after the offices opened and at the direction of OIP, each office utilized those categories of activities to develop a plan for fiscal year 2010 to describe its initial activities and short-term goals. The offices tailored the plans to reflect circumstances of the country or region in which they are located. For example, the China Office's plan included activities related to implementing FDA's memorandums of agreement with Chinese regulatory agencies. These plans remained in draft form and were not finalized. OIP officials said that these draft plans were primarily intended to help guide the initial activities of each overseas office and that they will lay the groundwork for long-term planning.

With the overseas offices now open, FDA has begun to develop a 5-year strategic plan to manage the activities of the offices. Officials said that the draft fiscal year 2010 plans and the initial experiences of the offices are helping to guide the development of a 5-year plan. Officials said that it was necessary for FDA to gain experience overseas before OIP could begin long-term planning. Rather than have each overseas office continue to complete its own strategic plan, activities and goals specific to each office will be incorporated into a single OIP-wide strategic plan. Officials stated that, as of July 2010, they were in the process of developing the 5-year plan and anticipated completing the plan by October 2010.

As part of its strategic planning, FDA is in the process of identifying a set of short-term and intermediate performance goals and measures that demonstrate overseas office contributions to long-term outcomes, though agency officials said that doing so will be a challenge. To identify goals and measures, officials said that the agency first needs to gather performance information on overseas office activities and to develop an understanding of how overseas office activities can contribute to intended agency outcomes. As part of an agencywide FDA initiative,<sup>30</sup> OIP is currently tracking information on selected overseas office activities, such as the number of inspections conducted by overseas staff. It is also

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<sup>30</sup>OIP identified measures to track and each of the overseas office selected a key office project as a part of FDA-TRACK, an FDA-wide performance management initiative that was initiated in January 2010.

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tracking each office's progress toward completing a specific project. For example, it is tracking the Middle East Office's progress planning a conference on food safety in the region. Officials stated that tracking this type of performance information will help the agency identify performance goals and measures that demonstrate how overseas office activities contribute to agency strategic goals. However, officials said that developing performance goals and measures for the overseas offices will be a challenge due to the difficulty in directly attributing contributions to long-term outcomes specifically to the activities of the offices, as they feed into the work of the centers and ORA. In addition, they said that many benefits of the offices, such as improved relationships with regulatory counterparts, will be difficult to quantify. Agency officials said that this challenge is not confined to the overseas offices, as FDA as a whole has encountered challenges identifying goals and measures that capture its performance. According to officials, while OIP intends to include a set of short-term and intermediate goals and measures in the 5-year plan, they said that these will be considered developmental and may change. Officials indicated that the establishment of baselines and targets for those measures will take additional time, and the time line for achieving meaningful targets may extend well beyond 5 years.

OIP officials have identified the coordination of overseas office activities with the centers and ORA as a management challenge and OIP is taking steps during strategic planning to align the overseas offices with the rest of the agency. The lack of coordination regarding the overseas offices' development of documents on foreign product regulation and involvement in inspection planning highlights this challenge. To help coordinate overseas office and domestic FDA activities, OIP hosted a retreat with senior staff from the centers, ORA, and Office of the Commissioner to discuss OIP's planning for the overseas offices in December 2009. After the retreat, OIP officials held follow-up meetings with center and ORA officials to obtain more information on how the offices can meet the needs of the centers and ORA. OIP officials told us that another retreat to discuss long-term planning is scheduled for October 2010. Furthermore, there are also agencywide international workgroups that provide forums to discuss FDA's international activities. OIP hosts one such group, in which OIP officials and officials who represent internationally focused programs within the centers and ORA meet monthly to discuss FDA's international

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activities, including the activities of overseas offices.<sup>31</sup> Monthly meetings have also been initiated between certain centers and overseas offices. For example, because of the volume of pharmaceuticals manufactured in India, the India Office holds monthly teleconferences with officials from the Center for Drug Evaluation and Research to help coordinate their activities. Given the diversity of agency components involved in overseeing imported products, it is important that the activities of the overseas offices are effectively coordinated with those of the rest of the agency.

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### FDA Has Not Developed a Strategic Workforce Plan to Prepare for Potential Staffing Challenges for Its Overseas Offices

FDA has not yet developed a long-term workforce plan to ensure that future overseas office staffing needs are met. As of June 2010, FDA workforce planning for the overseas offices had focused on addressing short-term staffing issues to prepare for upcoming vacancies. Given the 2-year rotations required by HHS, the first group of staff who went overseas in 2009 will have the option of returning to the United States in 2011. FDA has established procedures for overseas staff to renew their rotations and a preliminary time line for staffing possible upcoming vacancies. According to FDA's time line, staff will make their renewal decisions 9 months before the end of their 2-year rotation. The majority of staff arrived overseas in the middle of 2009 and they will therefore make their decisions around fall 2010. While FDA officials told us they expect most staff will renew their rotations, they expect some staff will return home and FDA will need to fill those positions. FDA officials acknowledge the value of a workforce plan, but do not expect to develop one until the offices have been open longer. They said a workforce plan will be more important after the agency assesses turnover from the first 2-year rotation.

FDA has already experienced challenges staffing some locations, and recruitment and retention issues associated with FDA's overseas offices necessitate advance workforce planning. Although FDA officials state that the agency was generally able to recruit staff with the desired level of experience for most overseas office locations, the agency has already encountered staffing difficulties. As of July 2010, it had one such vacancy in Mexico and four in India. Domestic FDA staff have been sent to Mexico on temporary assignments to address a staffing gap in that office and FDA

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<sup>31</sup>This workgroup is known as the International Working Group. In addition, FDA has the Globalization Steering Committee, an agencywide workgroup examining FDA's regulation of foreign products.

