FDA's Global Shield for American Consumers

The Agency Acts Worldwide to Ensure High Quality Imports

To protect the health of American consumers, the FDA can no longer focus its activities only on products made in the United States. More than 20 percent of all fresh produce, 80 percent of all seafood, and millions of other FDA-regulated products—medications, medical devices, and veterinary products—consumed or used in the United States are **produced abroad.** These imports, whose safety and high standards are also the FDA's responsibility, reached nearly 8 million entries in 2002, and they continue to rise. Over 9 million entries are expected in 2003.

Because the enormous volume and variety of imports make their inspection in the United States difficult, the FDA has developed numerous strategies to ensure that imported products meet the high U.S. public health standards before they leave the exporting country.

These are the FDA's main international programs:

- **Memoranda of Understanding (MOUs).** The FDA has more than 50 MOUs with foreign governments to help ensure that products exported from their countries to the United States meet U.S. public health standards.
- **Inspections.** Each year, the FDA's specialists inspect approximately 1,000 foreign plants that export food, medications and other critical regulated products to the United States to make certain that they follow quality-enhancing good manufacturing practices (GMPs).
- **Training.** The FDA trains its regulatory counterparts in countries that export food and other regulated products to the United States to ensure that the exported products meet U.S. public health requirements.

Keeping Out Hazardous Products

The terrorist attacks on Sept. 11, 2001, heightened the importance of the FDA's role in ensuring that regulated imports do not endanger the health of the U.S. public. As part of its counterterrorism program, the FDA is substantially strengthening its inspection staff in the U.S. ports of entry. The agency is also requesting an authority to take rapid measures in an emergency to protect the public against potentially hazardous imported food. The agency does not hesitate to take action against suspect imports. For example, in recent years the FDA has detained shipments of certain products of animal origin from more than 30 countries whose cattle herds have, or are at a high risk for, bovine spongiform encephalopathy (BSE), the so-called "mad cow disease."

- **Higher international standards.** The FDA is making significant contributions to the efforts of United Nations-sponsored organizations, such as the Codex Alimentarius Commission and the International Organization for Standardization, to raise the standards for food, medical devices and other regulated products worldwide.
- **Harmonization of guidelines.** The FDA has taken the lead in founding four international organizations that combine the efforts of regulatory authorities and industrial associations to harmonize regulatory guidelines for new drugs, medical devices, veterinary medications, and cosmetics.
- **Mutual Recognition Agreements.** The FDA is implementing an agreement under which the FDA and its counterparts in the European Union share inspection reports and other information relating to firms that export pharmaceuticals and medical devices.

For more information, contact the FDA's Office of International Programs at 301-827-4480 or visit the FDA Web site at *www.fda.gov/oia/homepage.htm.*

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