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December 2016

# DRUG SAFETY

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

# GAO Highlights

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

## Why GAO Did This Study

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

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

## What GAO Recommends

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

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

December 2016

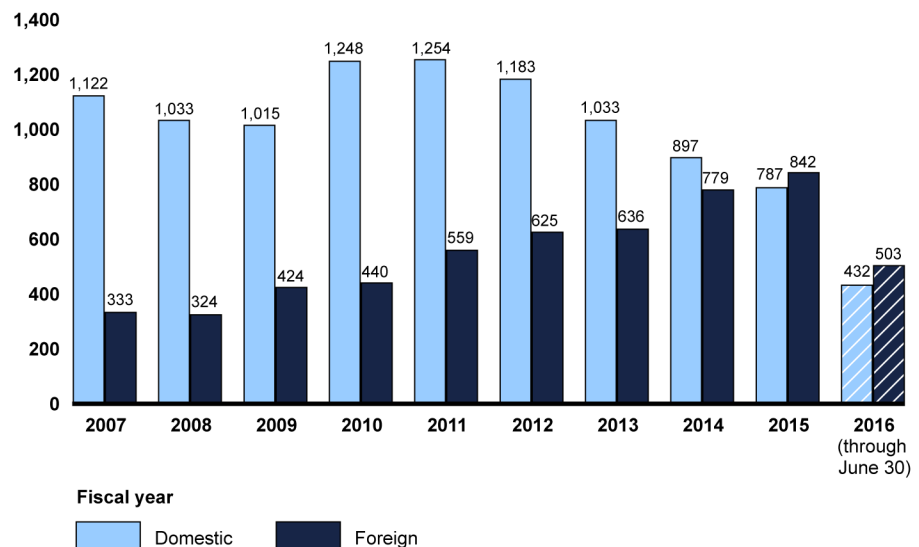
## DRUG SAFETY

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

## What GAO Found

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

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



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

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

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## Abbreviations

API	active pharmaceutical ingredient
CDER	Center for Drug Evaluation and Research
CGMP	current good manufacturing practice
D-U-N-S®	Data Universal Numbering System
eDRLS	electronic Drug Registration and Listing System
FACTS	Field Accomplishments and Compliance Tracking System
FDA	Food and Drug Administration
FDASIA	Food and Drug Administration Safety and Innovation Act
GDUFA	Generic Drug User Fee Amendments Act
HHS	Department of Health and Human Services
OIP	Office of International Programs
ORA	Office of Regulatory Affairs

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December 16, 2016

The Honorable Fred Upton  
Chairman  
The Honorable Frank Pallone Jr.  
Ranking Member  
Committee on Energy and Commerce  
House of Representatives

The Honorable Tim Murphy  
Chairman  
The Honorable Diana DeGette  
Ranking Member  
Subcommittee on Oversight and Investigations  
Committee on Energy and Commerce  
House of Representatives

Oversight of the nation's drug supply chain has become increasingly complicated for the Food and Drug Administration (FDA), an agency within the Department of Health and Human Services (HHS). Much of the U.S. drug supply is manufactured overseas. FDA estimates that nearly 40 percent of finished drugs and approximately 80 percent of active pharmaceutical ingredients (API) are manufactured in registered establishments in more than 150 countries; yet, the agency is responsible for overseeing the safety and effectiveness of all drugs marketed in the United States, regardless of where they are produced.<sup>1</sup> As testing a drug at the border cannot reliably determine whether drugs were manufactured in compliance with current good manufacturing practice (CGMP) regulations, FDA conducts several types of inspections of establishments that manufacture drugs for the U.S. market.<sup>2</sup> FDA began opening offices

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<sup>1</sup>Drugs are defined to include, among other things, articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, and include components of those articles. 21 U.S.C. §§ 321(g)(1)(B), (D). An API is any component that is intended to provide pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease. In this report, we refer both to drug products—drugs in their finished dosage forms—and to APIs as “drugs.” Establishments marketing their products in the United States are required to register annually with FDA.

<sup>2</sup>CGMPs provide for systems that assure proper design, monitoring, and control of manufacturing processes and facilities. See 21 C.F.R. pts. 210, 211, 212 (2016). FDA defines manufacturing to include the manufacture, preparation, propagation, compounding or processing of a drug. 21 C.F.R. § 207.3(a)(8) (2016).

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around the world in 2008 to obtain better information on the increasing number of products coming into the United States from overseas, to build relationships with foreign stakeholders, and to perform inspections.

We have had long-standing concerns with FDA's role in the increasingly global pharmaceutical supply chain. In 1998, we reported that FDA had significant problems managing its foreign inspection data and conducted infrequent inspections of foreign establishments.<sup>3</sup> Ten years later, in 2008, we determined that, because of inaccurate information in FDA's databases, the agency did not know how many foreign drug establishments were subject to inspection. In addition, we found that FDA continued to inspect relatively few foreign establishments, and that most such inspections were performed in response to an application to market a new drug in the United States, rather than to assess the continued quality of drugs already on the market.<sup>4</sup> In January 2009, we added FDA's oversight of medical products (i.e., drugs and medical devices) to our High-Risk Series, citing FDA's inability to ensure the quality of medical products manufactured overseas as an area of particular concern.<sup>5</sup> Although we found that FDA was conducting more inspections of foreign establishments in 2010, we also reported that many establishments may never have been inspected.<sup>6</sup> We also identified shortcomings in the operations of the agency's foreign offices in that year and again in 2015, raising questions about their effectiveness.<sup>7</sup>

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<sup>3</sup>See GAO, *Food and Drug Administration: Improvements Needed in the Foreign Drug Inspection Program*, [GAO/HEHS-98-21](#) (Washington, D.C.: Mar. 17, 1998).

<sup>4</sup>See 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>5</sup>See GAO, *High-Risk Series: An Update*, [GAO-09-271](#) (Washington, D.C.: January 2009).

<sup>6</sup>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). For a list of related reports, see the *Related GAO Products* page at the end of this report.

<sup>7</sup>See GAO, *Food and Drug Administration: Overseas Offices Have Taken Steps to Help Ensure Import Safety, but More Long-Term Planning Is Needed*, [GAO-10-960](#) (Washington, D.C.: Sept. 30, 2010); and *Food Safety: Additional Actions Needed to Help FDA's Foreign Offices Ensure Safety of Imported Food*, [GAO-15-183](#) (Washington D.C.: Jan. 30, 2015). Our 2010 report focused on the foreign offices' efforts to help ensure the safety of imported products, such as food and medical products, while our 2015 report specifically focused on their contributions related to the safety of imported food.

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Given the persistent challenge of globalization for FDA, you asked us to provide an update on the agency's activities and accomplishments related to its foreign drug inspection program and the operations of its foreign offices. This report examines

1. the enhancements FDA has made to its foreign drug inspection program in recent years; and
2. FDA's assessment of its foreign offices, and the challenges the foreign offices face in ensuring drug safety.

To examine the enhancements FDA has made to its foreign drug inspection program in recent years, we reviewed FDA's process for prioritizing and selecting establishments for inspections, including whether it incorporated certain factors into its selection process as required in 2012 by the Food and Drug Administration Safety and Innovation Act (FDASIA).<sup>8</sup> We also interviewed FDA officials about the sources of data the agency uses in this process, including any steps FDA may have taken to improve the completeness and accuracy of its data on foreign drug establishments. Additionally, we analyzed data from FDA's Field Accomplishments and Compliance Tracking System (FACTS), which contains information on the number of the agency's establishment inspections. Specifically, we examined FACTS data from fiscal year 2010 through June 30, 2016, to determine: (1) the number of foreign and domestic inspections conducted by FDA, (2) the type of inspections, and (3) the country in which the inspections took place. We also reviewed FACTS data presented in one of our prior reports on drug manufacturing establishment inspections conducted from fiscal years 2007 to 2009.<sup>9</sup> To assess the reliability of the data from FACTS, we reviewed related documentation, interviewed knowledgeable agency officials, and compared the data to published information from the same database. On the basis of these steps, we found these data sufficiently reliable for the purposes of our reporting objectives. We also reviewed relevant documentation related to FDA's inspections of foreign drug establishments, including staffing and funding information. To learn more about FDA's foreign drug inspection program, including the agency's

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<sup>8</sup>Pub. L. No. 112-144, § 705, 126 Stat. 993, 1066 (2012) (codified in pertinent part at 21 U.S.C. § 360(h)(4)).

<sup>9</sup>[GAO-10-961](#) included information on drug manufacturing establishment inspections conducted from fiscal years 2007 to 2009. For this report, we focused on drug manufacturing establishment inspections conducted from fiscal years 2010 through June 30, 2016, which were the most recently available data at the time we did our work.



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progress toward improving its information on foreign drug establishments and changes to the agency's approach to selecting and prioritizing drug establishment inspections, we interviewed officials from the Office of Regulatory Affairs (ORA), who are responsible for conducting inspections of foreign drug establishments, and from the Center for Drug Evaluation and Research (CDER), who are responsible for determining which establishments need inspection.

Our work focused on human drugs regulated by CDER and not on most biologics, medical devices, veterinary medicines, or other items or products for which FDA conducts inspections.<sup>10</sup> Further, our work focused on activities related specifically to the foreign drug inspection program. As part of its oversight of imported drugs, FDA undertakes other activities, such as working toward international harmonization of regulatory requirements, which are beyond the scope of our review.

To examine FDA's assessment of its foreign offices and the challenges the foreign offices face in contributing to the safety of drugs entering the United States, we reviewed documents pertaining to the foreign offices and their activities provided by FDA's Office of International Programs (OIP), of which the foreign offices are a part and which is responsible for overseeing FDA's overseas activities. Specifically, we examined OIP's strategic plan and strategic workforce plan for the foreign offices to identify the offices' goals, mission, and desired long-term results. We also reviewed the operational plans of the foreign offices, which are completed quarterly by each office and include the performance measures and targets used to assess their activities.<sup>11</sup> We also reviewed the report of a

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<sup>10</sup>Biologics are materials, such as viruses, therapeutic sera, toxins, antitoxins, vaccines or analogous products to prevent, treat, or cure human diseases or injuries, and are derived from natural sources, such as humans, animals, and microorganisms. See 42 U.S.C. § 262(i); 21 C.F.R. § 600.3(h) (2016). Medical devices include instruments, apparatuses, machines, and implants that are intended for use to diagnose, cure, treat, or prevent disease, or to affect the structure or any function of the body. 21 U.S.C. § 321(h). Our work focused on inspections related to the drug approval process or inspections conducted to determine an establishment's ongoing compliance with laws and regulations in the manufacture of human drugs already marketed in the United States. FDA conducts additional drug inspections that are beyond the scope of our review, such as inspections conducted to determine whether drug manufacturers are submitting to FDA, as required, complete and accurate data on adverse drug experiences associated with marketed drugs, inspections conducted for the President's Emergency Plan for AIDS Relief, and inspections of clinical trial sites, compounding pharmacies, and medical gas manufacturers.

<sup>11</sup>A performance measure is a means of objectively assessing the outputs or outcomes of programs, products, projects, or services.

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contractor retained by FDA to develop new performance measures for the foreign offices, as well as data from FDA's agency-wide performance tracking system, including some of the agency's performance measures and outcomes. We examined documentation pertaining to FDA's policies and procedures for staff deploying to and returning from the foreign offices, including materials related to the reintegration of staff into FDA's domestic offices upon their completion of their terms abroad.

Additionally, we analyzed the most recently complete FDA data on the number and type of authorized, filled, and vacant positions for each of OIP's foreign and domestic offices, as well as data on the number of staff assigned to the foreign offices on a temporary basis. This included data on the number of drug inspections conducted by foreign office personnel. To supplement this information, we interviewed FDA officials in OIP, which includes the China, India, Latin America, and Europe foreign offices, as well as officials in CDER and ORA, to obtain information on the foreign offices' contributions to drug safety and how these contributions are assessed by the agency. In addition, we interviewed 13 former foreign office staff who had responsibilities pertaining to drug safety—including those who were still with FDA and those who have since left the agency—about their experiences deploying to and working overseas, and, in some cases, returning to a domestic post with the agency. Finally, to identify criteria to evaluate FDA's assessment of its foreign offices' performances, we reviewed our previous reports on performance measures and standards for internal control in the federal government.<sup>12</sup>

We conducted this performance audit from February 2016 to December 2016 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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<sup>12</sup>See GAO, *Human Capital: Key Principles for Effective Strategic Workforce Planning*, [GAO-04-39](#) (Washington, D.C.: Dec. 11, 2003). Strategic workforce planning is an essential tool to help agencies align their workforces with their current and emerging missions and develop long-term strategies for acquiring, developing, and retaining staff. See also GAO, *Standards for Internal Control in the Federal Government*, [GAO-14-704G](#) (Washington, D.C.: September 2014). Internal control is a process affected by an entity's oversight body, management, and other personnel that provides reasonable assurance that the objectives of an entity will be achieved.

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## Background

Several FDA centers and offices play key roles in helping to ensure the safety and effectiveness of drugs marketed in the United States:

- CDER establishes standards for the safety, quality, and effectiveness of and manufacturing processes for over-the-counter and prescription drugs.<sup>13</sup>
- OIP, which is part of FDA's Office of Global Regulatory Operations and Policy, leads, manages, and coordinates FDA's foreign offices' activities, such as performing inspections in the countries in which the offices reside. OIP also engages with international health and regulatory partners on a variety of issues, including establishing confidentiality agreements with regulatory counterparts for sharing information on regulated products, and collaborates with the staff in FDA's centers and ORA.
- ORA inspects establishments and reviews imported products offered for entry into the United States to ensure compliance with applicable laws and regulations, among other things. ORA is also part of FDA's Office of Global Regulatory Operations and Policy.