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plans to fill staffing gaps in the India Office through temporary assignments of less than 60 days.<sup>32</sup> Staffing the FDA offices in China, India, and Mexico may be particularly challenging as the posts are located in cities classified by the Department of State as hardship posts. Furthermore, FDA officials have expressed interest in expanding the number of overseas offices, such as the addition of new locations in Africa, Brazil, and Canada. While FDA has no finalized plans for this expansion, additional locations would necessitate recruiting additional overseas staff. Advance planning is needed as the staffing process for overseas positions is lengthy due to several factors, such as obtaining necessary security and medical clearances to work overseas. FDA officials estimate that the process for recruiting and posting future overseas staff members will take 9 months.

FDA staff and staff from other federal agencies with overseas staff have identified potential challenges associated with staffing overseas offices that could impact recruitment and retention. One potential challenge for FDA is to ensure the effective reintegration of returning staff into domestic positions. Although all returning staff are guaranteed a position at FDA, they are not guaranteed their former position.<sup>33</sup> Some overseas FDA staff with whom we spoke questioned whether their posting overseas will serve as a career enhancing opportunity and expressed uncertainty regarding their ability to obtain a desired position within FDA upon their return. Similarly, CDC staff we talked with stated that CDC has also faced these types of reintegration challenges for its overseas staff and told us that uncertainty about career implications can negatively affect recruitment for overseas positions. FDA officials indicated that they are in the process of establishing a mechanism for returning staff to be selected for appropriate positions.

Recruiting overseas office staff with language skills, which has been cited as an advantage to forming relationships, may be a challenge in the future. Although not a requirement for FDA's overseas staff, all staff members in the Latin America Office and some members of the China, India, and Middle East Offices have local language skills. In the case of the Latin America Office, fluency in Spanish was identified by OIP as desirable,

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<sup>32</sup>FDA has limited the temporary assignments to less than 60 days overseas because the Department of State requires medical clearance for longer assignments.

<sup>33</sup>Returning ORA investigators are an exception and can assume their former positions with ORA upon their return.

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deeming language proficiency important for establishing relationships with government and industry officials in the region. Some China Office staff, along with other federal agency officials located in China, similarly stated that the ability to hold basic conversations in Mandarin is important for establishing diplomatic relationships with Chinese government officials. Although officials told us that government and industry officials in India generally speak English, FDA investigators in India stated that their being able to speak Hindi, or other local languages, can help in conducting inspections. In addition to its professional advantages, FDA and other officials said that language skills can benefit staff morale by improving their overseas living experience. However, maintaining or expanding the portion of staff with language skills would limit the pool of available candidates to staff positions overseas.

FDA also faces challenges that could affect recruitment and retention that result from certain HHS policies. For example, FDA and other HHS staff posted overseas do not receive locality pay,<sup>34</sup> though staff at certain locations may receive hardship pay, a cost of living adjustment, and other benefits.<sup>35</sup> Some staff experience an overall decrease in pay when they move overseas.<sup>36</sup> For example, four staff in the Latin America Office experienced an average decrease of about \$8,000 due to the loss of locality pay.<sup>37</sup> In addition, FDA staff near retirement age may be especially averse to accept or renew overseas positions because the lack of locality pay can affect retirement compensation and other overseas salary adjustments are not included in retirement calculations.<sup>38</sup> This could particularly pose

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<sup>34</sup>Locality pay is a supplement to the rate of basic pay that is provided to federal employees within given localities in the continental United States to offset any gap between federal and nonfederal salaries. According to FDA officials, HHS has the authority to provide locality pay to overseas staff and is currently in the process of examining whether to do so.

<sup>35</sup>A cost of living adjustment is provided to federal employees posted at overseas locations where the cost of goods and services is more expensive, relative to Washington, D.C. In addition, FDA staff posted at overseas locations receive benefits that are not provided to domestic staff, such as subsidized housing and reimbursed private education for staff members' school age children.

<sup>36</sup>Some staff experience an increase in pay when they go overseas.

<sup>37</sup>The decrease in salary for the four Latin America Office staff ranged from about \$600 to \$18,900. For one of these staff, FDA helped offset the loss of locality pay by approving the staff member for a student loan repayment program that provided \$10,000 to pay back student loans.

<sup>38</sup>The retirement compensation for federal employees is calculated, in part, upon the highest average pay—inclusive of locality pay—earned during any 3 consecutive years of service, which is typically the last 3 years of employment.

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recruitment problems given FDA's intent to staff the offices with experienced FDA personnel.

In addition, the HHS policy of 2-year staff rotations places a premium on staff retention and staff being trained and prepared when they arrive overseas. FDA and other officials generally estimated that it takes from 6 months to a year for incoming overseas office staff to adapt to, and become effective in, their new positions. Moreover, staff may need time to establish functional working relationships with regulatory counterparts and industry officials. Other federal agencies, such as the Foreign Agricultural Service, have cited benefits from maintaining minimum overseas posting commitments of 3 and 4 years, such as increased staff effectiveness and reduced relocation costs. FDA and CDC officials have each noted that minimum posting commitments in excess of 2 years could negatively affect recruitment for overseas positions and that a 2-year commitment provides the agency with flexibility if an employee has performance problems. However, the effectiveness of the overseas offices could be adversely affected if too many staff leave after their first 2-year rotation.

