# FDA's International Posts:

## *Improving the Safety of Imported Food and Medical Products*


**An FDA field inspector examines imported gingko nuts at a customs warehouse in California. FDA inspectors routinely examine food in facilities like this in the United States, taking samples back to the lab for further testing. By expanding its overseas presence, FDA can better ensure that imported products meet U.S. standards.**

Photo: FDA/Michael Ermarth

Working globally helps the Food and Drug Administration (FDA) better accomplish its domestic mission to promote and protect the public health of the United States. The posting of FDA staff in certain overseas regions is a key part of the agency's strategy for expanding oversight of imported food and medical products. Areas in which FDA is establishing overseas posts include China, India, the Middle East, Europe, and Latin America.

"To do our job more effectively at home, we've got to do our job more efficiently abroad," says Murray M. Lumpkin, M.D., Deputy Commissioner of International Programs at FDA. "What we have is a global supermarket and the products Americans purchase come from all over the world. More foreign facilities are supplying the United States with products, the volume of imported products is increasing, and the supply chains continue to grow in complexity."

An expanded overseas presence allows for greater access for FDA inspections and for greater engagement with foreign industry and foreign counterpart agencies. This all helps to ensure that products shipped to the United States meet FDA standards for safety and manufacturing quality. FDA's Office of International Programs in Rockville, Md., serves as the agency's focal point for all international matters. All of the agency's international offices—whether located overseas or in the United States—work to build stronger cooperative relationships around the world.


Photo: National Lab for Food Safety Testing; Guangzhou, China

**In September, 2009, with the assistance and support of the FDA China Office, FDA's Center for Veterinary Medicine held a conference in Guangzhou, China. In addition to Guangzhou, FDA's China Office includes posts in Beijing and Shanghai. The goals of the office include helping to strengthen Chinese regulatory bodies, increasing FDA inspections, and helping Chinese industry meet and understand FDA standards and expectations.**

## The China Office

In November 2008, FDA opened its China Office with posts in Beijing, Shanghai, and Guangzhou. FDA specialists at the China posts include senior technical experts in foods, medicines, and medical devices, along with inspectors. The opening of the office represents a new era in U.S.–China cooperation on the safety of food, animal feed, and medical products. The goals of this office include working in concert with the regulatory authorities in China to strengthen the capacity of Chinese regulatory bodies, increase FDA inspections, and help Chinese industry understand FDA standards and expectations.

In February 2009, a new food safety law was passed in China, creating a food safety committee and requiring licensure for all food producers, caterers, and retailers, among other provisions. The law also calls for an emergency response plan and a mandatory recall requirement when food doesn't meet standards. In 2007, a memorandum of agreement was established between the U.S. Department of Health and Human Services (HHS) and China's General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ); and between China's State Food and Drug Administration and HHS. These memoranda have specific provisions to help better assure that products exported from China to the United States meet U.S. standards for safety and manufacturing quality.

## The India Office

FDA's staff in the India Office are located in New Delhi and Mumbai. The first FDA employee to the India Office arrived in December 2008 at the U.S. Embassy in New Delhi. The India Office includes senior technical experts covering medicines, foods, and medical devices. The inspectors in Mumbai are based at the U.S. Consulate General and are consumer safety officers with expertise in FDA-regulated product areas.

FDA employees in the India Office are developing relations with foreign counterparts, are involved in inspections of many products destined for the United States, and are actively engaged with other U.S. government entities in India such as the U.S. Department of Agriculture and the Foreign Agricultural Services. The India office will allow FDA to more easily inspect manufacturing and processing facilities in India that are producing goods destined for the United States.

## The Africa and Asia Office

FDA's Africa/Asia office is currently based at FDA in Rockville, Md. This office is responsible for 71 countries throughout Sub-Saharan Africa and Asia—21 in Asia and 50 in Africa. The office does not include the countries of North Africa, which are part of the Middle East office, or the Asian territories of India, China, Hong Kong, Macau, or Taiwan.