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## Types of Drug Inspections

FDA conducts several types of inspections of drug manufacturing establishments to protect the drug supply. Drugs manufactured overseas must generally meet the same statutory and regulatory requirements as those produced in the United States.<sup>14</sup> CDER and ORA are primarily responsible for the agency's human drug inspection program. CDER requests ORA to inspect both domestic and foreign establishments to ensure that drugs are produced in conformance with federal statutes and regulations, including CGMP regulations. ORA investigators (based domestically and in the foreign offices) and, as needed, laboratory analysts are responsible for conducting the inspections.<sup>15</sup> Investigators

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<sup>13</sup>For purposes of this report, we consider drug quality to be a component of drug safety. Our references to drug safety are therefore meant to also encompass drug quality.

<sup>14</sup>FDA defines manufacturing to include the manufacture, preparation, propagation, compounding, or processing of a drug, and an establishment as a place of business under one management at one general physical location. 21 C.F.R. §§ 207.3(a)(7), (8) (2016). In this report, establishments may be engaged in the manufacture, preparation, propagation, or processing of drugs.

<sup>15</sup>ORA investigators lead inspections and are responsible for performing or overseeing all aspects of an inspection. ORA laboratory analysts are chemists or microbiologists and have expertise in laboratory testing. In some instances, staff from CDER may participate in inspections. ORA assists the agency's other product centers in planning establishment inspections of other FDA-regulated commodities, such as veterinary medicines and food.

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generally conduct three types of drug manufacturing establishment inspections:

1. Preapproval inspections of domestic and foreign establishments may be conducted before FDA approves a new drug to be marketed in the United States. These inspections are triggered by FDA's receipt of a new drug application or an abbreviated new drug application, and focus on the manufacture of a specific drug. Preapproval inspections are designed to verify the accuracy and authenticity of the data contained in these applications to determine that the establishment is following commitments made in the application. Preapproval inspections also assess whether the establishment can manufacture the product in the application in conformance with CGMPs. FDA's decision to inspect a particular establishment listed on the application is based on multiple factors, including the establishment's compliance history—that is, the results of previous inspections, product recalls, and other compliance information—and the attributes of the product being proposed for manufacture.
2. Surveillance inspections are conducted at establishments after drugs are already marketed in the United States and focus on compliance with system-wide controls for ensuring that the manufacturing processes produce high-quality drugs. Establishments are prioritized for surveillance inspections through a process using a risk-based site selection model. Systems examined during these inspections include those related to materials, quality control, production, facilities and equipment, packaging and labeling, and laboratory controls. These systems may be involved in the manufacture of multiple drugs.<sup>16</sup> FDA can use the results of a surveillance inspection to make decisions in the future if the establishment is listed on another application, as the results of a surveillance inspection can often be generalized to all drugs manufactured in a similar manner at a particular establishment.
3. For-cause inspections are conducted to investigate consumer complaints, reports of product quality defects submitted by consumers or health care professionals, or indications of potential manufacturing problems submitted by the manufacturers themselves through field alert reports, among other reasons. Additionally, these inspections

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<sup>16</sup>Although surveillance inspections focus on system-wide controls, FDA considers nearly all drug establishment inspections to include an assessment of CGMPs.

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may also be conducted as follow-up to warning letters or import alerts issued to manufacturers.<sup>17</sup>

While FDA may conduct a preapproval-only inspection or a surveillance-only inspection, FDA may also conduct an inspection that combines both preapproval and surveillance inspection components in a single visit to an establishment.<sup>18</sup>

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## FDA's Process for Prioritizing Establishments for Surveillance Inspection

FDA uses multiple databases to select foreign and domestic establishments for surveillance inspections, including

- The electronic Drug Registration and Listing System (eDRLS) contains information on foreign and domestic drug establishments that have registered with FDA to market their drugs in the United States. Establishments are required to register annually with FDA. Information in eDRLS includes the company's name, address, and the drugs they manufacture for commercial distribution in the United States, as reported by the establishment.
- FACTS contains information on domestic and foreign establishments inspected by ORA, the type of inspection conducted, and the outcome of those inspections. Investigators and laboratory analysts enter information into FACTS following completion of an inspection.

CDER relies on these and other databases to select establishments for surveillance inspections.<sup>19</sup> CDER primarily uses data from eDRLS, which provides information on all registered establishments at a given point in time, and FACTS, which provides information about additional establishments that may not appear in eDRLS, to annually compile a

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<sup>17</sup>A warning letter is a letter that notifies industry about violations that FDA has documented during its inspections. Warning letters are to be issued for violations of regulatory significance, i.e., those that may actually lead to an enforcement action if the documented violations are not promptly and adequately corrected. An import alert informs FDA field staff and the public that the agency has enough evidence to allow for detention without physical examination of products that appear to be in violation of FDA laws and regulations.

<sup>18</sup>Most combined inspections occur when FDA conducts a surveillance inspection at an establishment where a preapproval inspection was also being conducted.

<sup>19</sup>Other databases FDA uses to select establishments for inspection include the Operational and Administrative System for Import Support, which includes data on the number of establishments that have manufactured products that were shipped to the United States, and the FDA Inventory of Assets, which includes data on establishments producing products regulated by FDA.

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catalog of establishments that are to be prioritized for inspection.<sup>20</sup> Because the establishments to be prioritized are continuously changing as they begin, stop, or resume marketing products in the United States, FDA does not maintain a single list of them; rather, the annual catalog provides a snapshot in time of such establishments. Based on these databases, as of June 2016, CDER's catalog consisted of approximately 2,000 domestic and 3,000 foreign drug establishments.

Until 2012, requirements governing FDA's selection of domestic and foreign establishments to inspect differed. Until then, FDA was required to inspect domestic establishments that manufacture drugs marketed in the United States every 2 years, but there was no comparable requirement for inspecting foreign establishments. However, FDASIA eliminated this distinction, instead directing FDA to take a risk-based approach to inspecting both domestic and foreign drug manufacturing establishments, consistent with a recommendation we made to FDA in 2008.<sup>21</sup>

To prioritize establishments for surveillance inspections, CDER applies its risk-based site selection model to its catalog of establishments each year to identify those establishments (both domestic and foreign) that, based on the characteristics of the drugs being manufactured, pose the greatest potential public health risk should they experience a manufacturing defect. This model analyzes three major factors—facility score, product score, and time since last inspection—to develop a list of establishments that FDA considers to be a priority for inspection.<sup>22</sup> Establishments may also be selected for surveillance inspections for other reasons, such as FDA's focus on a particular product. Through this process, CDER develops a priority list of establishments selected for inspection that is then ranked and submitted to ORA. To be efficient with its resources, ORA staff may shift the order of establishments to be inspected on

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<sup>20</sup>In previous reports, we have referred to establishments that FDA identified as subject to inspection as an "inventory." FDA now refers to this compilation as a "catalog," a term we have adopted for the purposes of this report.

<sup>21</sup>Pub. L. No. 112-144, § 705, 126 Stat. 1066 (codified at 21 U.S.C. 360(h)(4)). For our previous recommendation, see [GAO-08-970](#).

<sup>22</sup>The facility score includes information about the facility and its history, such as the type of establishment (for example, a manufacturer or a laboratory), number of products produced at the facility, and inspection history. The product score, meanwhile, captures information about a product itself, such as its therapeutic category (for example, an anti-fungal), its dosage form, and whether it is sterile.

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CDER's prioritized list based on geographic proximity to other planned inspection trips.

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## FDA's Foreign Offices

FDA opened its foreign offices in 2008 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. To accomplish this, the foreign offices focus on the following activities:

1. establishing relationships with U.S. agencies located overseas and foreign stakeholders, including regulatory counterparts and industry, to facilitate collaborations that will streamline and enhance global drug development and regulation;
2. gathering better information locally on product manufacturing and transport to U.S. ports;
3. expanding FDA's inspectional capacity to include inspections of FDA-regulated commodities, such as drugs, medical devices, and food products, conducted by investigators based in the foreign offices; and
4. providing assistance to strengthen the regulatory systems of FDA's foreign counterparts to better assure the safety of the products manufactured and exported from their countries to the United States.<sup>23</sup>

Currently, FDA has foreign offices in China, Europe, India, and Latin America. Some offices have more than one office location, also known as a post.<sup>24</sup> (See fig. 1.) FDA previously had foreign offices located in Africa and the Middle East, but these offices have since closed and been consolidated under the Office of Regional and Country Affairs, an OIP

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<sup>23</sup>FDA's capacity building, also known as 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>24</sup>Specifically, the Latin America office has posts in Santiago, Chile; San Jose, Costa Rica; and Mexico City, Mexico. The Europe office has posts in Brussels, Belgium, and London, United Kingdom, and previously had a post in Parma, Italy that closed in 2012. Although the China office currently has one post in Beijing, it previously had posts in Guangzhou and Shanghai, which closed in 2014. Similarly, the India office currently has one post in New Delhi, but it previously had a post in Mumbai that closed in July 2016.

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office based domestically in FDA's headquarters.<sup>25</sup> For fiscal year 2016, FDA budgeted approximately \$35.2 million for the China, Europe, India, and Latin America offices, an increase over the \$29.9 million budgeted for them in fiscal year 2009.<sup>26</sup>

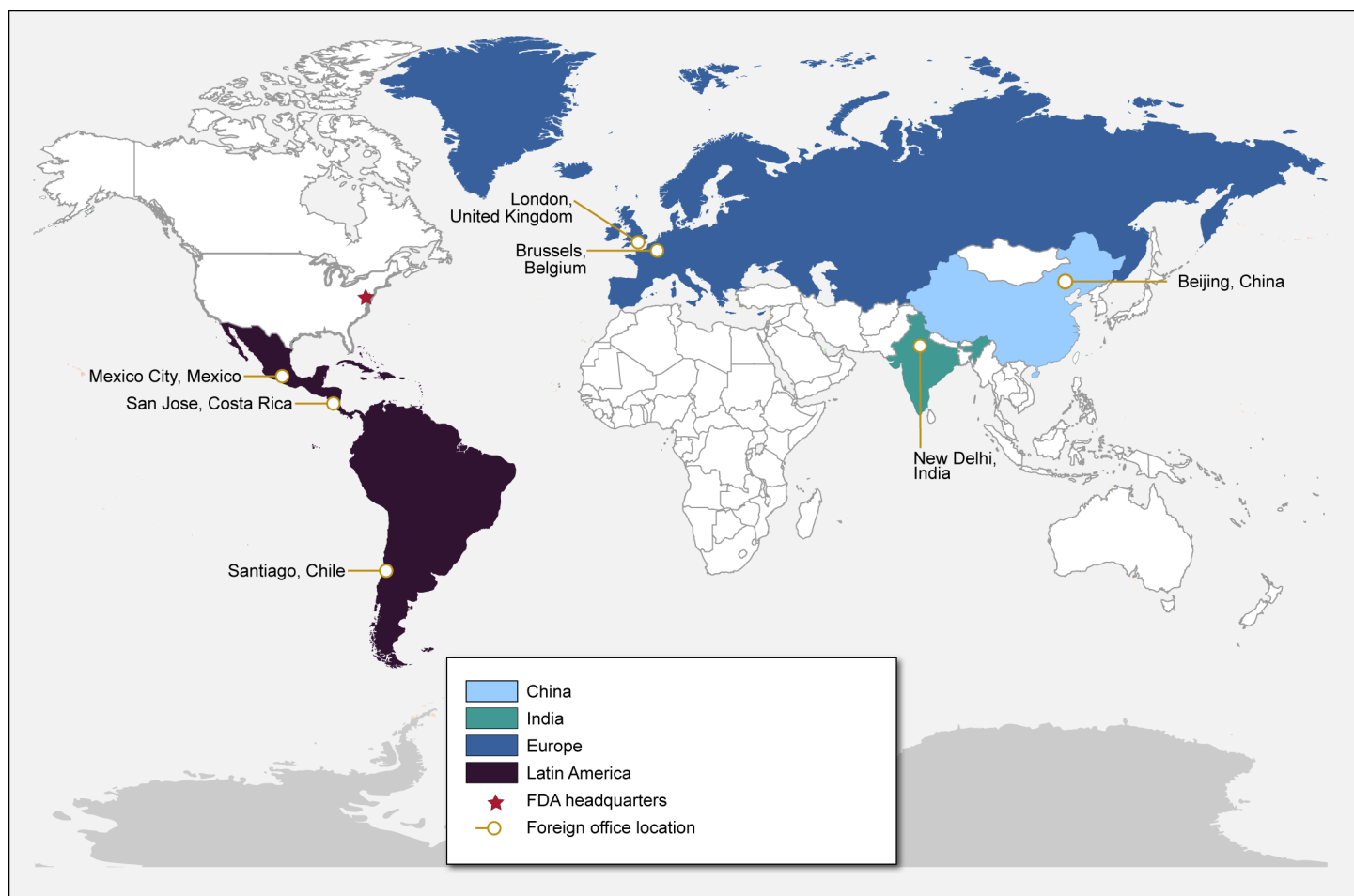
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<sup>25</sup>Specifically, FDA previously had foreign offices in Amman, Jordan, and Pretoria, South Africa, which closed in 2013 and 2015, respectively. Currently, the Office of Regional and Country Affairs manages FDA's activities in Asia and the Pacific (with the exceptions of India and China), the Middle East, Africa, and Canada. The office is responsible for fostering collaboration and the sharing of information and technical expertise with counterpart regulatory authorities throughout the regions, both directly and through their embassies in Washington, D.C. For the purposes of this report, we do not include this office when we refer to FDA's "foreign offices" since the office and its staff are based in the United States.

<sup>26</sup>The \$29.9 million budgeted for the foreign offices in fiscal year 2009 included some posts for the China and India offices that have since closed. All staffing and administrative costs associated with the offices are included in budgeted amounts.



**Figure 1: Geographic Responsibilities of the Food and Drug Administration's (FDA) Foreign Offices, Including Their Locations, as of October 2016**



Sources: GAO analysis of FDA information; Map Resources (map). | GAO-17-143

Note: The Latin America office encompasses three office locations, also known as posts, in Mexico City, Mexico; San Jose, Costa Rica; and Santiago, Chile. The Europe office includes two posts in London, United Kingdom, and Brussels, Belgium. FDA's Office of International Programs (OIP) also has a domestic office that covers other regions in the world. Specifically, OIP's Office of Regional and Country Affairs is responsible for agency interactions in other areas of the world, such as Canada, Australia, and the Middle East, which are not covered by one of FDA's foreign offices.