In addition to U.S. nationals, FDA also has to ensure it is able to recruit and retain locally employed staff in its overseas offices. As of July 2010, FDA had two overseas office vacancies for locally employed staff. FDA overseas staff told us that such staff provide valuable contributions toward the activities of the offices. For example, they have helped overseas staff better understand local regulations, connected staff to in-country stakeholders, and, in the China Office, provided translation services. In addition, locally employed staff are not limited in their length of service and can remain in their positions for an extended period of time. Therefore, officials from other federal agencies we talked with cited the important role that such staff play in providing continuity to overseas offices as U.S. national staff return home. However, federal officials also told us that locally employed staff are difficult to retain, often because staff have skills and expertise that are in demand.

CDC, which is also an agency within HHS, has long-standing overseas offices and has engaged in workforce planning to address these types of staffing challenges. In 2007, CDC established a strategic workforce plan to help recruit staff for international positions, developed a program that trains staff for international work and temporarily assigns them overseas, and instituted an initiative to help returning staff receive consideration for domestic positions upon their return. CDC reports that the training program has helped with staff interest and preparation for overseas

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postings. FDA does not have as many staff overseas as agencies such as CDC, nor does it have a history of overseas placements. The small number of staff at each FDA overseas office means that staffing gaps can leave specific mission areas unaddressed. For example, an office may have one staff member dedicated to pharmaceutical products, so a vacancy in that position could create a gap in that specific product area.

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## Conclusions

The opening of FDA's overseas offices represents a significant change for the agency as it attempts to respond to the needs of globalization. Although it is still early and the impact of the overseas offices on the safety of imported products is not yet clear, overseas FDA staff, domestic FDA staff, and foreign stakeholders have pointed to several immediate benefits. The offices have initially focused their efforts on cultivating relationships with foreign stakeholders, and they plan to continue working to strengthen FDA's efforts in building foreign capacity and gathering information about regulated products. The offices have also been used to inspect facilities that are exporting food and medical products to the United States, although their impact on the agency's overall number of foreign inspections may be minimal as most inspections are still conducted by domestic staff.

As we previously recommended for the agency overall, strategic planning will be important to ensure the overseas offices are able to effectively execute their mission. The agency's efforts to begin long-term strategic planning and identify initial goals and measures are a positive first step. The variety of potential activities that the overseas offices could perform and an already mounting workload make it necessary that FDA continue to engage in strategic planning to identify those activities most important to ensuring the safety of imported products. While identifying goals and measures that demonstrate overseas office contributions to long-term outcomes will be a challenge, continuing such planning will be critical for FDA to assess the extent to which the overseas offices are helping to ensure the safety of imported products. Given the variety of other FDA centers and offices that have responsibilities related to imported products, it will also be important that planning efforts ensure the activities of the overseas offices are effectively integrated with the centers and offices.

FDA reported that it has generally been successful in hiring qualified staff for the overseas offices, but without a comprehensive workforce plan, the agency has little assurance that it will be equipped to address future staffing challenges. Overseas assignments are new to the agency and staffing gaps overseas could leave specific mission areas, such as food or

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medical devices, unaddressed. As current staff rotate out of their positions and return to the United States, such a plan could ensure that a well-qualified pool of applicants, who possess diplomatic and, in some cases, language skills, are on hand to replace them. This planning could also make sure that FDA is able to attract and retain a talented pool of locally employed staff who can provide continuity to the operation of the offices. A strategic approach to workforce planning could also help FDA develop a strategy to reintegrate returning overseas staff into the agency's domestic operations. Such efforts could encourage overseas staff to extend their 2-year commitment and alleviate concerns about what will happen to their careers once they complete their tour of duty at overseas posts. Without a comprehensive, strategic approach to workforce planning, there is little assurance that FDA will be able to place the right people in the right positions at the right time.

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## Recommendations for Executive Action

To help ensure that FDA's overseas offices are able to fully meet their mission of helping to ensure the safety of imported products, we recommend that the Commissioner of FDA take the following two actions:

- Ensure, as it completes its strategic planning process for the overseas offices, that it develops a set of performance goals and measures that can be used to demonstrate overseas office contributions to long-term outcomes related to the regulation of imported products and that overseas office activities are coordinated with the centers and ORA.
- Develop a strategic workforce plan for the overseas offices to help ensure that the agency is able to recruit and retain staff with the experience and skills necessary for the overseas offices and to reintegrate returning overseas staff into FDA's domestic operations.

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## Agency Comments and Our Evaluation

We provided a draft of this report to HHS for review, and HHS provided written comments, which are reprinted in appendix III. In its comments, HHS noted that FDA concurred with our recommendations and stated that they would help strengthen the agency's efforts. HHS said that FDA has already begun a long-term strategic planning process. HHS also indicated that, now that FDA's overseas offices are staffed and functioning, the agency will begin a workforce planning process. In addition, HHS emphasized that FDA's collaboration with its foreign regulatory counterparts and other stakeholders has become critical to the agency's ability to fulfill its mission of overseeing the safety of food and medical products. HHS stressed that strong, well-developed, and well-maintained



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in-country relationships are required to accomplish this mission and pointed out that the establishment of the overseas offices is one major way in which FDA can strengthen its relationships and better coordinate with foreign stakeholders. HHS's comments also cited FDA's accomplishments since the overseas offices have opened and highlighted several challenges that the agency faces as it moves forward, including how to best focus overseas office interactions with regulatory counterparts, share information gathered by the overseas offices with the rest of the agency, and manage its overseas investigators. HHS also provided us with technical comments, which we incorporated as appropriate.

