FDA's China Offices Focus on Product Safety

More than three years after a series of safety scares involving Chinese exports, officials in the Food and Drug Administration's China office say the Chinese are on their way to developing an infrastructure that better ensures product safety.

FDA also trains Chinese regulators and manufacturers on techniques that promote safety. At a workshop in Zhejiang province, FDA's Daniel Geffin showed Chinese regulators how he inspects equipment used to sterilize canned foods.

Christopher Hickey, Ph.D., who leads FDA's 13-person staff in China, says the agency has trained more than 1,600 manufacturers and regulators on United States safety standards over the past two years.

"The FDA's China office represents a new era in cooperation between the United States and China on the safety of food and medical products," he says.

Michael Kravchuk, who served as deputy director in Beijing until he retired in September, says FDA has built solid relationships with Chinese regulators and exporters since officially opening an office in the capital city of Beijing in November 2008. After a two-year stint in China, Kravchuk says he realized that FDA and their Chinese counterparts are working toward a common goal.

"What I realize is we are all trying to ensure quality products are on the market—regardless of where they are sold. They want to learn how we (approach product safety) and use as many of our techniques as possible," says Kravchuk.

Toward that end, FDA held a hands-on workshop in the cities of Hangzhou and Zhoushan in September. The event included a half-day of classroom instruction and three full days of demonstrations at two plants that process low-acid canned foods—like mushrooms, sardines, artichoke hearts, and tuna.

Hickey says the workshop began with an FDA expert giving Chinese regulators step-by-step instructions on how their U.S. counterparts inspect facilities and products, covering everything from machinery maintenance to container specifications and labeling requirements.

On the second day, the workshop moved to a manufacturing plant where congee, a breakfast food similar to oatmeal, is made and packaged. Workshop participants watched an FDA investigator perform a mock inspection at the facility.

Past Problems

Some consumers have been wary of products made in China since a series of safety scares in 2007 and 2008. That's when contaminants in the blood thinner Heparin, pet food, toothpaste, seafood, and other products caused illnesses and some deaths in the United States and other countries.

The Chinese also suffered the consequences of contaminated products. In 2008, about 300,000 Chinese babies were sickened and six died from infant formula contaminated with the toxic chemical melamine, which is used to make concrete and plastics.

Some manufacturers purposely added melamine to formula because the chemical made it appear that the product contained more protein than it actually had. The incident resulted in numerous criminal prosecutions, and China executed two people connected to the scandal.

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Hickey says the incidents underscored the need for FDA staff permanently stationed in Beijing, Shanghai, and Guangzhou.

"Our primary duties have been to build relationships with FDA's regulatory counterparts and to work with Chinese firms that want to export products to the United States," he says.

The office also aims to increase the number of inspections at manufacturing plants; boost collaboration on product safety with other U.S. government agencies; and monitor events—like an earthquake or other natural disaster—that could affect the safety or availability of FDA-regulated products.

Kravchuk says the China team is making progress, greatly increasing the number of inspections and investigations.

And the team may be getting reinforcements. In his budget proposal for the 2013 fiscal year, President Obama has requested funding that will enable FDA to:

- strengthen its inspection and analytical capabilities by increasing its presence in China by sixteen inspectors and by adding three U.S.-based China analysts.
- broaden the range of its inspections. In addition to inspecting Chinese facilities that manufacture food and medical products for export to the United States, FDA will inspect sites of clinical trials and conduct follow-up inspections to ensure that firms continue to produce and manufacture food and medical products under safe conditions, and that they apply sound production practices.

Global Marketplace

Roughly 24 million shipments of FDA-regulated products were imported into the U.S. in the 2011 fiscal year—from Oct. 1, 2010, through Sept. 30, 2011—from 228 foreign jurisdictions. This represents a fourfold increase over the past decade. This steadily increasing volume of imports has made it more important than ever for FDA to build relationships with regulators and industry abroad, says Murray Lumpkin, M.D., FDA's senior advisor and representative on global issues.

Lumpkin says the foreign outposts give FDA a way to address safety issues before products leave the country of origin.

"By helping other nations develop stronger regulatory systems and helping industry to understand our expectations and realize they will benefit from them, we're also helping ourselves and keeping U.S. consumers safe," Lumpkin says.

In addition to China, FDA now has staff stationed permanently in New Delhi and Mumbai, India; Brussels, Belgium; London; Parma, Italy; San Jose, Costa Rica; Santiago, Chile; Mexico City; Pretoria, South Africa; and Amman, Jordan.

What the foreign offices are doing is a key part of FDA's new global strategy, which focuses on building coalitions with regulators in other countries, according to the FDA report Pathway to Global Product Safety and Quality. Working through these partnerships, FDA aims to develop an information network through which regulators worldwide can share knowledge about criminal enterprises, as well as cutting-edge investigative tools.

Deborah Autor, J.D., FDA's deputy commissioner for Global Regulatory Operations and Policy, says the safety and quality of U.S. food and medical products is facing serious challenges in the era of global supply chains, international trade, and the foreign sourcing and manufacture of regulated products.

"This paradigm change in how FDA regulates will improve the quality and safety of FDA-regulated products and benefit consumers and industry through streamlined regulation and additional assurance of quality and safety," she says.

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