As of July 2016, FDA had 29 staff members assigned to work in the foreign offices, including a director and deputy director in each office. The offices also have international program and policy analysts who analyze the impact of foreign issues on FDA programs and activities, and other staff who are responsible for engaging with foreign stakeholders and

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gathering information. There are also investigators who conduct inspections of establishments manufacturing food or medical products in the China, India, and Latin America offices.<sup>27</sup> The offices also have locally employed staff, who are non-U.S. citizens employed by the FDA foreign offices.<sup>28</sup> Finally, OIP staff based in its domestic offices assist the foreign offices in addition to performing other duties related to advancing FDA's global mission.

FDA foreign office staff are posted overseas for two-year assignments. In addition, FDA may send staff to the foreign offices to perform temporary duty assignments of up to 120 days. HHS policy requires that its overseas staff commit to assignments of no more than 2 years per tour; however, staff have the option to renew in increments of one or two years, for up to a total of 6 years in one country, subject to strategic goals and management concurrence on performance. Staff can then rotate to a new country, but HHS requires that staff spend no more than 12 consecutive years overseas before returning to the United States for at least 1 year.

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## FDA Has Increased Its Foreign Drug Inspections and Enhanced Its Ability to Prioritize Drug Establishments for Inspection

Since fiscal year 2009, FDA has increased the number of all foreign drug inspections conducted each year. Additionally, the agency has taken steps to improve the accuracy and completeness of its catalog of foreign drug establishments, although FDA still lacks inspection history for 33 percent of this catalog. FDA has also strengthened the management of its process for prioritizing drug establishments for surveillance inspection, in particular its risk-based site selection model.

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<sup>27</sup>These investigators come from ORA, but are assigned to OIP for the duration of their terms abroad. While stationed overseas, FDA investigators are considered to be consumer safety officers. For purposes of this report, we refer to these staff throughout as investigators.

<sup>28</sup>Locally employed staff are hired to work in the foreign offices to work on administrative issues or provide technical expertise as needed. As of July 2016, there were 19 locally employed staff located in the Europe, China, India, and Latin America offices. Adding these staff to the 29 FDA staff assigned to the foreign offices brings the total number of staff working in FDA's foreign offices to 48.

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## FDA Has Increased the Number of Foreign Drug Inspections Since Fiscal Year 2009

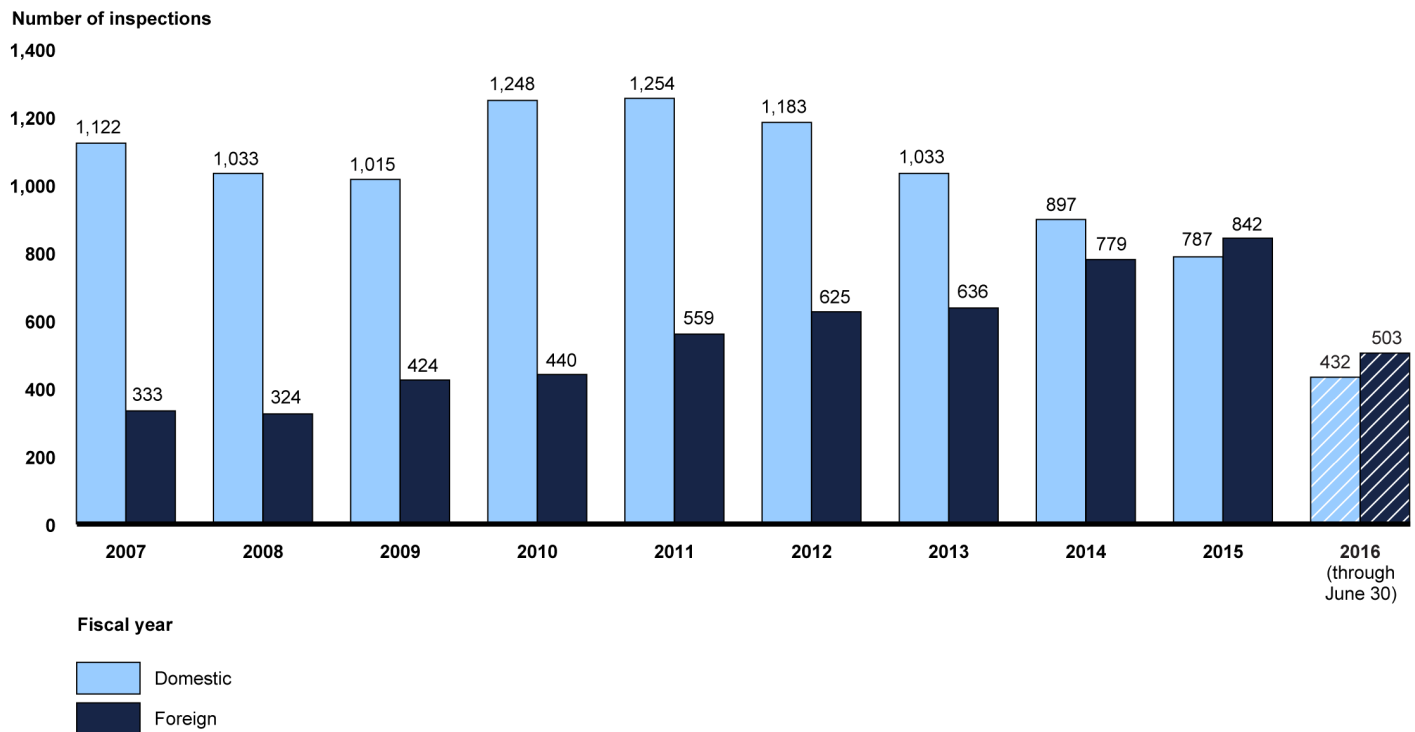
FDA has consistently increased the total number of foreign drug inspections—which include surveillance, preapproval, and for-cause inspections—conducted each year since fiscal year 2009, as shown in figure 2.<sup>29</sup> This is consistent with a recommendation we made in 2008, when we recommended that FDA conduct more inspections to ensure that foreign drug establishments are inspected at a frequency comparable to domestic establishments with similar characteristics.<sup>30</sup> Beginning in fiscal year 2015, FDA conducted more foreign than domestic inspections.

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<sup>29</sup>We are using the number of foreign drug inspections conducted in a fiscal year in our calculations, rather than the number of unique foreign drug establishments inspected. Although FDA can inspect an establishment more than once a year, during this time period there was not a sizeable difference between the number of foreign inspections conducted and the number of unique establishments inspected.

<sup>30</sup>See [GAO-08-970](#).

**Figure 2: Total Number of Food and Drug Administration (FDA) Inspections of Domestic and Foreign Drug Establishments, Fiscal Year 2007 through June 30, 2016**



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

Note: This figure shows the number of foreign drug inspections conducted in a fiscal year, rather than the number of unique foreign drug establishments inspected. Although FDA can inspect an establishment more than once a year, during this time period there was not a sizeable difference between the number of foreign inspections conducted and the number of unique establishments inspected.

According to FDA officials, the agency has leveraged multiple staff resources to enable it to increase the number of foreign drug inspections conducted by the agency in recent years.

- ORA investigators based in FDA's domestic district offices continue to represent the majority of people participating in FDA's foreign inspections (approximately 49 percent of the total number of inspections conducted).
- As we previously reported, though, FDA established a dedicated foreign drug cadre in January 2009. The group of 15 domestically

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based ORA staff exclusively participate in foreign drug inspections.<sup>31</sup> FDA told us that the agency increased the number of staff assigned to the foreign cadre to 20 in 2012. Currently, the foreign cadre represents the next highest percent of staff participating in foreign inspections (approximately 31 percent of total inspections).

- Additionally, the Generic Drug User Fee Amendments Act (GDUFA) of 2012 authorized FDA to collect user fees from manufacturers of generic drugs, providing the resources to hire 80 additional investigators focused on inspecting generic drug manufacturers.<sup>32</sup> FDA officials said that these investigators have primarily been assigned to foreign inspections, but during the period we reviewed, they participated in a relatively small percentage of the total number of foreign drug inspections conducted (approximately 8 percent of inspections).<sup>33</sup>
- Investigators assigned full-time to FDA's foreign offices have also participated in inspections of foreign drug establishments (approximately 5 percent of inspections).
- Since fiscal year 2012, the foreign offices have also made use of temporary duty assignments from ORA to assist the foreign offices in completing their work priorities, including inspections. Staff on temporary duty assignments have participated in approximately 2 percent of foreign drug inspections.
- In addition, there are a variety of other FDA staff who, on occasion, may participate in an inspection if certain subject matter expertise is needed.

In addition to using various FDA staff to conduct foreign inspections, the agency has increased funding dedicated to conducting foreign inspections. According to FDA officials, the agency obligated approximately \$53 million to foreign inspections in fiscal year 2010. This amount has increased each year since, to \$92 million in fiscal year

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<sup>31</sup>See [GAO-10-961](#).

<sup>32</sup>Pub. L. No. 112-144, tit. III, 126 Stat. 1008 (codified in pertinent part at 21 U.S.C. § 379j-42).

<sup>33</sup>The relatively low number of inspections conducted by the additional investigators hired using funds made available by GDUFA fees could be due to the fact that they only began conducting inspections in fiscal year 2014, when they participated in 3 inspections. The majority of their drug inspections occurred in fiscal years 2015 and 2016, when they participated in 172 and 179 inspections, respectively.

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2015.<sup>34</sup> The average cost of a foreign drug inspection has slightly decreased over the years. FDA had estimated that the average cost of a foreign inspection was between \$60,000 and \$62,500 for fiscal year 2009; for fiscal year 2015, the average cost was \$57,600.

The locations where FDA has conducted foreign inspections have largely remained the same from what we previously reported. Specifically, FDA conducted drug inspections in 68 total countries from fiscal year 2010 and June 30, 2016, with 76 percent of these inspections conducted in 10 countries. Establishments in India were the most frequently inspected, followed by ones in China and Germany. (See table 1.) This mirrors what we previously found in 2010.<sup>35</sup>

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<sup>34</sup>The agency has also increased its funding dedicated to conducting domestic inspections. According to FDA, the agency obligated approximately \$115 million in fiscal year 2010 for domestic drug inspections and increased the amount each year to eventually \$152 million in fiscal year 2015.

<sup>35</sup>In 2010, we found that the 10 most frequently inspected countries were (1) India, (2) China, (3) Germany, (4) Canada, (5) United Kingdom, (6) Italy, (7) France, (8) Japan, (9) Ireland, and (10) Switzerland, followed by all other countries.

**Table 1: Total Number of Food and Drug Administration (FDA) Drug Inspections of Foreign Establishments, by Country, Fiscal Year (FY) 2010 through June 30, 2016**

Country	FY 2010	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016 through June 30, 2016	Total	Estimated number of foreign establishments subject to surveillance inspection as of June 2016 <sup>a</sup>
India	72	99	140	110	114	204	101	840	572
China	48	89	59	74	113	129	81	593	535
Germany	50	35	59	60	72	68	37	381	191
Canada	24	43	49	51	39	52	30	288	166
Italy	33	36	38	45	50	41	34	277	146
Japan	23	22	49	28	47	31	39	239	162
France	32	24	25	36	44	45	22	228	146
United Kingdom	16	31	29	27	33	43	18	197	136
Switzerland	26	30	23	23	37	31	16	186	89
Ireland	12	17	14	21	26	17	14	121	60
All other countries	104	133	140	161	204	181	111	1,034	820
<b>Total</b>	<b>440</b>	<b>559</b>	<b>625</b>	<b>636</b>	<b>779</b>	<b>842</b>	<b>503</b>	<b>4,384</b>	<b>3,023</b>

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

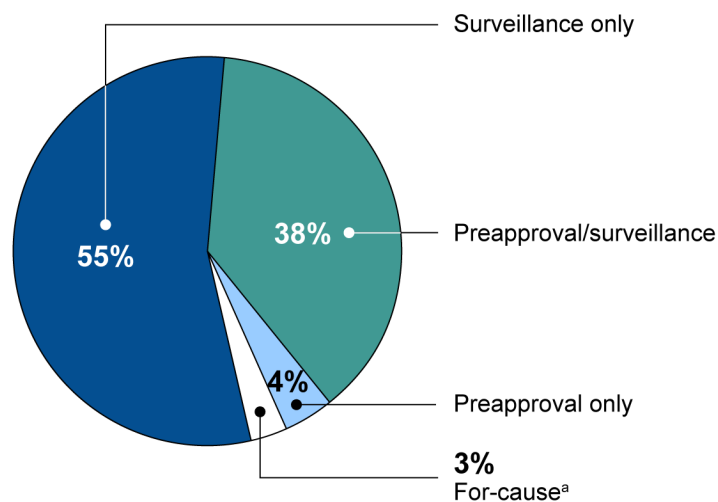
<sup>a</sup>The counts in this column represent the estimated number of foreign drug establishments that FDA will use for the fiscal year 2017 risk-based site selection model. FDA does not keep historical records reflecting the number of establishments subject to inspection each year. Agency officials told us they do not keep such records as the number of establishments subject to inspection frequently fluctuates as establishments begin, stop, or resume marketing products in the United States. As a result, we could not determine the estimated number of foreign establishments that were subject to inspection for fiscal year 2010 through fiscal year 2016.

Since 2009, FDA has changed the types of inspections it primarily conducts at foreign drug establishments. Specifically, more than half (55 percent) of all foreign inspections conducted from fiscal year 2010 through June 30, 2016, were surveillance-only inspections rather than preapproval inspections. (See fig. 3.) This is a significant increase since fiscal year 2009, when we found that 17 percent of foreign inspections were surveillance inspections, with the vast majority conducted in response to an application to market a new drug in the United States.<sup>36</sup> FDA officials acknowledged that foreign inspection priorities had previously been driven by pending applications for new drugs. However,

<sup>36</sup>See [GAO-10-961](#). For fiscal year 2009, we found that the majority of foreign drug inspections FDA conducted contained both a preapproval and surveillance component (74 percent), followed by surveillance-only (17 percent), then preapproval only (9 percent).

this was prior to the enactment of FDASIA, when FDA was required to inspect all domestic establishments every 2 years, and also before an increase in funding available for foreign inspections provided for by generic drug user fees. FDA officials also said the agency eliminated a policy whereby inspections conducted for preapproval purposes often drove the selection of foreign establishments for inspections. As a result, FDA officials said that the selection of foreign establishments for routine surveillance inspections is now entirely driven by the risk-based site selection model. (See app. I for information on the number and types of foreign drug inspections conducted from fiscal year 2010 through June 30, 2016.)