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As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies to the appropriate congressional committees, the Commissioner of the Food and Drug Administration, and other interested parties. The report also will be available at no charge on the GAO Web site at <http://www.gao.gov>.

If you or your staff have any questions about this report, please contact Marcia Crosse at (202) 512-7114 or [crossem@gao.gov](mailto:crossem@gao.gov) or Lisa Shames at (202) 512-3841 or [shamesl@gao.gov](mailto:shamesl@gao.gov). Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix IV.



Marcia Crosse  
Director, Health Care



Lisa Shames  
Director, Natural Resources and Environment

# Appendix I: U.S. Agencies and Other Stakeholders Interviewed during Site Visits

Table 2 lists the federal agencies and other stakeholders we met with during site visits to Beijing, Guangzhou, and Shanghai, China; San Jose, Costa Rica; and New Delhi and Mumbai, India.

**Table 2: U.S. Agencies and Other Stakeholders Interviewed during Site Visits**

Location	U.S. government agency	Other stakeholders
China		
Beijing	<ul style="list-style-type: none"> <li>Centers for Disease Control and Prevention, Department of Health and Human Services (HHS)</li> <li>Economic Section, Department of State</li> <li>Environment, Science, Technology, and Health Section, Department of State</li> <li>Foreign Agricultural Service, U.S. Department of Agriculture (USDA)</li> <li>Foreign Commercial Service, Department of Commerce</li> <li>Immigration and Customs Enforcement, Department of Homeland Security (DHS)</li> <li>National Institutes of Health, HHS</li> <li>Office of the U.S. Trade Representative</li> <li>Public Affairs Section, Department of State</li> </ul>	<ul style="list-style-type: none"> <li>American Chamber of Commerce China</li> <li>China Quality Association for Pharmaceuticals</li> <li>Covington &amp; Burling, LLP</li> <li>GE Healthcare</li> <li>General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China</li> <li>Natural Products Association</li> <li>Peking University</li> <li>R&amp;D Based Pharmaceutical Association Committee</li> <li>State Food and Drug Administration</li> <li>World Health Organization</li> </ul>
Guangzhou	<ul style="list-style-type: none"> <li>Agricultural Trade Office, USDA</li> <li>Economic/Political Section, Department of State</li> <li>Foreign Commercial Service, Department of Commerce</li> <li>Immigration and Customs Enforcement, DHS</li> <li>U.S. Patent and Trademark Office, Department of Commerce</li> </ul>	<ul style="list-style-type: none"> <li>American Chamber of Commerce in South China</li> <li>Guangzhou Luxe Seafood Enterprises, LTD</li> <li>Guangdong Food and Drug Administration</li> </ul>
Shanghai	<ul style="list-style-type: none"> <li>Agricultural Trade Office, USDA</li> <li>Foreign Commercial Service, Department of Commerce</li> </ul>	<ul style="list-style-type: none"> <li>American Chamber of Commerce Shanghai</li> <li>AstraZeneca</li> <li>BD Diagnostics</li> <li>Boehringer Ingelheim</li> <li>Ecolab</li> <li>Eurofins Technology Service</li> <li>General Mills</li> <li>Keller and Heckman, LLP</li> <li>Shanghai Pudong Medical Device Trade Association</li> <li>Shanghai Food and Drug Administration</li> <li>United States Pharmacopeia</li> <li>WuXi AppTec Co., Ltd.</li> <li>Yum! Brands</li> </ul>

**Appendix I: U.S. Agencies and Other Stakeholders Interviewed during Site Visits**

<b>Location</b>	<b>U.S. government agency</b>	<b>Other stakeholders</b>
<b>Costa Rica</b>		
San Jose	<ul style="list-style-type: none"> <li>• Animal and Plant Health Inspection Service, USDA</li> <li>• Drug Enforcement Agency, Department of Justice (DOJ)</li> <li>• Foreign Agricultural Service, USDA</li> <li>• Foreign Commercial Service, Department of Commerce</li> </ul>	<ul style="list-style-type: none"> <li>• Camara Costarricense de la Industria Alimentaria</li> <li>• Instituto Interamericano de Cooperación para la Agricultura</li> <li>• La Federación Centroamericana de Laboratorios</li> <li>• Ministerio de Comercio Exterior</li> <li>• Ministerio de Salud</li> <li>• Servicio Nacional de Salud Animal</li> </ul>
<b>India</b>		
New Delhi	<ul style="list-style-type: none"> <li>• Centers for Disease Control and Prevention, HHS</li> <li>• Drug Enforcement Agency, DOJ</li> <li>• Foreign Agricultural Service, USDA</li> <li>• U.S. Agency for International Development</li> </ul>	<ul style="list-style-type: none"> <li>• Agricultural and Processed Food Products Export Development Authority</li> <li>• Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy, Ministry of Health and Family Welfare</li> <li>• Central Drugs Standard Control Organization (CDSCO)</li> <li>• Confederation of Indian Industry</li> <li>• Federation of Indian Chambers of Commerce and Industry</li> <li>• Food Safety and Standards Authority of India</li> </ul>
Mumbai		<ul style="list-style-type: none"> <li>• CDSCO West Zone</li> <li>• Cipla Limited</li> <li>• Drug Information Association</li> <li>• Food and Drug Administration Maharashtra State</li> <li>• Laxmi Enterprises</li> <li>• Spices Board, Ministry of Commerce and Industry</li> </ul>

Source: GAO.

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# Appendix II: Overview of FDA's Overseas Offices

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This appendix describes the purpose, planning and development, and locations and staffing of the Food and Drug Administration's (FDA) overseas offices.

