

FDA Provides a Portal to India

The next time you stir black pepper, cumin, chili or cardamom into your stew, think about this: Nearly one quarter of the spices, oils and food colorings used in the United States comes from India. In fact, India is the largest producer, consumer and exporter of spices globally.

But that's not all. India is an important source of trade with the U.S. In 2011, India was the second largest drug exporter and the seventh largest food exporter to the U.S.

The Food and Drug Administration (FDA) works hard to make sure that these India-produced foods and drugs are safe, effective and of good quality.

With offices in New Delhi and Mumbai staffed by technical experts and experienced investigators in food and medical products, FDA maintains close contact with India's government, industries, trade associations, and scientific and academic communities. Consequently, India's officials are better informed about FDA's import requirements and the agency is able to share best practices involving the production of FDA-regulated products.

Such contacts have been especially helpful when unexpected issues arise. "We know who the decision-makers are and who to contact to mobilize a response when problems arise that could affect people at home," says Bruce Ross, FDA's country director in India, who is based in the New Delhi office.

Collaboration Pays Off

Ross cites an event that occurred in March 2012 as an example of the importance of FDA's presence in India. Experts from across FDA



FDA has two offices in India, one in Mumbai and the other in New Delhi.

worked around the clock to find the source of a Salmonella outbreak sweeping the United States. When the source was narrowed to a manufacturer in India, two FDA food investigators from the Mumbai office were dispatched to the facility. After FDA's inspection verified that the tuna product implicated in the outbreak came from the suspect facility and uncovered potential sources of contamination, the Indian government pulled the manufacturer's license, Ross says.

The incident demonstrates that when collaborating with officials in another country and supporting their efforts to resolve problems quickly, there's no substitute for being on the scene, rather than thousands of miles away, Ross says.

Similarly, when contaminated materials were discovered in an intra-

venous product manufactured in India, FDA investigators went to the manufacturing plant and helped identify the source of the contamination. FDA could then issue an import alert to flag the suspect product when offered for input into the U.S.

Ross describes FDA's India office as a portal through which safety information on food and drugs flows back and forth among FDA, the Indian government and industry. "Either we provide answers to their questions or we link them to the right people who can," he says. This relationship is essential when new requirements come along, including those that are part of the Food Safety and Modernization Act (FSMA), currently being implemented by FDA. FSMA requires importers to be responsible for ensuring that foreign suppliers have adequate controls to produce safe food.

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Staff in the India office this year joined a team from FDA’s Center for Drug Evaluation and Research to conduct workshops in four cities on new application requirements for approval of generic drug products and the fees that are tied to agency review of those products. There were more than 270 participants from over 70 companies.

FDA’s India office also shares information gleaned from facility inspections with Indian officials so they can take action to improve product safety and quality. Ross says FDA staff may see the same sanitation- or processing-related problem arising over and over again in different facilities. “We can tell them, ‘Hey, if you would only make these changes, you’ll be able to better ensure that safety and quality standards are being met.’”

Sharing Best Practices

FDA responds to requests from the Indian government to train representatives from industry, agriculture and commerce in agricultural and manufacturing standards and practices used in the U.S. “It’s a very proactive way for us to ensure products imported to the states are safe and meet our standards for quality,” Ross explains.

For example, FDA—working with India’s drug regulators—engaged in training that focused on good clinical practices. This training facilitated and supported the development of an Indian-specific program for the inspection and monitoring of clinical research sites.

And experts from FDA’s Center for Food Safety and Applied Nutrition (CFSAN) partnered with the Joint Institute for Food Safety and



An important source of trade with the United States, India is the source of about one quarter of our spices, oils and food colorings, as well as many of our foods and drugs. An outdoor market in New Delhi displays many colorful spices.

Applied Nutrition (JIFSAN) and the Indian Spices Board in September 2012 to present a week-long training program in Cochin, India. JIFSAN is administered by FDA and the University of Maryland.

More than 70 participants from India’s government, industry, universities and trade groups gathered to learn about effective methods for ensuring food safety for spices and botanicals (plant parts and extracts).

“For the most part, growing spices requires a tropical climate, so we can’t grow many in the U.S. and depend a lot on imports,” says George Ziobro, an FDA research chemist. “Spice production uses many traditional production techniques passed down from father to son. Many of India’s small farmers may not realize that their planting, harvesting, and storing practices can have a profound

effect on public health locally and internationally.”

JIFSAN’s James Rushing, Ph.D., explains, “We use these programs to point out some of the agricultural and industrial deficiencies FDA has observed both at home and abroad.” The message is that preventing contamination is far more efficient and less costly than any remedial action after the fact, he adds. [FDA](#)

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