Ensuring the Safety of Imported Products

Q & A with Deborah Ralston

As Director of FDA's Office of Regional Operations, Deborah Ralston coordinates the activities of a team of investigators and analysts located throughout the United States to ensure that regulated products destined for the U.S. market meet FDA's standards. Since joining FDA in 1972, Ms. Ralston has held various positions within the regulatory arena including investigator, compliance officer, and case review and enforcement officer.

Black Star / Michael Falco for FDA

An FDA imports specialist examining hardshell clams harvested in international waters. Laboratory analysis later confirmed the product to be safe.

Q. The number of imported goods that FDA regulates has more than doubled 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 dedicated, scientifically trained specialists who conduct inspections, collect and analyze product samples, do investigations, oversee recalls, take enforcement actions, and monitor the entry of regulated products at our nation's borders. We're responsible for overseeing the full range of FDA-regulated products: human food, animal feed, human drugs, vaccines and other biologics, medical devices, and veterinary drugs.

FDA analyzes about 30,000 import product samples annually. We also performed over 80,000 examinations of imported goods in the field and conducted over 800 foreign inspections during the past fiscal year—from Oct. 1, 2006, through Sept. 30, 2007.

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

A. FDA has been in frequent discussions with Chinese officials. A delegation of senior Health and Human Services and FDA officials visited China in September, and FDA leadership went in October to begin negotiating agreements with our regulatory counterparts. These formal agreements will encourage a greater exchange of information and provide opportunities for

us to collaborate with regulators and industry in China on the science and standards to ensure product quality and safety. This past year, we conducted approximately 30 inspections of manufacturing and processing sites in China for products that FDA regulates.

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

A. Because of the tremendous volume of imports—about $2 trillion worth of products each year from more than 150 countries—we cannot physically inspect or examine every product entering the United States. We use a targeted, risk-based approach, which means that we're working to inspect the right imports—those that may pose a significant public health threat.

For example, we work cooperatively with U.S. Customs and Border Protection to help identify shipments containing potentially dangerous foods and prevent them from entering the country. By law, certain information must be submitted to FDA about food products before they are allowed to enter the U.S. We keep our Prior Notice Center open to receive this information 24 hours a day, 365 days a year. This means that FDA knows in advance when and where specific food shipments will enter the United States, what those shipments will contain, the countries and entities where they originate, and the facility where the food was manufactured.

So although we don't physically inspect every product, we electronically examine 100% 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 further and, if warranted, do a physical examination of the product.

Q. How else is FDA improving 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 feedback so we can do inspections better. One tool that we'll soon be using is a device that can detect counterfeit drug products. It was developed by FDA's Forensic Chemistry Center and will be put to work by FDA investigators responsible for screening international mail.

Another new hand-held device that we're using can detect numerous elements in products, both food and drugs, many of which can be toxic.

We're continuing to explore existing technologies to adapt them for use in the field—not only for investigators, but also for use in our mobile laboratories. We collect samples of products in hundreds of locations, so it's not possible to have a laboratory established in close proximity to every collection site. We do have two mobile labs that can be sent to the borders when needed. Most recently, our microbiology mobile lab has been to the southern border to detect bacteria and other pathogens on leafy greens. And at the northern border, our chemistry mobile lab has looked for pesticides, poisons, and toxins on a variety of food commodities. No contaminated product was found during either deployment.

Q. What else is FDA doing to improve import safety?

A. We're working to shift responsibility to produce a safe product—and, in the case of a drug or device, an effective product as well—to the people who are presenting the product for entry into the United States. We want controls to be built in before products reach our borders. We are planning to increase our work with foreign governments and with our federal partners who may already have a presence in other countries to provide consultation to these governments on FDA standards and science. We want to help them develop their regulatory systems and be able to identify unsafe products so that those products never leave their countries. But if they do make it to our ports, our inspections at the border will provide a second layer of protection instead of a first layer, which is the case for many of them now.

We also have agreements with 31 foreign counterpart agencies in 17 countries that allow FDA to share and receive non-public information about imported products. For example, if the European Union has a problem with an imported commodity, they send us notices. We're able to input that data into our automated systems to learn whether or not we have received any of those products and to make sure that we set up the appropriate controls to ensure that those products don't come into the United States.

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

A. Consumers need to maintain a level of awareness about their purchases. For example, people who order foreign drugs by mail, thinking they are saving money, can often get comparable generics here for less than what they're paying abroad. They're spending more money and the quality of the product is in question.

Pay attention to the media reports that come out from FDA, the U.S. Department of Agriculture, and other government agencies that regulate products for your protection to make sure you aren't using a product that has been recalled. Actively participate in reporting problems with products you purchase.

See "Your Guide to Reporting Problems to FDA" (*www.fda.gov/consumer/updates/reporting_guide061008*).

This article appears on FDA's Consumer Health Information Web page (*www.fda.gov/consumer*), which features the latest updates on FDA-regulated products. Sign up for free e-mail subscriptions at *www.fda.gov/consumer/consumerenews.html*.