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## Purpose of FDA's Overseas Offices

The posting of staff in FDA's overseas locations is a key part of the agency's strategy for expanding its oversight of imported food and medical products. Products regulated by FDA are manufactured in countries throughout the world, although there is significant variation in the types of products coming from different regions. From fiscal year 1998 to fiscal year 2008, the volume of FDA-regulated imported products more than tripled from less than 5 million import entry lines to more than 17 million import entry lines.<sup>1</sup> These imported products arrive from about 200 countries. According to the U.S. Department of Agriculture's (USDA) Economic Research Service, the growing presence of imported foods reflects various trends: seasonal demands for produce from warm-weather regions; rising consumer demand for ethnic food, beverages, and spices; integration of nontraditional regions into global supply chains; and falling agricultural trade barriers. Based on USDA data, imported food comprises 15 percent of the U.S. food supply, including 60 percent of fresh fruits and vegetables and 80 percent of seafood. Likewise, the pharmaceutical industry has increasingly relied on global supply chains in which each manufacturing step may be outsourced to foreign establishments. According to FDA, the number of drug products manufactured at foreign establishments has more than doubled since 2002, with China and India accounting for the greatest shares of this growth.

FDA has acknowledged that globalization has fundamentally changed the environment for regulating food and medical products and created unique regulatory challenges for the agency. The increasing number of foreign establishments precludes FDA from being in a position to inspect them all to ensure the safety of all imported products. We have previously recommended that FDA conduct more inspections of foreign drug establishments and FDA has agreed that it should do so.<sup>2</sup> However, agency officials have emphasized that a variety of strategies are necessary to ensure the safety of imported products and that conducting inspections is

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<sup>1</sup>An entry line is each portion of an import shipment that is listed as a separate item on an entry document. Items in an import entry having different tariff descriptions or FDA product codes must be listed separately.

<sup>2</sup>See [GAO-08-970](#), p. 43.

one of multiple approaches it is taking.<sup>3</sup> In establishing the overseas offices, FDA recognized that gathering information to make decisions and building the technical capacity of foreign counterparts, with the goal of improving their regulatory systems, was especially important for ensuring the safety of imported products.

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## Planning and Development

Initial planning and development of the overseas offices was led by the Office of the Commissioner, in consultation with internal and external federal stakeholders. An FDA official involved in early planning said that the Office of International Programs (OIP) collaborated with center and ORA officials in various ways, such as through senior leadership meetings and one-on-one meetings. In addition, OIP held regular FDA-wide teleconferences to update staff on the progress and activities of the overseas offices. FDA officials said their planning was aided by advice they sought from certain federal departments and agencies with staff located overseas. For example, FDA obtained advice on budgeting from the Centers for Disease Control and Prevention (CDC) and USDA's Foreign Agricultural Service. In addition, CDC and the Department of State were both helpful in walking FDA through the process of establishing the overseas offices.

FDA initially identified several broad categories of activities in which the overseas offices would engage. FDA officials indicated that these activities would serve as the initial focus for the offices and could be refined as the agency gains experience overseas, although they have not yet changed substantially. These activities included (1) establishing relationships with U.S. agencies located overseas and foreign stakeholders, including regulatory counterparts and industry; (2) gathering better information locally on product manufacturing and transport to U.S. ports;

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<sup>3</sup>The cost of these approaches varies. For example, in fiscal year 2009, FDA budgeted \$29.9 million for the overseas offices. FDA also indicated that the Office of Regulatory Affairs (ORA), which conducts inspections, had average inspections costs of \$22,100 for food establishments, \$30,300 for medical device and radiological health establishments, \$41,700 for animal drug establishments, \$53,000 for human drug establishments, and \$63,600 for biologic establishments. Based on these average costs, we calculated that, in that year, if ORA had dedicated \$29.9 million to conducting overseas inspections, it may have been able to inspect an additional 470 to 1353 establishments, depending on the type of establishments inspected. The estimates do not include some costs—including those for translation and security services, the FDA centers' costs for reviewing foreign inspection reports and related compliance activities, the Office of International Programs overseas office related costs, and the Office of Commissioner overhead.

(3) improving FDA's capacity to conduct foreign inspections; and  
(4) providing assistance to help build the capacity of counterpart agencies to better assure the safety of the products manufactured and exported from their countries. FDA described how these activities are intended to enhance the decisions the agency makes about imported products:

- Establishing relationships with foreign stakeholders, including regulatory counterparts and industry, is intended to help them better understand U.S. regulatory requirements and help FDA better understand the regulatory and business practices of other countries, with the ultimate goal of improving the quality of imported products manufactured in these countries. Collaborating with other federal agencies, such as CDC, that are located overseas and have complementary missions allows the agencies to coordinate activities and share information on product quality and safety issues.
- Routinely gathering information on a wide variety of potential factors, such as weather events and key changes among foreign regulatory counterpart agencies, is intended to help FDA identify potential problems and respond more quickly to developing problems.
- Improving its capacity to conduct foreign inspections will enable FDA to more rapidly obtain information regarding whether foreign establishments comply with FDA requirements.
- Providing capacity building to foreign stakeholders and leveraging the resources of other international organizations, is intended to build the technical capacity of foreign counterparts, with the goal of improving the regulatory systems in these countries to ensure the safety of products exported to the United States.