**Figure 3: Food and Drug Administration (FDA) Inspections of Foreign Drug Establishments by Type of Inspection, Fiscal Year 2010 through June 30, 2016**



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

<sup>a</sup>This category includes any inspection that included a “for-cause” component. For-cause inspections are conducted to investigate consumer complaints, reports of product quality defects submitted by consumers or health care professionals, or indications of potential manufacturing problems submitted by the manufacturers themselves, among other reasons.



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## FDA Has Improved Information on Its Catalog of Foreign Drug Establishments, but Lacks Inspection History on One-Third of Them

Since 2010, FDA has taken steps to improve the accuracy and completeness of its catalog of foreign drug establishments. These steps are intended to address what FDA acknowledged as a challenge as early as 1988, following an internal evaluation that recommended that the agency develop a comprehensive catalog of all foreign establishments shipping drugs to the United States that could be used to improve long-range inspection planning and scheduling.<sup>37</sup> We also highlighted this challenge in our previous reports.<sup>38</sup> Most recently, in 2010, we found that a majority (64 percent) of foreign establishments in FDA's catalog may never have been inspected by the agency. Since then, FDA officials said that the agency has taken steps to improve the accuracy and completeness of its catalog by

- Requiring establishments to use a unique, numeric identifier. FDASIA required establishments to provide a unique facility identifier during their annual registration with FDA, and FDA elected to require establishments to use the Dun and Bradstreet Data Universal Numbering System (D-U-N-S®) number.<sup>39</sup> Using this number allows FDA to automatically validate data from every registration submission against the Dun and Bradstreet database to ensure the accuracy of the information. Any mismatch may result in rejection of a registration submission. The D-U-N-S® number also allows FDA to determine whether a firm has gone out of business or relocated. FDA officials said that it has also helped FDA improve the interoperability of the agency's data systems that collect or use registered facility information, as well as the interoperability of other agencies' systems.
- Adding two foreign inventory coordinators in 2013 tasked with incorporating foreign registrations and annual updates into FDA's master inventory. Additionally, these coordinators are responsible for updating FDA's inspection data to reflect accurate inventory updates.
- Establishing a data governance board to define standards, best practices, and policies for inventory data management. According to FDA officials, the governance board, which was created in May 2015, meets biweekly to examine the databases responsible for storing

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<sup>37</sup>Office of Regulatory Affairs, Program Evaluation Branch, "An Evaluation of FDA's Foreign Inspection Program," Rockville, Md., March 1988. This internal evaluation found that FDA did not maintain a catalog (previously referred to by FDA as an inventory) of all foreign drug establishments that were subject to FDA regulation.

<sup>38</sup>See [GAO/HEHS-98-21](#); [GAO-08-970](#); and [GAO-10-961](#).

<sup>39</sup>Pub. L. No. 112-144, § 702(b), 126 Stat. 1065 (codified at 21 U.S.C. § 360(i)).

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information about drug establishments. Officials said the board has developed guidance for merging data processes and is working toward defining data metrics to determine whether they have improved on their reporting. The board has also defined data standards for storing key attributes of establishments, such as companies' names, and continues to examine best practices for sharing establishment data across FDA.

As a result of these steps, FDA has reduced its catalog of establishments that may never have had a surveillance inspection. Currently, FDA lacks information on the inspection history of 33 percent of the foreign establishments in its catalog, compared to the 64 percent for which it lacked inspection history in 2010. According to FDA officials, the establishments that are subject to inspections are continuously changing. For example, they said that some of the establishments without an inspection history may be newly registered with the agency, thus accounting for their lack of an inspection history; others could be establishments that are not subject to inspection, such as those that may have gone out of business or that have never shipped products to the United States. Although this may be the case for some—or even many—of these establishments, the fact remains that FDA does not know whether or for how long these establishments have or may have supplied drugs to the U.S. market, and has little other information about them. While the agency has made progress in reducing this knowledge gap, it is important to note that the overall number of foreign establishments with no surveillance inspection history (about 1,000 of the approximately 3,000) remains large.<sup>40</sup> (See app. II for information on the numbers and locations of the establishments for which FDA lacks an inspection history.)

To address this persistent concern, the agency plans to inspect all establishments in its catalog with no prior surveillance inspection history over the next 3 years (approximately one-third each year), beginning in fiscal year 2017. FDA will consider these establishments' risk scores as determined by the agency's risk-based site selection model to prioritize them for inspection, starting with those establishments having the highest risk scores. Some recent FDA inspections have uncovered significant issues at foreign drug manufacturing establishments, including raw material storage rooms that had never been cleaned and the presence of

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<sup>40</sup>The majority of these establishments are in China, India, and South Korea.

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pests in a controlled processing area, underscoring the importance for FDA to fill this knowledge gap.

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### FDA Has Strengthened the Management of Its Risk-Based Site Selection Model

FDA has strengthened the management of its process for selecting drug establishments (domestic and foreign) for surveillance inspection. First, FDA generated a combined list of foreign and domestic establishments for use with the fiscal year 2016 risk-based site selection model. Using a combined list of establishments with the risk-based site selection model reflects the agency's full implementation of the 2012 FDASIA provision that directed FDA to take a risk-based approach to inspecting both foreign and domestic establishments. This is also consistent with a recommendation we made to the agency in 2008.<sup>41</sup> For fiscal year 2016 and beyond, FDA officials said that ORA will only select establishments for surveillance inspection from the combined prioritized list—beginning with those establishments with the highest risk score, regardless of whether they are foreign or domestic—until they have exhausted their surveillance inspection capacity for that year. Prior to fiscal year 2016, foreign and domestic establishments were selected for inspection from separate prioritized lists, and in different manners.<sup>42</sup> As a result, during this time, FDA officials said that a one-for-one match between the lists of foreign establishments prioritized for inspection and the final list of actual inspections conducted would be unlikely. Officials said that the prioritized lists of foreign establishments for fiscal year 2010 through fiscal year 2015 provided a framework for planning surveillance inspections, but that ORA was given discretion as to which specific establishments from the priority list would be inspected each year. Collectively, FDA officials said that the results from the priority list, the needs of the centers, and any unforeseen events dictated the final list of foreign establishments

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<sup>41</sup>See [GAO-08-970](#).

<sup>42</sup>Specifically, FDA officials said that investigators were required to first inspect domestic facilities with risk scores above a certain threshold (but allowing for substitutions as needed), before inspecting remaining domestic establishments. In comparison, according to FDA officials, inspecting foreign establishments with the highest risk scores was not a requirement; rather, ORA was given discretion in selecting foreign establishments from the priority list to account for logistical challenges associated with planning foreign inspection trips.

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inspected prior to fiscal year 2016, and the final list could differ from the priority list generated by the risk-based site selection model.<sup>43</sup>

Second, in 2015, the agency formalized its process for selecting establishments for inspection according to an establishment's known safety risks, based on certain risk factors specified by FDASIA. These factors are an establishment's compliance history, recall history, inherent product risk, inspection frequency and history, and whether the establishment has been inspected by a foreign government or agency.<sup>44</sup> FDA officials said that the agency has long considered certain FDASIA factors in selecting establishments to inspect, such as an establishment's inspection history. However, its risk-based site selection model has become increasingly sophisticated in factoring in specific details about establishments, the products they make, and other elements into the site selection process. Officials acknowledged that FDA cannot yet systematically determine whether an establishment has been subject to inspection by a foreign government or agency, because this requires the agency to negotiate agreements with foreign regulators to obtain meaningful foreign inspection results. Officials stated that FDA is in the process of doing so. However, FDA has been working on pursuing such agreements and determining how they may help the agency to assess the risk of foreign establishments when prioritizing them for almost a decade.<sup>45</sup> As they continue to explore these agreements, FDA officials said the agency does, on a case-by-case basis, review and exchange information with certain foreign regulators, which may result in the agency re-prioritizing its inspection schedule to address emergent issues.

Third, in fiscal year 2017, FDA plans for the first time to allow no more than 5 years to elapse between surveillance inspections at a specific establishment. That is, if an establishment included in FDA's catalog of

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<sup>43</sup>FDA officials explained that, at the beginning of each year, ORA would engage with the centers to discuss inspection priorities for the upcoming year. ORA would then consider its available resources before proceeding with inspections. In addition, unplanned events, such as a natural disaster, could affect the total number of inspections that could be conducted in a given year.

<sup>44</sup>FDASIA also authorizes the Secretary of Health and Human Services to consider additional criteria deemed necessary and appropriate. Pub. L. No. 112-144, § 705, 126 Stat. 1066 (codified at 21 U.S.C. § 360(h)(4)).

<sup>45</sup>GAO, *Drug Safety: Preliminary Findings Suggest Recent FDA Initiatives Have Potential, but Do Not Fully Address Weaknesses in Its Foreign Drug Inspection Program*, [GAO-08-701T](#) (Washington, D.C.: Apr. 22, 2008).

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establishments subject to inspection has not been inspected in 4 years, the establishment is automatically included on the inspection list for the fifth year. According to FDA officials, the agency previously did not include a “hard stop” of a predetermined time in its model. For fiscal year 2017, after FDA inspects one-third of the establishments with no inspection history the agency will prioritize for inspection these establishments that have not had a surveillance inspection within the past 5 years. Once these inspections are completed, FDA plans to inspect establishments that were prioritized by the risk-based site selection model through its annual process. Should FDA complete inspections of all of the establishments prioritized through the risk-based site selection model, the agency plans to conduct additional inspections of as many of the remaining two-thirds of establishments with no inspection history as possible, given remaining inspection resources.

Fourth, FDA recently formalized its process for developing, evaluating, and documenting key decisions about its model each year. Prior to this effort, FDA lacked a formal approach to evaluating its model and documenting key decisions. As a result, in some cases, FDA was unable to recall or explain how the model—or the process to update it—had changed over time. Officials said that our prior reviews reinforced the need for a written procedure and a formal governance structure to support the development of the risk-based site selection model. In fiscal year 2016, FDA instituted a formalized process for developing and evaluating its fiscal year 2017 model and documenting key decisions made as a result of this evaluation. As part of this process, FDA created a review board that features multiple levels of input of the model’s design from FDA experts and senior management, and in October 2016 finalized a document that outlines roles and responsibilities related to the model, and that indicates how it is to be annually updated and implemented. FDA also incorporated best practices learned from its first experience using the review board to guide the development of the model. Officials said the document, going forward, will chronicle the decisions officials make regarding which factors were included in the model for a particular year and why. FDA’s formalized process for evaluating and updating its risk-based site selection model may improve the agency’s ability to monitor whether establishments that pose the greatest risk to public health, were they not to comply with CGMPs, are being selected for inspection. FDA is performing monitoring activities through its formalized process by annually updating the factors and weights included in the model through its newly formalized governance structure. This process allows subject matter experts to provide input each year on the relative importance of each factor and whether the factor should be included in the model.

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## FDA Has Not Yet Assessed Its Foreign Offices' Contributions to Drug Safety, and Their Efforts are Impeded by High Vacancy Rates

FDA has begun to take steps to enhance the agency's strategic planning for the foreign offices and has developed two performance measures. However, FDA could not readily cite the effectiveness of the offices' contributions, which began opening in 2008. High vacancy rates in the foreign offices threaten to impede the offices' efforts to ensure drug safety.

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## FDA Has Made Progress in Strategic Planning for Its Foreign Offices

FDA has made progress in its strategic planning efforts for its foreign offices since we last reported on them in 2010. For example, FDA has standardized how the foreign offices relay information about their activities. Specifically, each foreign office now completes an annual operational plan—updated quarterly—to ensure their activities are consistently reported and to facilitate tracking the outcomes of their efforts. Foreign office officials said that they worked closely together to align the core activities listed in the operational plans with OIP's strategic goals to improve officials' understanding of how each foreign office contributes to fulfilling OIP's mission of helping protect public health. For example, the plans include examples of activities related to data gathering, analysis, and information sharing, which support one of OIP's strategic goals of collecting and sharing intelligence and information. Officials said they use the operational plans to track whether the foreign offices' annual accomplishments are fulfilling OIP's goals, and noted that having a common operational plan across the offices allows for a common language amongst officials when discussing their efforts.

In addition, FDA officials noted they have taken the step of convening the foreign office directors and deputy directors at FDA headquarters at least once a year since 2010 to discuss their ongoing efforts and exchange best practices with each other, with the most recent convening occurring in April 2016. FDA officials also said that communication between the foreign offices and other FDA offices, including CDER and ORA, has increased over the years. For example, officials told us that OIP management and the foreign office directors and deputy directors have been meeting three times per month to ensure that the foreign offices are obtaining the types of information that would be most helpful in ensuring the safety of drugs entering the United States.

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Since 2010, FDA Has Developed Two Performance Measures, but They Do Not Meaningfully Assess the Foreign Offices' Contributions to Drug Safety

FDA has begun to take steps in response to two recommendations we previously made to enhance the agency's strategic planning for the foreign offices. Specifically, we recommended in 2010 that FDA develop (1) performance goals and measures that can be used to demonstrate the offices' contributions to long-term outcomes related to imported FDA-regulated products; and (2) a strategic workforce plan for the foreign offices to help ensure that the agency is able to recruit and retain staff with the experience and skills necessary for the foreign offices, and to reintegrate returning staff from overseas into FDA's domestic offices.<sup>46</sup> Since then, OIP has developed two performance measures with established targets—number of inspections conducted by full-time medical product investigators at foreign offices and number of collaborative actions by OIP—that are used to assess the foreign offices' contributions.<sup>47</sup> According to FDA, the agency met its collective targets for these measures for fiscal year 2015.

