

Ensuring the Safety of Imported Products

Q&A with David Elder



David Elder is the regional operations director in the Food and Drug Administration (FDA) Office of Regulatory Affairs. He manages a team of investigators and analysts that works nationwide to ensure that imported regulated products meet FDA's standards, rules, and regulations.

Since joining FDA in 1988, Mr. Elder has been an investigator, compliance officer, and branch leader, as well as director of the Office of Enforcement.

Q: The number of imported goods that FDA regulates has increased by 35 percent in the past five years. What is FDA doing to ensure the safety of these products?

A: FDA has a team of more than 2,000 scientifically trained specialists who conduct inspections and investigations, collect and analyze product samples, oversee recalls, take enforcement actions, and monitor regulated products coming across our nation's borders.

The agency oversees the importation of the full range of regulated products, including food, animal feed, human and veterinary drugs, vaccines and other biologic products, cosmetics, and medical devices.

FDA electronically screens all import entries and performs more than 100,000 analyses on about 31,000 import product samples annually. During Fiscal Year (FY)

2009, we performed more than 210,000 examinations of imported goods in the field and conducted at least 1,196 foreign inspections.

FDA also administers more than 250 Import Alerts each year that help to prevent the entry of thousands of products that violate the Federal Food, Drug, and Cosmetic Act (FDCA) because they are contaminated, mislabeled, or otherwise not in compliance with the law.

Q: FDA inspects or samples less than 1 percent of all regulated products seeking entry into the United States. Why doesn't the agency do more?

A: The tremendous volume of imports—about \$2 trillion worth of products each year from more than 230 countries—makes it impossible to physically examine every product entering the country. Instead, we use a targeted, risk-based approach.

We work to inspect the right imports—those that may pose a significant public health threat—and take additional preventative actions such as issuing import alerts.

FDA also works cooperatively with U.S. Customs and Border Protection and other agencies to help identify shipments that may pose a threat.

By law, certain information must be submitted to FDA about food products before they are allowed to enter the U.S. This information is collected and analyzed by our Prior Notice Center 24 hours a day, 365 days a year.

This gives FDA advanced knowledge about when and where specific food shipments will enter the U.S., what these shipments contain, the countries and entities where they originate, and the facilities where the food was processed.

So although we don't physically inspect every product, we electronically examine 100 percent of imported food products before they reach our borders. Based on criteria we have set up, an automated system alerts us to any concerns. Then we investigate fur-

ther and, if warranted, do a physical examination of the product.

Also, 100 percent of drug products offered for importation receive an additional level of review by FDA imports personnel to ensure key compliance verification before a drug enters interstate commerce.

Q: How is FDA using technology to improve its inspection capabilities?

A: We're providing our investigators with state-of-the-art inspection tools that can be used in the field to screen products and provide immediate scientific analysis.

Two of these tools are portable devices. One can detect potentially counterfeit drug products. It was developed by the agency's Forensic Chemistry Center and is being used by FDA investigators responsible for screening incoming shipments.

The other device can detect numerous elements, including heavy metals in food and drugs. Many of these elements can be toxic.

Also, we explore existing rapid technologies to adapt them for use in the field—not only for investigators, but also for use in our fixed and mobile laboratories.

Q: How do the mobile laboratories improve FDA's abilities to monitor the safety of imported foods?

A: It's clearly not possible to have a permanent laboratory close to every site from which we collect samples to analyze and investigate. These samples are collected in hundreds of locations. Also, immediate response is a must when it comes to work related to food-associated outbreaks or other emergencies.

Thus we have two mobile labs that we can deploy to areas of interest, including our borders.

Most recently, our microbiology mobile lab was at the southern border to check for bacteria and other pathogens on leafy greens.



FDA mobile lab analysts in Nogales, Ariz., test samples for Salmonella and E. coli.

Our chemistry mobile lab took part in response and recovery associated with the Gulf of Mexico oil spill. Before that, it was deployed to the northern border to examine food samples for pesticides, poisons, and toxins.

Q. What other highlights can you point out in regard to FDA efforts to improve import safety?

A: We're employing a multifaceted approach that includes foreign inspection, partnerships with foreign regulatory counterparts, technical support and outreach, targeted surveillance of imported products, and effective compliance initiatives that include holding importers accountable for introducing safe products to the U.S. marketplace.