This office seeks to work with the national regulatory authorities to build the regulatory capacity of its countries and gain a better understanding of production and transport of products to U.S. ports. A few countries under this office have confidentiality agreements with FDA. These agreements allow both parties to exchange certain types of nonpublic, regulatory, inspectional, or pre-decisional information with each other.

Under the President's Emergency Plan for AIDS Relief (PEPFAR), FDA has been responsible for coordinating a process whereby generic antiretroviral medicines, including formulations for children, have received approvals that certify that they meet the safety and quality standards of products in the United States. Purchasers of products under the PEPFAR program use these so-called "tentative" approvals to guide their purchases. These approvals save many millions of dollars per year and enable millions of people in PEPFAR countries, including those in Africa and Asia, to receive these life-preserving therapies for HIV/AIDS. Antiretroviral treatment usually involves a combination of at least three drugs. This approach can dramatically reduce the number and severity of illnesses associated with HIV infection, and can also improve the duration and quality of life.

### The Latin American Office

FDA staff first arrived at the U.S. Embassy in San Jose, Costa Rica, in April 2009. There is also an FDA office in Santiago, Chile, and some staff work out of FDA in Rockville, Md. Another office in Mexico City will be opening by the end of 2009.

The Latin American Office is responsible for FDA's interactions with Mexico and the countries of Central America, South America, and the Caribbean. As with the other international offices, by working with FDA counterpart agencies in the region, along with the local industry and other U.S. government agencies in the region, the Latin American office aims to ensure that FDA-regulated products that are manufactured or processed from this region and exported to the United States meet U.S. standards of quality and safety.

### The Europe Office

FDA first arrived at its office in Brussels, Belgium, in May 2009. Other FDA staff members are located at the European Medicines Evaluation Agency (EMEA) in London, with plans for an FDA employee to join the European Food Safety Agency (EFSA) in Parma, Italy, in 2010.

FDA has an ongoing, robust collaboration with EMEA in a number of areas. For example, FDA and Europe exchange large amounts of data and reports on various products and firms. A staff person from EMEA will join FDA in the Rockville, Md., location later in the year. The counterpart liaison official from EFSA has already joined FDA.

### The Middle East Office

FDA's Middle East Office is currently based in Rockville, Md. Interactions with the Middle East are important because of the sensitivity of products traded between the United States and Middle Eastern countries. The increased volume of trade in FDA-regulated products is evidenced by the increasing number of Middle East facilities registered with FDA.

The agency plans to open posts in the Middle East, but dates are uncertain at this time. The goals of the Middle East Office are to learn more about the region by working with FDA's counterpart agencies to identify capacity building opportunities.

### The Quadrilateral and Trilateral Office

Operated from Rockville, Md., this office is responsible for FDA's interactions with FDA counterparts in Canada, Australia, and New Zealand. The name of this office comes from two initiatives—the Food Safety Quadrilateral Group between Canada, Australia, New Zealand, and the United States; and the Trilateral Cooperation between Canada, Mexico, and the United States. The emphasis is on sharing regulatory and enforcement information through confidentiality commitments between FDA and counterparts in these countries.

### The Office of Harmonization and Multilateral Relations

FDA's Harmonization and Multilateral Relations Office, operated from Rockville, Md., is responsible for coordinating and collaborating food and drug activities with various international organizations and governments, including the World Health Organization, the international foods standards organization Codex Alimentarius, and the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use. The office coordinates and collaborates on similar harmonization initiatives for veterinary drugs, medical devices, and cosmetics. In partnering with these global organizations and regulators, FDA and its counterpart agencies around the world help to promote public health globally.

This office also handles various other cross-cutting initiatives and pilot programs such as anti-counterfeiting efforts and harmonizing certain global standards. FDA

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This article appears on FDA's Consumer Updates page (*www.fda.gov/ForConsumers/ConsumerUpdates*), which features the latest on all FDA-regulated products.

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