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## Locations and Staffing

FDA's selection of locations for the overseas offices was influenced by characteristics relevant to product regulation. Most overseas offices are in regions or countries that export a significant percentage of the total volume of products to the United States. The Middle East Office was identified as an area from which the volume of imported products is expected to rise. The goals of the Middle East Office are to increase knowledge about the region by working with FDA's counterpart agencies and to identify opportunities for capacity building. The offices are also generally located in regions that FDA described as having regulatory systems less mature than FDA's. The agency indicated that it intended to work with regulators in these regions to help strengthen their capacity. For example, FDA officials indicated that the Indian government is in the

process of making significant changes to its food and drug regulatory systems and has specifically requested FDA's help with the implementation of its new system. FDA also sought to work with local industry in these locations to ensure that products that are manufactured or processed from this region and exported to the United States meet U.S. standards of quality and safety. In contrast, FDA selected Europe to provide an opportunity for the agency to further partner with a mature regulatory system. Therefore, the Europe Office has staff in the U.S. mission to the European Union, in Brussels, Belgium, to engage with the European Commission and staff members embedded within the European Medicines Agency and the European Food Safety Authority so that FDA can further leverage its preexisting relationships with those regulators.<sup>4</sup> Other issues also factored into FDA's selection of certain locations. For example, FDA also selected China and Latin America because they were the source of recent problematic products, such as contaminated heparin and produce.

FDA officials stressed the importance of staffing the overseas offices with experienced personnel who would be equipped to represent the agency and speak on its behalf in the foreign country. The number and type of staff assigned to each office varies, depending on the office priorities and the kinds of products, such as food, drugs, or medical devices, most commonly imported from the country or region. Each office has a director to whom all staff members in that country or region report, and technical experts, who are responsible for engaging with foreign stakeholders and gathering information in the area of food, medical products, or both. FDA placed investigators in Mumbai, India and Guangzhou and Shanghai, China, in part to ensure that investigators could reach establishments more quickly when necessary. According to FDA, having investigators in these countries will also allow the agency to more rapidly inspect manufacturing and processing facilities that are producing goods destined for the United States. FDA elected not to position investigators in Latin America because it determined that U.S.-based investigators are able to more easily travel and gain access to establishments in that region. Overseas office investigators perform inspections and also engage in information gathering and capacity building. The India, China, and Latin America Offices have hired locally employed staff with technical expertise

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<sup>4</sup>As part of the agreement between FDA and European officials, the European Medicines Agency and the European Food Safety Authority also have staff embedded within FDA in the United States.

**Appendix II: Overview of FDA's Overseas Offices**

regarding regulated products as well as locally employed staff to perform administrative functions.<sup>5</sup> Table 3 shows the number of FDA staff currently working in overseas locations as of July 2010.

**Table 3: Number of FDA Staff Currently Working in Overseas Locations, as of July 2010**

Location	Country or regional director	Technical experts	Food investigators	Medical product investigators	Locally employed staff	Total
China						
Beijing	1	3	0	0	2	6
Guangzhou	0	0	2	0	1	3
Shanghai	0	0	0	2	2	4
Europe						
Brussels, Belgium	1	0	0	0	0	1
London, England	0	1	0	0	0	1
Parma, Italy <sup>a</sup>	0	0	0	0	0	0
India						
New Delhi	1	4	0	0	2	7
Mumbai	0	0	0	3	1	4
Latin America						
San Jose, Costa Rica	1	3	0	0	2	6
Mexico City, Mexico	0	1	0	0	2	3
Santiago, Chile	0	1	0	0	2	3
<b>Total<sup>b</sup></b>	<b>4</b>	<b>13</b>	<b>2</b>	<b>5</b>	<b>14</b>	<b>38</b>

Source: GAO analysis of FDA data.

<sup>a</sup>FDA has hired a technical expert who has not yet posted to the agency's office located in Parma, Italy.

<sup>b</sup>The Middle East Office has not yet opened overseas, but a Regional Director and two technical experts have been hired and are located in the United States.

Some of the overseas offices were not fully staffed at the time that they opened. Table 4 shows the dates that the FDA staff arrived at each of the overseas locations.

<sup>5</sup>Locally employed staff are foreign nationals and other locally employed residents (including U.S. citizens) who are legally eligible to work at U.S. missions abroad.



**Table 4: Dates That Overseas Staff Arrived on Site**

<b>Office</b>	<b>Arrival of first staff</b>	<b>Arrival of additional staff</b>
<b>China</b>		
Beijing	November 2008	May 2009 to July 2009
Guangzhou	July 2009	N/A
Shanghai	May 2009	June 2009
<b>Europe</b>		
Brussels, Belgium	May 2009	N/A
London, England	June 2009	N/A
Parma, Italy <sup>a</sup>	N/A	N/A
<b>India</b>		
New Delhi	November 2008	June 2009 to August 2009
Mumbai	June 2009	July 2009 to January 2010
<b>Latin America</b>		
San Jose, Costa Rica	April 2009	August 2009
Mexico City, Mexico	February 2010	N/A
Santiago, Chile	August 2009	N/A
<b>Middle East</b>		
Office location(s) not yet determined		

Source: GAO analysis of FDA data.

<sup>a</sup>FDA has hired a technical expert who has not yet posted to the agency's office located in Parma, Italy.

As of July 2010, the Latin America Office and the India Office had two vacancies each for technical experts, and the India Office also had two food investigator vacancies. Two of the offices also had vacancies for locally employed staff. In addition, the Middle East Office had one vacancy for a medical product investigator and three vacancies for locally employed staff that the agency plans to fill once the office is located overseas.