First, regarding the number of inspections by foreign office staff, FDA set a performance measure in fiscal year 2016 for full-time medical product investigators assigned to the China, India, and Latin America offices for each to conduct 15 medical product inspections.<sup>48</sup> In other words, if there were two medical product investigators assigned to the China office, their target for the year would be 30 medical product inspections. Moreover, according to FDA, this goal applies to not only drugs, but all FDA medical product inspections, including medical devices and bioresearch monitoring inspections. There is not a specific "drug inspection" performance measure, although in practice, foreign office investigators are assigned a specific commodity (for example, food, drugs, or medical devices) to inspect. Depending on the current staffing composition, foreign office investigators could meet their target of 15 medical product inspections by inspecting establishments manufacturing medical products other than drugs.

Although FDA opened foreign offices abroad, in part, to help improve FDA's capacity to conduct foreign inspections, the staff in those offices

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<sup>46</sup>See [GAO-10-960](#).

<sup>47</sup>FDA defines a collaborative action as concrete regulatory and public health actions, or initiatives that contribute toward supporting OIP objectives and outcomes.

<sup>48</sup>The Europe office does not have investigators assigned to its office, although officials said it has assisted with planning for foreign drug inspections that are conducted by investigators based in the United States.

have conducted relatively few drug inspections since fiscal year 2010. Specifically, of the total number of drug inspections conducted between fiscal year 2010 and June 30, 2016 (4,384), investigators assigned full-time to the foreign offices participated in 241 (5 percent) of these inspections. The total number of drug inspections conducted each year by these full-time investigators ranged from 29 to 52, with the India office investigators conducting about two-thirds of the total number of inspections. See table 2 for more information on the number of drug inspections conducted by the foreign offices in India, China, and Latin America.

**Table 2: Total Number of Food and Drug Administration (FDA) Drug Inspections in which Foreign Office Investigators Participated, Fiscal Year (FY) 2010 through June 30, 2016**

FDA Foreign Office	FY 2010	FY 2011	FY 2012	FY 2013	FY 2014 <sup>a</sup>	FY 2015	FY 2016 through June 30, 2016	Total
India office	25	20	28	38	24	17	9	161
China office	8	11	1	11	2	9	15	57
Latin America office	0	0	0	3	4	11	5	23
<b>Total</b>	<b>33</b>	<b>31</b>	<b>29</b>	<b>52</b>	<b>30</b>	<b>37</b>	<b>29</b>	<b>241<sup>a</sup></b>

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

<sup>a</sup>Between fiscal year 2010 and June 30, 2016, FDA conducted a total of 4,384 foreign drug inspections. Foreign office investigators participated in 241 (5 percent) of these inspections.

We previously reported in 2010 that FDA did not have a goal for how many inspections it would like foreign office investigators to conduct—although this has since changed with its inspection targets—but that the agency would like to see overall increases in the number of inspections conducted in both China and India.<sup>49</sup> However, in the case of drug inspections, this goal has not yet been fully realized, as the number of inspections conducted by the India office has decreased since fiscal year 2013 and the number of inspections conducted by the China office has only just reached a new high in fiscal year 2016. We understand and previously reported that the China office had difficulty in obtaining visas from the Chinese government for its staff to deploy overseas for several years, which may have contributed to the low number of inspections conducted by the office during these years.<sup>50</sup> FDA appears to have been

<sup>49</sup>See [GAO-10-960](#).

<sup>50</sup>See [GAO-15-183](#).



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able to overcome this particular challenge in 2014, and FDA officials told us there has been an overall increase in the total number of authorized foreign office staff who can perform foreign inspections since we reported in 2010. Specifically, in 2010 there were four investigators in the China office and three in the India office. As of July 2016, there were 11 of 18 authorized investigators in China, 3 of 13 authorized investigators in India, and 1 of 2 authorized investigators in the Latin America office, although these additional investigators may be conducting inspections of establishments that manufacture other FDA-regulated products, such as food. For example, according to FDA, in fiscal year 2015, foreign office investigators conducted 150 inspections of food establishments; 79 medical product inspections; and 8 veterinary medicine inspections; for a total of 237 inspections.<sup>51</sup> FDA has also authorized 18 additional investigators for its foreign offices that the agency has yet to fill and of which at least 9 are intended to be assigned to performing drug inspections.

Drug inspections may also be conducted by temporary duty staff who are deployed to the foreign offices for 30-, 60-, 90-, or 120-day assignments to, in part, supplement the number of inspections conducted by the foreign offices. From fiscal year 2012, when staff began serving temporary duty in the foreign offices, through June 30, 2016, these staff participated in an additional 105 foreign drug inspections—bringing the total number of inspections in which full-time and temporary foreign office staff participated to 346. (For more information on the number of foreign drug inspections temporary duty staff have performed by year, see app. III.)

Regarding the second measure, collaborative actions, FDA set a target of completing 25 such actions for all of OIP for fiscal year 2016, according to FDA officials. The outcomes of this measure have been tracked internally by OIP since fiscal year 2014, when the measure was first implemented. OIP officials told us they use specific criteria to determine whether an activity qualifies as a collaborative action. For example, activities qualify only if they include collaboration with an external stakeholder or U.S. government agency other than FDA. Similarly, inspections conducted by foreign office investigators are excluded (as these are tracked separately) unless a foreign regulatory counterpart participates in the inspection with

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<sup>51</sup>Of the 237 inspections completed by foreign office investigators in fiscal year 2015, 148 involved full-time foreign office investigators and 89 involved investigators on temporary assignment to the foreign offices.

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FDA staff. In addition, activities are excluded if no tangible deliverable or result was identified. FDA reported exceeding its goal of 25 collaborative actions in fiscal year 2015 by 2, for a total of 27 collaborative actions.

We identified shortcomings with using the collaborative action measure to assess the foreign offices' performances. First, the measure and its target are not unique to the foreign offices. According to FDA officials, this measure applies to all of OIP's offices—both foreign and domestic. When asked about its decision to expand this target to all of OIP, rather than specifically focusing on the foreign offices, officials said that they prefer to adopt a holistic approach to assessing OIP's contributions. However, in adopting this approach, the measure does not reflect the unique contributions of the foreign offices as they are not distinguished from those made by OIP as a whole. Second, the target of 25 collaborative actions for all OIP does not necessarily target actions that are specific to drug safety-related efforts. FDA officials said the efforts could be focused on any commodity regulated by FDA, such as food and medical devices, meaning that the target could potentially be met without performing a single activity related to enhancing drug safety. Third, the measure is not expressed in terms of an end outcome. End outcomes are the results of programs and activities compared to their intended purpose.<sup>52</sup> In this case, FDA's collaborative action measure is not expressed in terms of the foreign offices' purpose of enhancing drug safety. Furthermore, FDA officials—those in the foreign offices who engage in collaborative actions and those at FDA headquarters—acknowledge that it can be difficult to link the results of a foreign office's actions to enhanced drug safety.

Beyond the shortcomings of the collaborative action measure, FDA could not readily cite the overall effectiveness of the offices' contributions, and it has not completed a thorough assessment of their accomplishments, despite the implementation of the two performance measures within the last six years. Standards for internal control in the federal government call for agencies to have control activities that are designed appropriately to (1) conduct top-level reviews of actual performance, (2) review activities at the activity level, and (3) review performance measures and indicators.<sup>53</sup> While the foreign office staff may be engaged in meaningful

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<sup>52</sup>See GAO, *Managing for Results: EPA Faces Challenges in Developing Results-Oriented Performance Goals and Measures*, [GAO/RCED-00-77](#) (Washington, D.C.: Apr. 28, 2000).

<sup>53</sup>See [GAO-14-704G](#).

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activities, the activities cannot be systematically tracked by FDA using the two performance measures currently in place nor, according to officials, does the agency have a process in place to formally assess the offices' contributions. For example, FDA has not systematically tracked how information obtained from the foreign offices, and subsequently shared with FDA's centers and offices, contributed to increased drug safety, as such information would only be tracked if obtained in collaboration with foreign stakeholders. Additionally, FDA's two current performance measures do not capture a range of activities specifically undertaken by the foreign offices that resulted in drug safety related outcomes. Such outcomes could include additional inspections of foreign establishments in their host countries, warning letters to manufacturers in violation of CGMPs, or import alerts for products that appear in violation of FDA regulations. However, we found that the foreign offices were engaging in activities that produced potentially positive outcomes. When asked, FDA officials provided us with the following examples:

- In 2012, the India office discovered that an Indian establishment had manufactured and distributed API from one of its sites without fulfilling FDA's registration requirements. The India office shared this information with FDA's domestic offices and received concurrence to conduct an inspection at the firm's unregistered establishment, along with the firm's establishment that was registered with FDA. Inspections at both establishments revealed significant CGMP deficiencies. As a result, FDA issued a warning letter to the firm emphasizing the deficiencies and criticizing, among other things, its lack of oversight. Both establishments are on import alert.
- In 2013, the India office collected intelligence about an Indian company manufacturing APIs that had been linked to deaths in another country. The company and an affiliate were thought to be manufacturing sub-standard and fraudulent APIs, although FDA could not corroborate this through its own inspections since the U.S. embassy prohibited the agency from doing so due to security concerns. However, the India office followed up with the local government and obtained information about the company's establishments from the local government inspections. The local government in India had found the company not complying with CGMPs. As a result of the India office's intelligence gathering, the company and its affiliate were placed on import alert.

(See app. IV for examples of activities from each foreign office that may have helped ensure the safety of drugs entering the United States.)

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However, positive examples such as these are not systematically tracked as they do not meet FDA's criteria of what constitutes a collaborative action. FDA's exclusion of activities that may enhance drug safety because they must be performed with a foreign counterpart or other U.S. government agency, for example, is not adequate as it does not include accomplishments made exclusively by foreign office staff, and leaves the agency with no reason to track them. While foreign office investigators have participated in for-cause inspections, for example, FDA officials said there is no tracking of the foreign offices' actions that led to such inspections in the first place. Therefore, if foreign office staff collect and share intelligence about an establishment in a host country with domestically based FDA staff that results in an action, which spurs a for-cause inspection or detaining a product at the border, this contribution is not assessed by any performance measure. An internal evaluation completed by FDA's Office of Planning in July 2016 similarly described the need for the foreign offices to make efforts to measure their benefits by recording instances of, for example, shortened recall time, signed FDA-relevant treaties, and other outcome measures. Without tracking how information collected by the foreign offices has resulted in these types of outcomes, FDA does not have reasonable assurance that the foreign offices' activities have helped ensure the safety of drugs entering the United States.

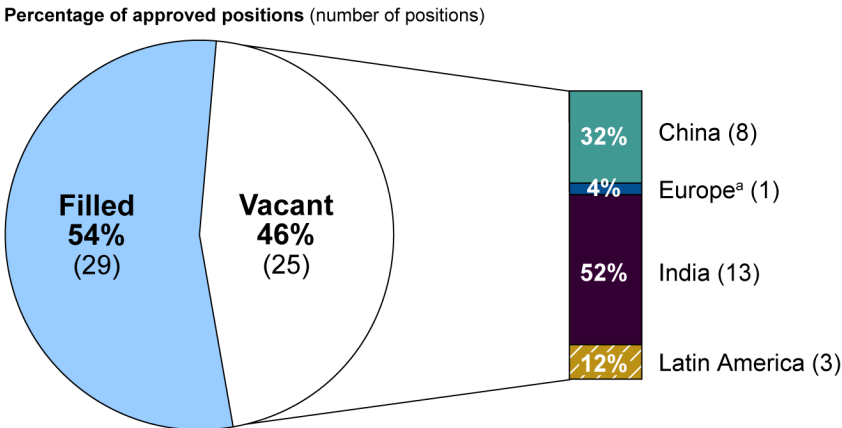
Furthermore, without evidence on the types of outcomes that resulted from information collected by the foreign offices, FDA cannot consider these outcomes and plan accordingly as the agency continues to test new performance measures for the foreign offices. FDA also cannot ensure that it has the correct number of staff deployed with the appropriate skills to perform such activities and enable the foreign offices to help fulfill FDA's mission overseas. FDA officials explained to us that the foreign offices have not existed for very long and that the changes and progress they have undergone since opening have been "remarkable." However, the limitations of FDA's two current performance measures to demonstrate such contributions reinforces the need for FDA to continue exploring new performance measures that will better assess the contributions of the foreign offices. FDA's July 2016 internal evaluation also described the need for OIP to establish performance measures that are aligned with selected outcomes for each foreign office, and that are tracked on a consistent basis to allow for continuous improvement and management oversight. FDA officials said they are considering using five other measures to assess the performance of its foreign offices that are currently included in the foreign offices' operational plans. However, these measures have not yet been adopted. FDA considered these measures

to be in the testing phase for fiscal year 2016, and said it plans to evaluate them in fiscal year 2017.

FDA Continues to Experience High Vacancy Rates in Its Foreign Offices, Limiting Its Ability to Ensure Drug Safety

Persistently high vacancy rates in FDA’s foreign offices threaten to impede the offices’ efforts to ensure drug safety. Our concerns extend back to 2010, when we reported that FDA had experienced challenges in staffing some of the foreign offices. For example, at that time, FDA had 2 vacant staff positions in the Latin America office out of a total of 14 positions (14 percent), and 4 vacancies in the India office out of a total of 15 positions (27 percent). In subsequent years, the number of vacancies in the foreign offices has increased. We later found that these rates were considerably higher—44 percent overall—as of October 2014.<sup>54</sup> This high vacancy rate has persisted. As of July 2016, the foreign offices were authorized to have 54 full-time positions overseas, but 25 of these positions (46 percent) were vacant. The India office has the highest vacancy rate at 68 percent (13 vacancies), followed by the Latin America office at 43 percent (3 vacancies), the Europe office at 33 percent (1 vacancy), and the China office at 32 percent (8 vacancies). (See fig. 4 for an analysis of vacancies by foreign office.)

Figure 4: Filled and Vacant Staff Positions at the Food and Drug Administration’s (FDA) Foreign Offices, as of July 2016



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

Notes: These numbers exclude approved and vacant positions for locally employed staff.  
<sup>a</sup>This number excludes the Europe office’s staff who are based in the United States.