Essentially, we want controls to be built in before products reach our borders. As we increase our work with foreign governments—and with our federal partners who may already have a presence in other countries—we want to ensure that there is clarity in regard to FDA standards and expectations.

We want to help other nations develop and improve their regulatory systems and their abilities to support the manufacture and export of safe products.

That's why FDA has established an on-the-ground foreign presence to improve the safety, quality, and

security of agency-regulated products exported to the United States.

There are now FDA Office of International Programs posts in China (Beijing, Guangzhou, and Shanghai); India (New Delhi and Mumbai); Europe (Brussels; London; and Parma, Italy); and Central and South America (San Jose, Costa Rica; Santiago, Chile; and Mexico City).

These posts will help ensure that manufacturers build safety into the products from the beginning, and that FDA has better information about the safety and quality of imported products on which to base admissibility decisions.

FDA also has international staff based in the agency's Maryland headquarters. There are offices there dedicated to Asia/Africa, the Pacific region, and the Middle East and North Africa. It is also the location of our Quadrilateral and Trilateral Office and the Harmonization and Multilateral Relations Office.

In addition to their work with other nations, these offices are engaged in international outreach that includes relationship building, technical assistance, and working collaboratively with other U.S. government agencies.

Additionally, from 2009 to 2010, FDA has engaged in training designed to address specific areas of supply chain safety for foods and medical products. For example, we conducted training in Latin America and China related to aquaculture, veterinary drug residues, current Good Manufacturing Practices, and Good Clinical Practices, among other areas.

So if unsafe products do make it to our ports, our imports entry review, inspections, and sampling at the border will provide a second layer of protection, instead of a first layer.

FDA also has Confidentiality Arrangements with 41 foreign counterpart agencies in 20 countries, as well as with the European Union and the World Health Organization.

These arrangements permit us to share and receive non-public information about imported products.

Q. What is FDA doing to ensure that products from China are safe?

A: FDA's China Office, opened in November 2008, provides information that our experts apply toward assuring that products from that country being sold in the U.S. meet FDA's safety and quality requirements.

The China Office has built strong working relationships with that nation's State Food and Drug Administration and its General Administration of Quality Supervision, Inspection, and Quarantine. FDA collaborates with these agencies on training, including targeted training conducted in key industry sectors. This has helped make China's food safety oversight more robust.

FDA now has investigators deployed in China full time, allowing us to do more food and drug inspections than ever before. This, as we continue to examine imported products on a frequent basis.

In addition, we monitor and report on conditions, trends, and events that may affect the safety and quality of FDA-regulated Chinese products, and collaborate closely with other U.S. government and international agencies in China that work to strengthen product safety.

Q. What can consumers do to help protect themselves from potentially unsafe or ineffective imported products?

A: Consumers need to keep aware about the products they purchase. They need to be wary about buying prescription drug products over the Internet. The safety and effectiveness of drug products cannot be assured when they are bought outside of the control of the U.S. drug supply system. Also, drugs purchased outside the U.S. drug supply

system may be counterfeit.

In addition, people who order foreign drugs online or by mail thinking they are saving money can often get comparable generic drugs in the U.S. for less money.

FDA recommends three specific steps:

- Buy only from U.S.-based and known Internet pharmacies. Consult a reliable source, such as the National Association of Boards of Pharmacies website (at www.nabp.net).
- Do not buy prescription drugs from sites that do not require a prescription or have a pharmacist available for questions
- Always consult your physician before taking any drug products.

Consumers can also stay updated on FDA's Imports Alerts online at www.fda.gov/forindustry/importprogram/importalerts/default.htm.

A good practice is to pay attention to media reports from FDA, the U.S. Department of Agriculture, and other government agencies to make sure you aren't using a recalled product or a product that is the subject of a consumer safety alert.

Also, actively participate in reporting problems with products you purchase. You can learn about this in the Consumer Update, "Your Guide to Reporting Problems to FDA," online at www.fda.gov/ForConsumers/ConsumerUpdates/ucm095859.htm.

Find this and other Consumer Updates at www.fda.gov/ForConsumers/ConsumerUpdates

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