# Appendix III: Comments from the Department of Health and Human Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation  
Washington, DC 20201

SEP 09 2010

Marcia Crosse  
Director, Health Care  
U.S. Government Accountability Office  
441 G Street N.W.  
Washington, DC 20548

Dear Ms. Crosse:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled: "Food and Drug Administration Overseas Offices have Taken Steps To Help Ensure Import Safety, But Long-Term Planning Is Needed" (GAO-10-960).

The Department appreciates the opportunity to review this report before its publication.

Sincerely,

Jim Esquea  
Assistant Secretary for Legislation

Attachment

**GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED, "FOOD AND DRUG ADMINISTRATION: OVERSEAS OFFICES HAVE TAKEN STEPS TO HELP ENSURE IMPORT SAFETY, BUT LONG-TERM PLANNING IS NEEDED" (GAO-10-960)**

The Department appreciates the opportunity to comment on the GAO's findings in this draft report. HHS and FDA appreciate GAO's recognition of the progress FDA has made standing up its overseas offices, and look forward to using the report to further strengthen these efforts.

Annually, the United States imports more than \$2 billion worth of FDA-regulated products from roughly 200 countries or territories, using almost 100,000 importers, through over 300 U.S. ports-of-entry. According to the Operational and Administrative System for Import Support (OASIS), last year, there were 20 million line entries of FDA-regulated product that crossed our borders; ten years ago, there were just 6 million. That's around 100,000 shipments each working day that cross our borders. These shipments included 40 percent of our finished drugs, 80 percent of our active pharmaceutical ingredients, the majority of our seafood, and large quantities of the fresh fruits and vegetables in our supermarkets.

The globalization of the production and manufacture of these products presents consumers, practitioners, regulators, and companies with many challenges. These challenges are consuming an ever larger amount of FDA's time and effort, and they have fundamentally changed the environment for regulating food and medical products.

Some of these unique regulatory challenges for FDA include:

- More "non-traditional" foreign facilities and clinical trials sites supplying pivotal data;
- An ever-increasing volume of imported products and data, even with the recent turndown in the global economy;
- Greater complexity in supply chains and clinical trials;
- Imports of products and data coming from countries with less well resourced and less well developed regulatory systems;
- Less clarity on accountability by both regulators and industry during various segments of a product's movement through its global supply chain; and
- Greater opportunities for economic fraud.

Within the context of its domestic mission, FDA is increasingly assuming the role of a global public health agency and is a significant leader in the larger global regulatory and scientific enterprises that affect the products for which we are responsible in the United States. Today, FDA is responsible for the oversight of tens of millions of foreign shipments every year, and ensuring public health at home now mandates that we continue to engage ever more strategically abroad. As FDA expands its engagements within the international community and as it works to implement standards and oversight that help protect the safety of food and medical products at home and abroad, collaboration with counterparts and other stakeholders within the global regulatory and scientific enterprises has become critical to fulfilling our public health mission. International engagement is

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no longer a discretionary component of FDA's activities; it is a fundamental component of how the Agency fulfills its mission.

One major way in which FDA is strengthening and better coordinating its international engagements is by establishing permanent FDA posts abroad in strategic locations. These initial posts are now staffed with experienced senior FDA technical experts and inspectors. The process of "standing up" these posts began approximately 22 months ago. It was a new undertaking for FDA, as the Agency had never previously had its staff permanently assigned overseas.

The report documents the many accomplishments that the Agency has made since that decision to establish FDA overseas posts.

These accomplishments include:

- Selecting sites and identifying goals for the overseas offices;
- Hiring of staff;
- Deploying 42 staff members (and their families) to the various foreign posts;
- Establishing secure IT communications between deployed staff and headquarters;
- Obtaining and communicating information that is contributing to the Agency's decision-making to improve the safety and quality of imported products;
- Providing technical cooperation to help further build the capacity of certain foreign regulatory authorities to undergird efforts to help their countries produce safe products for export to the United States and produce safer products for their own citizens;
- Developing first year strategic plans for each office; and
- Developing SOPs for administrative handling of the first cycle of renewals of overseas appointments.

We want to highlight, and concur strongly with, the report's discussion of the importance of and the challenges associated with building personal and organizational relationships in foreign locations. For many years, the Agency has had very good knowledge of regulatory structures and contacts in the countries with which we had regular interaction, including many of those in which we now have offices. We believe the new foreign posts have provided a much richer context for a more dynamic relationship with our counterpart agencies in those countries, and the report highlights the benefits that such day-to-day interaction provides to the Agency.

For FDA, these strong personal and organizational relationships lead to the trust that is necessary to enable the discussions and promote the information exchanges that are pivotal in preventing and, when necessary, responding to product safety problems. Through these engagements, FDA personnel located in foreign posts can obtain and transmit more robust and timely information to FDA's Centers and border personnel so

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that they can make better decisions about the safety and quality of the products they allow to be imported into the United States. Being able to accomplish that mission requires having strong, well-developed, and well-maintained in-country relationships at multiple levels.

*FDA's Response to GAO Recommendations*

GAO recommends that the U.S. Commissioner of Food and Drugs take steps to enhance long-term strategic planning to ensure coordination between overseas and domestic activities and develop a workforce plan to help recruit and retain overseas staff.

FDA concurs with these recommendations and, as the report notes, already has begun a long-term strategic planning process as part of a broader FDA initiative. Now that the overseas posts are staffed and functioning, OIP will initiate a workforce planning process. As noted in the report, FDA recognizes that this process will be iterative and will benefit from the experience of several cycles of overseas staff appointments (deployment and return). Although FDA has a very small number of overseas staff compared to the Centers for Disease Control (CDC), FDA looks forward to benefiting from the experience of CDC's established efforts in workforce planning for its international assignments as we proceed with this undertaking.