<sup>54</sup>See [GAO-15-183](#).

Across all foreign offices, the position with the greatest proportion of vacancies is international program policy analysts, who analyze the impact of foreign issues on FDA programs and activities (6 of 10 authorized positions are vacant), followed by investigators, who conduct inspections (18 of 33 authorized positions are vacant). (See table 3.)

**Table 3: Number of Authorized and Vacant Positions in the Food and Drug Administration’s (FDA) Foreign Offices, by Office and Position-Type, as of July 2016**

		Director	Deputy Director	Supervisory Investigator	Investigator	International Program Policy Analyst	Total
China Office	Authorized	1	1	2	18	3	25
	Vacant	0	0	0	7	1	8
India Office	Authorized	1	1	1	13	3	19
	Vacant	0	0	1	10	2	13
Latin America Office	Authorized	1	1	0	2	3	7
	Vacant	0	0	0	1	2	3
Europe Office <sup>a</sup>	Authorized	1	1	0	0	1	3
	Vacant	0	0	0	0	1	1

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

Note: The Europe office has three staff members authorized to work overseas in Belgium and the United Kingdom: the director, deputy director, and one international program policy analyst. Additionally, the Europe office has two other international program policy analysts and one program support specialist assigned to it who are based in the United States.

Given that one of the reasons for opening the foreign offices was to conduct inspections, the large number of vacant investigators is concerning. FDA officials have stressed that there are significant benefits to having investigators stationed overseas. For example, officials noted that foreign office investigators can remain at an inspection site longer, if necessary, as they are not limited by travel arrangements to return to the United States. They can also initiate for-cause inspections more quickly than their domestic counterparts, as they are already in country. Former foreign office staff that we spoke with noted that the ability of foreign office investigators to conduct inspections quickly in response to emergencies is a great advantage of having FDA offices overseas. Former foreign office staff also said that it was valuable for investigators to be able to focus on their host country’s manufacturers, and to better understand how they satisfy CGMPs or their difficulties with doing so.

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FDA acknowledged that recruiting and hiring staff for OIP, especially for the foreign offices, can be challenging, but that it is critical for achieving FDA's global mission. FDA's Office of Planning recently proposed a process for selecting foreign office locations and determining the correct mix of staffing and position types for them. However, the Office of Planning's proposal did not contain suggestions for overcoming high vacancy rates in the foreign offices. OIP has yet to implement this proposed process. OIP officials based in the United States and in the foreign offices cited several factors contributing to the foreign offices' persistently high vacancy rate. Although some of these factors may be beyond the agency's ability to resolve, others are issues we cited in our 2010 and 2015 reports that continue to challenge FDA.<sup>55</sup> Specifically, FDA officials said the following factors contribute to FDA's difficulty in filling its full-time positions overseas:

- Length of time to be cleared for deployment: Officials estimated that it takes approximately 9 to 12 months to complete the overseas deployment process, which includes, among other things, obtaining the appropriate security clearance for the employee, as well as medical clearances for the employee and any dependents who will be accompanying the employee overseas. Former foreign office staff that we spoke with confirmed that the deployment process could be quite lengthy, and two former staff specifically mentioned experiencing challenges navigating the process. We reported on these challenges in both 2010 and 2015.<sup>56</sup> FDA officials explained that there is little they can do to expedite this timeframe given the length of time involved to obtain necessary security and medical clearances required to work abroad. Furthermore, the process involves other government stakeholders, such as the Department of State, which is responsible for the medical clearances, limiting FDA's ability to control the deployment timeframe.
- Reintegration into FDA's domestic offices: Our discussions with former foreign office staff who have since returned to FDA's domestic offices or left the agency following their time spent overseas confirm that challenges reintegrating into FDA persist. For example, some former foreign office staff reported having to find a job in a domestic office on their own, or who faced considerable uncertainty about what their new role in the agency would be. Several also noted that the

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<sup>55</sup>See [GAO-10-960](#) and [GAO-15-183](#).

<sup>56</sup>See [GAO-10-960](#) and [GAO-15-183](#).

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skills they developed abroad were not being leveraged, and indicated that there was no effort by FDA management or OIP to debrief them upon their return. For example, a former policy analyst said he developed a unique set of skills for working with foreign regulators on potential drug safety issues that were no longer being leveraged by the agency once he returned to a domestic position. A former investigator, meanwhile, said he had developed a unique set of skills for determining whether establishments were falsifying their records, but it was unclear how he could best share these skills with other investigators upon his return to the United States. We reported on concerns about such challenges in both 2010 and 2015, and recommended in 2010 that FDA develop a strategic workforce plan to, in part, help ensure that the agency was able to reintegrate returning foreign office staff into FDA's domestic offices. FDA developed and finalized such a plan in 2016, and prior to this implemented a formal reintegration policy in 2015. However, FDA officials have not been formally debriefing returning foreign office staff. Of the 13 former foreign office staff we interviewed, only 3 of them reported being debriefed by OIP. When asked why OIP has not debriefed with returning foreign office staff, FDA officials said that they are developing a formal exit interview process for returning staff to be implemented in fiscal year 2017. However, officials also said that the offices are still "young and evolving," despite having been in operation for eight years. These challenges may discourage FDA officials from applying for a foreign office position and thus contribute to the foreign offices' vacancies.

- Financial concerns: Our discussions with former foreign office staff also show that financial concerns with working overseas persist. For example, FDA staff posted overseas do not receive locality pay, so staff may have a reduction in their purchasing power when they are assigned to a foreign office.<sup>57</sup> However, staff at certain locations may

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<sup>57</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. We previously reported that FDA officials said that HHS was considering locality pay to overseas staff. When asked for an update on this effort, FDA officials said HHS is still in the process of examining whether to do so. Notwithstanding the possibility that certain compensation adjustments and subsidies may be made for their benefit, the fact that FDA overseas employees do not receive locality pay increases concerns for individuals considering overseas employment.



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receive hardship pay, a cost of living adjustment, and other benefits.<sup>58</sup> We reported on this challenge in 2010.<sup>59</sup> Additionally, staff may experience an increase in pay when they move overseas and may receive a promotion while abroad, but such pay increases and promotions are considered temporary and staff must return to their original salaries and roles when they return to the United States. Some former foreign office staff said that these temporary promotions were disincentives to working overseas. When asked about this issue, FDA officials said they are considering how the agency might be able to make the promotions permanent by taking into account experience gained while working overseas.

- Environmental and security concerns: FDA has noted that some of FDA's foreign offices are in countries that make recruitment difficult due to environmental concerns (such as poor air quality) or security concerns (such as dangerous locations). Although hardship pay accompanies some of these places, staff may still be hesitant to live in these locations for extended periods of time. We reported on this challenge in 2010.<sup>60</sup>
- Personal reasons: Officials said that personal reasons affect the willingness of staff to spend time living overseas, such as whether spouses will be able to find a job abroad and concerns about the educational opportunities available for their children.
- Unfamiliarity with FDA's global mission: According to FDA officials, some FDA staff do not fully understand FDA's global mission and the importance of FDA's presence overseas. Over the years, FDA has been transforming from a domestically focused agency operating in a globalized economy to an agency operating in a regulatory environment that functions across borders. FDA noted that some agencies, such as the Centers for Disease Control and Prevention, have a longstanding foreign presence. In contrast, FDA's foreign posts are still relatively new, which presents a number of challenges, the agency noted. FDA officials described some of their recruitment

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<sup>58</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. In October 2016, FDA officials said that they are considering other incentives, including incentive pay, for eligible foreign office employees.

<sup>59</sup>See [GAO-10-960](#).

<sup>60</sup>See [GAO-10-960](#).

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efforts aimed at educating staff about its increasingly global mission. For example, the foreign offices have published blog postings highlighting the activities of their offices overseas and how they contribute to FDA's mission. FDA officials also told us they have met with selected FDA staff located across the country to advocate foreign offices as career considerations.

Another step FDA has taken to help reduce its vacancy rates in its foreign offices is to encourage staff to apply for a temporary duty rotation of 30-, 60-, 90-, or 120-days. In addition to helping the offices fulfill their mission, according to FDA, these rotations are a recruitment mechanism that allows staff to experience working overseas in the hope that they will eventually apply for a full-time position in a foreign office. Since 2011, 37 FDA staff have completed at least one drug-related temporary rotation in an FDA foreign office—some of these people completed more than one rotation. Of these 37 staff, 9 (24 percent) went on to work in a full-time position overseas.

In addition, to address these challenges, OIP finalized its strategic workforce plan in March 2016.<sup>61</sup> The plan offers a strategic and long-term view of the challenges OIP faces, and addresses the agency's plan to recruit, hire, retain, and develop employees with the skills and abilities to fulfill the agency's global mission, consistent with a recommendation we made in 2010.<sup>62</sup> We previously recommended that FDA develop a strategic workforce plan to help ensure that the agency was able to recruit and retain staff with the experience and skills necessary for the foreign offices, and to reintegrate returning foreign office staff into FDA's domestic offices. The plan outlines OIP's activities, performance measures, and timeline for addressing its workforce planning challenges. The activities are categorized by specific focus areas and include, for example, developing a hiring strategy, ensuring that employees separating from the agency participate in exit surveys to determine actions for improving retention, establishing a succession plan for anticipated vacancies, and working to maximize a returning foreign office employee's new skill set from his or her deployment.<sup>63</sup> FDA's workforce plan also addresses reintegration challenges and determining how the

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<sup>61</sup>OIP has since updated its workforce plan in August 2016.

<sup>62</sup>See [GAO-10-960](#).

<sup>63</sup>The specific focus areas are (1) recruitment and hiring, (2) retention, (3) acclimation, (4) training and development, (5) deployment, (6) succession, and (7) reintegration.

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agency can better leverage the skills staff develop while working abroad, which reflects concerns expressed to us by former foreign office staff. For example, one activity in the workforce plan is to evaluate FDA's new reintegration policy, which the agency issued in 2015, to determine whether it can be made more strategic and career enhancing for overseas deployment. Given that this plan has been recently developed, FDA has yet to evaluate it, but plans to do so in fiscal year 2017, and, if necessary, revise the activities or performance measures specified in the plan.

We reviewed OIP's workforce plan and identified concerns with some of the six performance measures OIP developed for the focus areas it plans to assess first.<sup>64</sup> For example, the recruitment and hiring performance measure calls for OIP to reduce its vacancy rate by 5 percent—taking it from 32 percent (its vacancy rate at the conclusion of fiscal year 2015) to 27 percent at the beginning of fiscal year 2017. However, this goal is not targeted to the vacancy rates in the foreign offices. Instead, the measure targets the OIP-wide vacancy rate. As of July 2016, OIP's domestic offices had a vacancy rate of 34 percent, in contrast to the foreign offices' collective vacancy rate of 46 percent. Because the 5 percent reduction to OIP's vacancy rate is a combined goal for both domestic and foreign offices, OIP could theoretically hire 8 new staff members in its domestic offices and achieve its goal without reducing any vacancies in the foreign offices.<sup>65</sup>

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<sup>64</sup>The workforce plan includes six performance measures for select focus areas. Officials told us the performance measures may change upon assessment. Currently, the six performance measures (and their accompanying focus area) are (1) reduce the OIP vacancy rate by 5 percent from the baseline of 32 percent by the end of fiscal year 2016 (recruitment and hiring); (2) revise and implement a new employee orientation program by the second quarter of fiscal year 2017 (acclimation); (3) refine and document an acclimation program specifically for foreign assignments by the second quarter of fiscal year 2017 (acclimation); (4) evaluate and measure deployment processing time, monitor quarterly, and identify trends and areas for improvement that is within OIP's control, by the first quarter of fiscal year 2017 (deployment); (5) develop a system for tracking deployments by the third quarter of fiscal year 2017 (deployment); and (6) develop a concept paper on how FDA can better utilize the skills of employees returning from an overseas appointment by the first quarter of fiscal year 2017 (reintegration).

<sup>65</sup>The workforce plan calls for a 5 percent reduction from the baseline vacancy rate of 32 percent (at the end of fiscal year 2015) to a vacancy rate of 27 percent. However, we based our calculations off of the most recent vacancy data available (as of July 2016), from which we found that OIP's vacancy rate had increased to 38 percent. Keeping consistent with the goal of a 5 percent reduction to the vacancy rate, our calculations were based off of a new goal of a 33 percent vacancy rate.

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Meanwhile, the development of a concept paper on how FDA can better leverage the skills of employees returning from overseas, intended as the reintegration performance measure, is a positive step, but it does not constitute a performance measure. It may serve as a guide, but it does not measure FDA's outcomes in this area. Some of the other performance measures identified by FDA also do not measure outcomes. For example, the implementation of a new employee orientation program may help new foreign office staff better acclimate to their new positions, but such a program does not measure outcomes in this area.

A final concern with the workforce plan is that it does not take into account the recommendations of the 2016 internal evaluation of the foreign offices or the summaries of the operating states and workforce compositions of the China, Europe, India, and Latin American offices that were completed in 2014. For example, the workforce plan does not reflect the recommended foreign office staffing and position types specified in the 2016 evaluation, or address how these specifications might be achieved.

We have previously reported on the importance of workforce planning, which is utilized by agencies to align their workforce with current and emerging mission and program goals, and develop long-term strategies for acquiring, developing, and retaining staff. Workforce planning helps agencies think strategically about how to put the right people with the right skills in the right places at the right time. We have previously identified key approaches for effective strategic workforce planning. These approaches may vary with each agency's particular needs and mission, but should share certain principles, such as identifying skills and competencies to fill critical workforce gaps and the strategies needed to recruit them; developing specific strategies that are tailored to address gaps in number, deployment, and alignment of human capital; and monitoring and evaluating the agency's progress toward its human capital goals.<sup>66</sup> Similarly, federal internal control standards require agencies to establish and operate monitoring activities, evaluate results, and remediate deficiencies on a timely basis—which could be done when staff are returning from overseas deployments.<sup>67</sup> Without a specific focus on reducing the number and types of foreign office vacancies, OIP may find it difficult for the foreign offices to fulfill their mission. Furthermore, by not

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<sup>66</sup>See [GAO-04-39](#).