FDA also notes that we are supporting our strategic planning efforts by employing the FDA-TRACK performance management initiative to identify and track performance indicators and milestones for key program activities. The transparency of this management process contributes to the coordination of our overseas and domestic activities.

There are additional challenges that OIP and FDA face, and opportunities we must pursue:

In China, we had a challenge identifying our responsible Chinese regulatory counterpart when the first melamine contamination issue arose. The overriding problem was that, early in the crisis, the Chinese authorities themselves did not know readily whether the issue would fall under their regulatory, criminal, or other state function. Until the Chinese clarified who would be leading their government's response, FDA interacted with its routine counterparts and, through them, was informed how the Chinese government planned to manage the situation.

Similarly, the India Office staff has now come to understand the complexities of the Indian regulatory system, and it has enabled FDA to stay abreast of and, when requested, to engage with Indian regulators regarding their system and the reform currently underway. In short, the establishment of the foreign posts has significantly enhanced our knowledge of other countries' regulatory structures and has allowed for the development

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of the kinds of relationships that now benefit FDA, especially when public health crises with FDA-regulated products arise, and as those countries develop and enhance their regulatory programs.

Another challenge that presents opportunity is how to focus our interactions with our counterpart agencies through international arrangements we have with them. These arrangements can take various forms, depending on the need and the issues to be addressed. For example, the HHS 2007 agreements with Chinese regulators were signed at the Departmental level. More typically, the Agency itself negotiates and signs our arrangements with counterparts on an agency-to-agency basis. They include confidentiality commitments and product specific arrangements and are used on a daily basis to help facilitate FDA's public health work with other countries. In addition, FDA has developed "implementation plans" and other documents to help better define and focus FDA's engagements with our regulatory counterparts. FDA is currently exploring with its Indian and other counterparts whether such documents would help facilitate and focus interactions.

Additionally, our foreign offices face how best to provide information to the rest of FDA and assure OIP efforts add value to the Agency. As one approach to meeting this challenge, we are currently developing prototypes of "analytical papers" on specific in-country topics for use by the Agency's centers and ORA. Once the Centers and ORA comment on these prototypes, we can better assess their usefulness and determine how best to implement this approach. OIP can then produce analytical papers on the topics that the Centers and ORA have already identified as potentially useful.

The foreign offices also produce environmental scanning reports (i.e., weekly reports from foreign posts regarding in-country events that might affect the safety, quality, or availability of FDA-regulated products from their respective regions). These reports have been the genesis of FDA public health actions, and, in order to enhance their use by the Agency, OIP has developed a searchable electronic database in which this information is now housed, and, in the near future, Agency officials will have access to this database and will be able to use the information both in acute situations and for longer term programmatic and operational planning. At present, we provide information from the database through weekly electronic OIP reports. OIP expects a continuing need to refine these reports and continually enhance the other ways we engage with and communicate the information we gather to ORA and the Centers.

Another challenge is how our in-country inspectors will use their time. Inspectors can, for example, conduct establishment and facility inspections, participate in training workshops for and interact with local inspectors, learn more about the abilities and practices of the local inspectorates to help determine how much FDA could leverage the information they provide, and participate in conferences to help educate various stakeholders in-country about FDA requirements and expectations regarding the safety

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and quality of products destined for U.S. consumers. The mix for an inspector in any given country at any given time will vary and be driven by the conditions in that country at that time. Our challenge will be to choose the mix that maximally enhances the safety of products destined for the United States.

GAO's observations and recommendations will help us meet these challenges as we move forward in implementing this new, and now fundamental, part of FDA's organization and work program.

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# Appendix IV: GAO Contacts and Staff Acknowledgments

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## GAO Contacts

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Lisa Shames at (202) 512-3841 or [shamesl@gao.gov](mailto:shamesl@gao.gov)

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## Staff Acknowledgments

In addition to the contact name above, Jose Alfredo Gómez, Assistant Director; Geraldine Redican-Bigott, Assistant Director; Kevin Bray; Michael Erhardt; William Hadley; Cathleen Hamann; Rebecca Hendrickson; Julian Klazkin; Deborah Ortega; and Michael Rose made key contributions to this report.



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# Related GAO Products

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## FDA—High Risk Reports

*High-Risk Series: An Update.* [GAO-09-271](#). Washington, D.C.: January 22, 2009.

*High-Risk Series: An Update.* [GAO-07-310](#). Washington, D.C.: January 31, 2007.

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## FDA—Food Production and Medical Product Oversight

*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](#). Washington, D.C.: September 30, 2010.

*Food Safety: FDA Could Strengthen Oversight of Imported Food by Improving Enforcement and Seeking Additional Authorities.* [GAO-10-699T](#). Washington, D.C.: May 6, 2010.

*Food and Drug Administration: Opportunities Exist to Better Address Management Challenges.* [GAO-10-279](#). Washington, D.C.: February 19, 2010.

*Food Safety: Agencies Need to Address Gaps in Enforcement and Collaboration to Enhance Safety of Imported Food.* [GAO-09-873](#). Washington, D.C.: September 15, 2009.

*Food and Drug Administration: FDA Faces Challenges Meeting Its Growing Medical Product Responsibilities and Should Develop Complete Estimates of Its Resource Needs.* [GAO-09-581](#). Washington, D.C.: June 19, 2009.

*Seafood Fraud: FDA Program Changes and Better Collaboration among Key Federal Agencies Could Improve Detection and Prevention.* [GAO-09-258](#). Washington, D.C.: February 19, 2009.

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