<sup>67</sup>See [GAO-14-704G](#).

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focusing specifically on the foreign offices' vacancies by position type. FDA may be missing an opportunity to determine why particular positions are more difficult to fill than others and take appropriate action in response.

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## Conclusions

The United States' increasing dependence on global markets has been challenging for FDA. The rapid pace of globalization has complicated the agency's efforts to ensure the safety of our drug supply. Our concerns with FDA's response to globalization go back two decades. In that time we have made multiple recommendations to help the agency tackle this challenge. The enactment of FDASIA also provided the agency with new flexibility to help FDA cope with the growth of drug manufacturing overseas. To its credit, FDA has made important strides. It has implemented some of our 2008 and 2010 recommendations and is taking steps to address others. FDASIA has further enhanced the agency's efforts. To date, FDA has increased the number of foreign drug inspections, improved information on foreign establishments manufacturing drugs for the U.S. market, and opened offices overseas.

While FDA has made progress on some fronts, it has been incremental on others. FDA is now using a single risk-based model to select domestic and foreign establishments to inspect so that those that pose the greatest risk are prioritized for inspection, but the agency still lacks inspection history on approximately 33 percent of foreign establishments. While FDA has a plan to fill this knowledge gap over the next few years, this is an issue it has been aware of since at least 1988. Given the longevity of this issue, it will be important for the agency to fully execute its plan to inspect those remaining establishments for which it has no inspection history over the next three years.

FDA has also made progress in its strategic planning for the foreign offices, but despite these efforts, the agency has yet to determine whether the foreign offices meaningfully contribute to drug safety, because FDA has no formal process for assessing the offices' contributions. In 2008, the agency determined that opening foreign offices was an instrumental part of its response to globalization. Our recommendation that FDA develop performance goals and measures for these offices followed in 2010, two years after the first office was opened. We believe this recommendation has not been fully implemented. The two performance measures currently used to assess the foreign offices do not fully capture the specific contributions these offices have made. While FDA officials shared examples of the foreign offices' accomplishments, they do not systematically track such information, nor

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have they fully assessed the extent to which the offices are helping to ensure drug safety. We believe it is important for FDA to track these types of results-oriented outcomes, and for the agency to determine how their performance measures—whether the existing ones or those currently being tested—can be used to demonstrate such results. Having performance measures that demonstrate results-oriented outcomes will better enable FDA to meaningfully assess the foreign offices' contributions to ensuring drug safety.

FDA should also consider including an examination of the appropriate staffing levels for its current foreign offices in its assessment of them. FDA's internal evaluation proposed a process for determining the correct mix of staffing and position types for the foreign offices, but as OIP has yet to implement and apply the process to the foreign offices, such an examination has not yet been completed. While the agency's progress overseas may be aggravated by the difficulties it faces in decreasing their vacancy rates, the agency must determine what outcomes it is working to achieve through these offices and then consider the appropriate staffing to reach those goals. Regardless, the current overall foreign office vacancy rate of 46 percent could easily undermine even the best strategic plan and precludes the offices from being as effective as possible. As we also recommended in 2010, FDA has now completed a strategic workforce plan for the foreign offices to help ensure that the agency is able to recruit and retain staff with the necessary experience. We recognize the value of the completion of this plan. However, FDA has not fully addressed our recommendation, because some of the reasons for the high vacancy rates in the foreign offices are not addressed. While FDA may not be able to address some of these reasons, such as time to deployment, it is all the more important that it addresses those within its span of control, such as addressing the financial concerns raised by staff and discussed in our 2010 report, as doing so may contribute to a decrease in its foreign office vacancy rate. It is also imperative that FDA fully implement its new reintegration program as outlined in the plan. The difficulties staff have experienced upon their return to domestic positions is one that former foreign office staff repeatedly shared with us when we prepared this and our 2010 reports. While the workforce plan contains goals and measures, the plan circumvents the high foreign office vacancy rate, rather than directly tackling it, by targeting a 5 percent reduction in OIP vacancies overall, rather than applying this goal exclusively to the foreign offices. The plan also does not target vacancies by specific position types. In essence, the current goal targeting OIP vacancies overall obscures the underlying challenges the agency faces of staffing people overseas and for particular positions. Without targeting the foreign

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offices specifically or the types of positions most likely to have vacancies, FDA will not have a meaningful measure reflecting its true staffing position overseas.

FDA's response has been, in part, that the offices are still new and evolving, and it is too soon to expect more than it has already accomplished. We believe sufficient time has elapsed for the agency to address its remaining challenges. Otherwise, given their significance, FDA may not know the extent to which its foreign offices are actually assisting the agency in its efforts to ensure drug safety.

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## Recommendations for Executive Action

To help ensure that FDA's foreign 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 as the agency continues to test performance measures and evaluate its OIP strategic workforce plan:

1. Assess the effectiveness of the foreign offices' contributions by systematically tracking information to measure whether the offices' activities specifically contribute to drug safety-related outcomes, such as inspections, import alerts, and warning letters.
2. Establish goals to achieve the appropriate staffing level for its foreign offices, which would include separating foreign office vacancies from the OIP-wide vacancy rate, and setting goals by position type.

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## Agency Comments and Our Evaluation

We provided a draft of this report to HHS for comment. In its written comments, reproduced in appendix V, HHS concurred with our two recommendations and said it is taking immediate steps to address them. For example, starting in fiscal year 2017, FDA plans to conduct internal reviews of its foreign offices' performances annually, review the offices' programs and efforts at the activity level, and review performance indicators. To accomplish this, HHS said that OIP has recently hired two designated full-time employees to work on strategic planning, operational plans, and performance measures. HHS also said that OIP plans to, among other things, adjust its performance measures to track the foreign offices' measures separately from its domestic offices, and characterize the offices' contributions by type of commodity, including drugs. Additionally, HHS said that OIP's strategic workforce plan will be updated to reflect the disaggregation of performance measures that track foreign office vacancy rates and targets by position type. Furthermore, FDA said it is developing recruitment, hiring, retention, and reintegration strategies

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to enable the agency to utilize the unique experiences that foreign office employees develop overseas. HHS also provided 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 Secretary of Health and Human Services and the appropriate congressional committees. In addition, the report will be available at no charge on the GAO website at <http://www.gao.gov>.

If you or your staff have any questions about this report, please contact me at (202) 512-7114 or [crossem@gao.gov](mailto:crossem@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 VI.



Marcia Crosse  
Director, Health Care



# Appendix I: Types of Foreign Drug Establishment Inspections Conducted, Fiscal Year 2010 through June 30, 2016

**Table 4: Food and Drug Administration's (FDA) Foreign Drug Establishment Inspections by Type of Inspection, Fiscal Year (FY) 2010 through June 30, 2016**

Type of Inspection	FY 2010	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016 through June 30, 2016	Total
Surveillance	132	271	351	339	476	527	335	<b>2,431 (55%)</b>
Preapproval/surveillance	260	257	253	258	267	250	101	<b>1,646 (38%)</b>
Preapproval	44	24	17	25	13	23	43	<b>189 (4%)</b>
For-cause <sup>a</sup>	4	7	4	14	23	42	24	<b>118 (3%)</b>
<b>Total</b>	<b>440</b>	<b>559</b>	<b>625</b>	<b>636</b>	<b>779</b>	<b>842</b>	<b>503</b>	<b>4,384</b>

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

<sup>a</sup>This row includes any inspection that included a "for-cause" component. For-cause inspections are conducted to investigate consumer complaints, reports of product quality defects submitted by consumers or health care professionals, or indications of potential manufacturing problems submitted by the manufacturers themselves, among other reasons.

# Appendix II: Drug Establishments that the Food and Drug Administration May Never Have Inspected

**Table 5: Drug Establishments in the Food and Drug Administration's (FDA) Fiscal Year 2017 Catalog That May Never Have Been Inspected, by Country**

	Establishments	Establishments that may never have been inspected <sup>a</sup>	Percent of establishments that may never have been inspected
India	572	189	33%
China	535	243	45%
Germany	191	25	13%
South Korea	171	154	90%
Canada	166	45	27%
Japan	162	36	22%
France	146	35	24%
Italy	146	23	16%
United Kingdom	136	37	27%
Switzerland	89	10	11%
All other countries	709	194	27%
<b>Foreign total</b>	<b>3,023</b>	<b>991</b>	<b>33%</b>
<b>Domestic total</b>	<b>2,026</b>	<b>291</b>	<b>14%</b>

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

<sup>a</sup>This count represents the number of establishments for which FDA could not identify a previous surveillance inspection when FDA compiled its catalog of establishments subject to inspection for fiscal year 2017.

# Appendix III: Number of Foreign Drug Inspections in which Temporary Duty Staff Participated

**Table 6: Number of Drug Inspections in which Temporary Duty Staff Assigned to the Food and Drug Administration's (FDA) Foreign Offices Participated, Fiscal Year (FY) 2012 through June 30, 2016**

FDA Foreign Office	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016 through June 30, 2016	Total
China office	8	7	30	12	22	79
India office	0	1	9	8	8	26
<b>Total</b>	<b>8</b>	<b>8</b>	<b>39</b>	<b>20</b>	<b>30</b>	<b>105</b>

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

Note: Temporary duty staff did not conduct any foreign inspections in fiscal year 2010 or fiscal year 2011. Additionally, the number zero indicates that no drug inspections were conducted by temporary duty staff assigned to the foreign offices in that country in that fiscal year.

# Appendix IV: Efforts by the Food and Drug Administration’s Foreign Offices to Enhance Drug Safety

The Food and Drug Administration’s (FDA) foreign offices have helped ensure drug safety by collaborating with foreign counterparts in their host countries. According to FDA officials, each foreign office had examples of collaborative activities with their respective foreign counterparts that may have increased drug safety. For example, FDA’s China and India offices both conducted workshops on the importance of data integrity for industry representatives and foreign regulators, while the Latin America office sponsored a training session for Mexican regulators on current good manufacturing practices and inspections. See table 7 for examples of activities from each foreign office provided by FDA officials that may have helped ensure the safety of drugs entering the United States.

**Table 7: Food and Drug Administration (FDA) Examples of Foreign Office Activities that May Have Resulted in Increased Drug Safety**

FDA foreign office	Examples of activities related to enhancing drug safety
China office	<ul style="list-style-type: none"> <li>In May 2012, the China Food and Drug Administration requested help from FDA’s China office to verify a list of Chinese language websites selling adulterated dietary supplements and medical products to Chinese and U.S customers. FDA’s China office verified the list of websites supplied by the China Food and Drug Administration and forwarded the information to FDA headquarters. The following month, FDA headquarters sent requests to the companies responsible for managing the websites to take action, which then reported back to FDA headquarters that the websites had been disabled.</li> <li>In January 2015, FDA headquarters provided its China office with information about a biotechnology firm that was manufacturing and distributing counterfeit drugs to various countries, including the United States. FDA’s China office investigated the firm’s website and collected additional evidence demonstrating that the firm was selling counterfeit drugs. In March 2015, FDA’s China office notified the China Food and Drug Administration about the case and provided the foreign regulator with supporting documents and evidence. The case was then brought to the Chinese Public Security Bureau, which seized the counterfeit drugs and money and shut down the site.</li> <li>FDA’s China office led the in-country effort to gather intelligence on establishments that manufactured FDA-regulated products that could potentially be impacted by explosions at two separate chemical warehouses in Tianjin, China in August and October 2015. Screening criteria were put in place for all FDA-regulated products being imported from the Tianjin area. During the period of increased screening, two drug product entries were detected with elevated levels of cyanide. FDA detained and refused the products and alerted the China Food and Drug Administration that the products would be returned to China. Subsequently, the China Food and Drug Administration inspected the manufacturer’s establishment, confirmed cyanide contamination had occurred, and halted production of the products until the contamination was addressed.</li> <li>FDA’s China office has held workshops to educate regulators from China’s Food and Drug Administration and industry about the importance of data integrity. For example, a workshop held in August 2015 had over 1,200 participants. At the conclusion of the training, the China office provided a survey for participants to complete. From the 202 responses the China office received, 54 participants indicated they planned to upgrade their data management software; 21 said they planned to revise their standard operating procedures; and 67 indicated they planned to conduct training on the importance of data integrity to their workforces. To continue to address the need of stakeholders, additional workshops on current good manufacturing practices and good clinical practices are planned to be held throughout China in October 2016 and November 2016, respectively.</li> </ul>

**Appendix IV: Efforts by the Food and Drug  
Administration's Foreign Offices to Enhance  
Drug Safety**

FDA foreign office	Examples of activities related to enhancing drug safety
<b>India office</b>	<ul style="list-style-type: none"> <li>• In 2012, the India office discovered that a drug manufacturer in Western India manufactured and distributed drugs from one of its sites without fulfilling FDA's registration requirements. The FDA India office contacted FDA headquarters and was instructed by FDA to initiate an inspection at both the manufacturer's registered and non-registered sites. The inspections uncovered major deficiencies with current good manufacturing practices, and FDA issued a warning letter to the manufacturer and placed the sites on import alert.</li> <li>• An Indian company manufactured drugs linked to deaths in Pakistan in 2013. For security reasons, the U.S. Embassy in India prohibited an FDA inspection of the facility. Instead, the India office obtained information about the company's facilities from the local Indian government inspection, which had found the facility to be in a poor state of compliance with current good manufacturing practices. Additionally, the owner was found to be involved in significant criminal activities. Both the manufacturer and its affiliate were placed on import alert as a result of the India office's information-gathering.</li> <li>• The India office hosted a workshop for Indian regulators in April 2016 on emerging good clinical practice issues, regulatory updates, and practical approaches to inspectional methods, tools, report writing, fraud detection, and assessment of clinical trial data integrity. The goals of the workshop were for participants to be able to (1) identify general concepts utilized by regulatory investigators when performing inspections of clinical investigators, clinical trial sites and ethics committees; (2) identify techniques for detecting bias and the accuracy of data in clinical trials; and (3) develop evidence and determine the appropriate observations to include in the inspection report. Approximately 60 Indian regulators attended the workshop.</li> </ul>
<b>Europe office</b>	<ul style="list-style-type: none"> <li>• According to the Europe office, a primary focus of the office has been enhancing the exchange of information between the FDA and European regulatory counterparts. One way the office accomplishes this is through the development of a legal infrastructure that permits more expeditious exchanges of information. According to the Europe office, the office has been successful in signing confidentiality agreements with European regulatory agencies, resulting in more than two times the number of such agreements the agency had in place since the Europe office opened. As of May 2016, the Europe office reported FDA had 37 confidentiality agreements encompassing 17 European countries and 6 confidentiality agreements in place with the European Union.</li> <li>• According to FDA, Swiss law bars foreign investigators from doing inspections of drug establishments inside Switzerland. However, FDA investigators can obtain a waiver in order to gain access to Swiss establishments. FDA's Europe office was responsible for working with Swiss regulators to request and approve such waivers for FDA's investigators until 2012. After this time, FDA's Office of Regulatory Affairs became responsible for requesting the waivers, but the Europe office is still the primary point of contact with Swiss regulators if they need more information to approve such waivers.</li> </ul>
<b>Latin America office</b>	<ul style="list-style-type: none"> <li>• In September 2011, FDA conducted an inspection of a Mexican establishment producing drugs and issued a warning letter based on the outcomes of the inspection in April 2012. Prior to issuing the warning letter, the Latin America office communicated with Mexican regulators about the deficiencies found in the inspection. As a result of this information, Mexican regulators suspended the production of several drug products by the manufacturer and issued a recall of one of its products.</li> <li>• In September 2013, the Mexico post of the Latin America office developed and delivered a one-week training session for investigators and compliance officers from Mexico's drug regulatory agency with the purpose of providing instruction on FDA's current good manufacturing practice standards for manufacturers and FDA's inspection techniques. The training included, among other topics, current good manufacturing practices for drugs, establishment inspections, inspection classifications, regulatory actions, and data integrity. Twenty regulatory counterparts (investigators and compliance officers) from Mexico's regulatory agency participated in this training session.</li> </ul>

Source: GAO review of FDA provided foreign office information. | GAO-17-143

# Appendix V: 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

NOV 23 2016

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

Dear Ms. Crosse:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, *"Drug Safety: FDA Has Improved Its Foreign Drug Inspection Program, but Needs to Assess the Effectiveness and Staffing of Its Foreign Offices"* (GAO-17-143).

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

Jim R. Esquea  
Assistant Secretary for Legislation

Attachment

**GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED: DRUG SAFETY: FDA HAS IMPROVED ITS FOREIGN DRUG INSPECTION PROGRAM, BUT NEEDS TO ASSESS THE EFFECTIVENESS AND STAFFING OF ITS FOREIGN OFFICES (GAO-17-143)**

The Department of Health and Human Services (HHS) welcomes the opportunity to review and comment on this draft report. HHS appreciates GAO's recognition of the significant progress that the Food and Drug Administration (FDA or the Agency) has made toward strengthening its foreign drug inspection program and assessing the effectiveness and staffing of its foreign offices, and looks forward to using the report to further strengthen these efforts.

Globalization has dramatically shifted FDA's regulatory landscape. FDA operates in an increasingly complex regulatory environment in which products are produced, manufactured, and travel through supply chains in countries all over the world, many with less developed regulatory systems and capacity than the United States. The number of FDA-regulated shipments at US ports more than doubled in the past 10 years with approximately 17 million shipments of imported food and medical products crossing our borders in 2007, while over 37 million were received in 2016.<sup>1</sup> Over 80% of registered active pharmaceutical ingredient manufacturers are located outside our borders.

Since Fiscal Year (FY) 2009, FDA has consistently increased the number of foreign inspections each year, and in FY 2015 conducted more foreign drug surveillance inspections than domestic surveillance inspections. The Agency has also improved the accuracy and completeness of its catalog of foreign drug establishments. FDA has plans to inspect all establishments with no surveillance inspection history within the next 3 years, and in fact has inspected nearly 10% of those establishments within the latter part of FY 2016. FDA has also strengthened its risk-based site selection model for surveillance inspections. As the draft report notes, these efforts reflect FDA's implementation of the Food and Drug Administration Safety and Innovation Act's (FDASIA) provisions requiring the use of a risk-based approach to prioritize inspection of domestic and foreign establishments.

During the last decade, as threats emerged to the safety and quality of food and medical products imported from outside the US, such as contaminated heparin and pet food containing melamine, FDA established overseas offices to engage more proactively with counterpart regulatory authorities in-country, increase FDA knowledge of the global regulatory landscape, and conduct inspections. The Office of International Programs (OIP) helps to lead and manage FDA's mission globally and oversees the operations of the Agency's foreign offices in China, India, Latin America and Europe. In fulfilling FDA's international mission, OIP consults with FDA Centers and the Office of Regulatory Affairs, and collaborates with governments, industry, and academia in foreign countries as well as with multilateral organizations, to inform FDA's regulatory decision-making and help ensure that food and medical products imported to this country meet US standards.

<sup>1</sup> FDA Operational Administrative System for Import Support (OASIS) Database

**GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED: DRUG SAFETY: FDA HAS IMPROVED ITS FOREIGN DRUG INSPECTION PROGRAM, BUT NEEDS TO ASSESS THE EFFECTIVENESS AND STAFFING OF ITS FOREIGN OFFICES (GAO-17-143)**

In alignment with FDA priorities, the foreign offices focus on the following activities:

1. Establishing relationships with foreign stakeholders, including regulatory counterparts and industry, to facilitate collaborations that streamline and enhance global drug development and regulation;
2. Gathering better information locally on product manufacturing and transport to US ports;
3. Expanding FDA's inspectional capacity to include inspections of FDA-regulated commodities, such as drugs, medical devices, and food products, conducted by investigators based in the foreign offices; and
4. Providing assistance to strengthen the regulatory systems of counterpart foreign agencies to better assure the safety of the products manufactured and exported from their countries to the United States.

In its report GAO acknowledges the significant progress that FDA has made in strategic planning for the foreign offices, including development of standardized operational plans aligned with OIP's strategic goals, the gathering of foreign office and headquarters leadership, and our strengthened communication between foreign offices and FDA Centers and ORA.

The GAO report concentrates on the role of the overseas offices to assure drug safety with a specific focus on drug inspections. However, the overseas offices' roles are much broader than performing drug inspections. All overseas offices' efforts, including inspections, cover all commodities regulated by FDA, such as foods, veterinary products, tobacco and medical products.

While GAO asserts that FDA could not readily cite the effectiveness of overseas office contributions, the report also describes FDA's efforts to capture the contributions of its overseas offices through operational plans that are updated on a quarterly basis and ongoing efforts to develop more quantifiable and outcome-oriented metrics.

Of note, within the past year FDA launched the International Activities Council to provide oversight and guidance on the Agency's global strategic direction, as well as cross-cutting policy and operational direction related to FDA's international efforts in support of its public health mission. This Council, which meets quarterly and is coordinated by OIP, is chaired by the Commissioner, and its membership includes Deputy Commissioners, Center Directors, the Associate Commissioner for Regulatory Affairs and other members of FDA's senior leadership. In addition to the International Activities Council, FDA's foreign offices meet in person at least yearly with FDA Centers and ORA to strengthen collaboration and ensure that OIP can better serve FDA Centers' and ORA's priorities. OIP is exploring ways to further develop collaboration and pre-established information loops with FDA Centers and ORA and to allow for efficient data flow and informed decision-making. In this manner, overseas offices would become aware of evolving Center priorities and, similarly, overseas offices would be able to convey key developments on the ground that might require immediate FDA actions.



**GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED: DRUG SAFETY: FDA HAS IMPROVED ITS FOREIGN DRUG INSPECTION PROGRAM, BUT NEEDS TO ASSESS THE EFFECTIVENESS AND STAFFING OF ITS FOREIGN OFFICES (GAO-17-143)**

GAO's report states that the continued high vacancy rate in FDA overseas offices constrains FDA efforts to implement its global mission, and GAO cites specific factors that hinder OIP's recruitment, hiring, and retention efforts. Since FDA established its first international office in 2008, OIP has had difficulty recruiting and retaining capable, expert, and knowledgeable employees for term appointments at levels needed to fully staff FDA's overseas offices. Recruitment has been hampered by the specialized qualifications and experience needed, unique geographical and environmental challenges associated with international postings, pay discrepancies, and impact on one's family when deployed overseas. For those employees with families, decisions to deploy for two or more years in an overseas office pose additional hurdles and uncertainties, often with financial implications, such as limited opportunities for spousal employment, and eldercare issues, as well as cultural, linguistic and security issues.

In addition to the factors noted by GAO that contribute to FDA's difficulty in filling positions within its overseas offices, FDA faces impediments not mentioned in the report. OIP customarily recruits for its overseas office positions from within FDA and HHS, given the specialized nature of and experience required by the positions. This practice attracts candidates familiar with the Agency, but also creates a situation in which OIP, FDA Centers and ORA compete for a limited pool of experienced, highly skilled individuals. The need for trained and qualified consumer safety officers to conduct inspections has become even more acute following the increase in congressionally-mandated international inspections due to requirements of the Food Safety Modernization Act (FSMA) and the Food and Drug Safety and Innovation Act (FDASIA). International inspections have been increasing under the Prescription Drug User Fee Act (PDUFA) and Generic Drug User Fee Act (GDUFA); these programs include strict timelines for completion, enhancing the value of having highly skilled investigators forward-deployed in countries such as China, India and Latin America. Training of consumer safety officer positions can take up to two years within FDA before personnel can deploy, further limiting the number of available candidates.

Despite these challenges to recruit highly qualified investigators, OIP has been successful in strengthening inspection capabilities in FDA's overseas offices through increased inspections in recent years by overseas offices and by investigators on temporary duty assignments. FDA remains committed to addressing the factors within its control that impede the recruitment, hiring and retention processes, as well as further improving the reintegration process upon completion of an overseas assignment.

**GAO Recommendations**

To help ensure that FDA's overseas offices are able to fully meet the mission of helping to ensure the safety of imported products, GAO recommends that the Commissioner of FDA take the following two actions as the Agency continues to test performance measures and evaluate OIP's strategic workforce plan:

**GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED: DRUG SAFETY: FDA HAS IMPROVED ITS FOREIGN DRUG INSPECTION PROGRAM, BUT NEEDS TO ASSESS THE EFFECTIVENESS AND STAFFING OF ITS FOREIGN OFFICES (GAO-17-143)**

1. Assess the effectiveness of the foreign offices' contributions by systematically tracking information to measure whether the offices' activities specifically contribute to drug safety-related outcomes, such as inspections, import alerts, and warning letters.
2. Establish goals to achieve the appropriate staffing level for its foreign offices, which would include separating foreign office vacancies from the OIP-wide vacancy rate and setting goals by position type.

**HHS Response**

HHS concurs with GAO's recommendations and is taking immediate steps to address them.

FDA is committed to strengthening its monitoring and evaluation approaches to systematically and quantitatively track overseas offices' progress in achieving FDA's mission and objectives, including drug safety-related outcomes. FDA considers this an opportunity to focus resources on strategic priorities, link more explicitly with Center and ORA imperatives, and provide additional evidence of its contributions to FDA's global mission. Starting in FY2017, FDA plans to conduct internal reviews of overseas offices' performance annually, review programs and efforts at the activity level, and review performance indicators, as recommended by GAO. To accomplish this, OIP has recently hired two designated full-time employees to work on strategic planning, operational plans, and performance measures, and will be updating operational and employee performance plans to include these new metrics.

OIP is taking the following steps to address GAO's concerns that OIP's current performance measures do not sufficiently separate overseas offices from headquarters offices, track contributions to drug safety outcomes separately, and link to outcomes. In the near term, OIP is adjusting its performance measures to track overseas office metrics separately, characterize contributions by FDA-regulated commodity including drugs, and develop an indicator framework model, similar to EPA's hierarchy of indicators<sup>2</sup> that will link to OIP's Strategy Map. Under this framework, the number of inspections, import alerts and warning letters (among other outputs), intermediate outcomes, and end outcomes will be systematically collected and analyzed. Since import alerts and warning letters may not correlate directly to public health outcomes, OIP expects to work with Centers and ORA to develop additional measures that incorporate FDA's new preventive focus on food and drug safety and quality, set performance goals where appropriate, track and analyze results, and provide a feedback loop for continuous improvement.

In alignment with GAO's second recommendation, the Strategic Workforce Plan (SWFP) will be updated to reflect recent progress made to disaggregate performance measures that track overseas office-specific vacancy rates and targets by position type. Under its ongoing Strategic Workforce Planning efforts, OIP will further identify mission critical skills, competencies and

<sup>2</sup> See GAO/RCED-00-77 (EPA's Performance Goals and Measures)

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STAFFING OF ITS FOREIGN OFFICES (GAO-17-143)**

performance goals to meet FDA's global needs through positions at foreign office locations. Recruitment, hiring, retention, and reintegration strategies that will enable the Agency to utilize the unique experience that these employees develop overseas are being developed, as are learning and development approaches to address gaps identified in skills and competencies for staff in these positions. As with the overseas office overall performance measures, the updated strategies will be implemented, monitored and evaluated for continuous improvement.

FDA is well positioned to address GAO's recommendations through these efforts and looks forward to working collaboratively across the Agency towards demonstrating drug safety impact.

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# Appendix VI: GAO Contact and Staff Acknowledgments

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## GAO Contact

Marcia Crosse, (202) 512-7114 or [crossem@gao.gov](mailto:crossem@gao.gov)

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## Staff Acknowledgments

In addition to the contact named above, Geri Redican-Bigott (Assistant Director), Kaitlin Coffey (Analyst in Charge), Nick Bartine, George Bogart, Zhi Boon, Muriel Brown, Drew Long, and Michael Rose made key contributions to this report.

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## *Reports and Testimonies*

*Food Safety: Additional Actions Needed to Help FDA's Foreign Offices Ensure Safety of Imported Food.* [GAO-15-183](#). Washington, D.C.: January 30, 2015.

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