FDA Beyond Our BORDERS

Each year, approximately $2 trillion worth of products enter the United States from more than 150 countries and territories around the world.

The Food and Drug Administration (FDA) regulates a large number of these products and is responsible for ensuring that they meet U.S. standards for safety and quality and do not jeopardize the public health or national security.

The volume of imports regulated by FDA doubled in the last five years and it continues to multiply. This increasingly global economy presents new challenges and growing international work for the agency. To address these challenges, FDA launched an initiative called "Beyond Our Borders."

FDA's Beyond Our Borders initiative recognizes that

- many products come from countries with little ability to provide the regulatory oversight needed to assure the safety of the products exported
- lax oversight in many foreign places presents opportunities for products to be unintentionally contaminated, or intentionally contaminated by those who mean harm, by counterfeiters, or by those who try to profit by "cutting corners"
- working more closely with counterpart agencies in other countries allows FDA to be more efficient and thorough in performing its oversight responsibilities

FDA can better address international challenges to public health and national security by

- increasing collaboration with its foreign counterparts
- learning more about foreign exporters and their products
- providing technical assistance to foreign regulators and industries
- establishing overseas offices within some foreign countries

"Public health challenges know no borders, and public health officials and regulators must work together to address many of the public health and safety issues that confront us today," says Murray M. Lumpkin, M.D., FDA's deputy commissioner of international and special programs.

Increasing Collaboration

In the past five years, the number of FDA agreements with its regulatory counterparts throughout the world more than doubled and it continues to grow. FDA has over 100 formal agreements with its counterparts in 29 countries, 18 with the European Commission or its European Union members, and two with the World Health Organization.

These agreements allow FDA and its counterparts to

- share human, scientific, and investigational resources and knowledge
- share scientific expertise
- promote responsible international standards and regulations

FDA has more than 30 additional agreements with foreign counterpart agencies, many of which allow the sharing of inspection reports and other otherwise non-public information. FDA intends to use these agreements more extensively to obtain information that can help the agency make more informed judgments on the acceptability of products from foreign sources, in prioritizing FDA's foreign inspection activities, and on detaining unsafe products.

"While the agency has partnered with its foreign regulatory counterparts for many years, the Beyond Our Borders initiative is intended to advance and enhance those partnerships in many new ways," says Lumpkin.

For example, through a new pilot program, FDA and its partners in the European Union and Australia are jointly planning and conducting inspections of facilities in certain countries that manufacture the starting materials for many of the drugs taken by Americans, Europeans, and Australians.

Import Safety: A High Priority

International issues and import safety have been a high priority for Mike Leavitt, secretary of Health and Human Services (HHS). Leavitt led an interagency working group that created the Import Safety Action Plan in 2007. The plan supports increased collaboration with trading partners and companies exporting goods to the United States.

HHS also signed precedent-setting Memoranda of Agreements with FDA's counterparts in China to enhance the safety of food, drugs, medical devices, and animal feed imported into the United States from China. These legally binding agreements will build stronger cooperative relationships between U.S. and Chinese agencies, enhance technical cooperation between the agencies, and foster the flow of information between regulatory systems.

As part of these agreements, Chinese counterpart agencies will require registration of products exported to the United States. In addition, the Chinese agencies will work toward a system to certify that FDA standards are met for products before they are exported to the United States.

Learning More About Foreign Exporters

Foreign manufacturers who export FDA-regulated products to the United States must register their company and product information with FDA, but the agency has been unable to verify all of the information provided by the many manufacturers.

FDA is working to enlist the help of non-government organizations to visit the foreign facilities to verify that the manufacturers exist and that they manufacture the products listed in FDA's records.

FDA is also recruiting resources to verify that products made or processed overseas conform to FDA safety standards and requirements before they are imported. These third-party resources may include foreign government agencies and independent organizations that have been officially approved (accredited) by FDA or accreditation organizations recognized by FDA. This verification would complement FDA's own inspections and other regulatory activities.

Providing Technical Assistance

A large portion of the nation's increased trade volume comes from countries with developing economies and developing regulatory authorities. FDA is frequently asked to partner with these countries as their public health and regulatory officials work to enhance their systems. FDA is helping these foreign regulators and foreign industries to understand FDA standards, laws, and regulations.

In addition, FDA is providing guidance to importers in the United States to help them take appropriate steps to ensure the safety of the products they sell.

Establishing Overseas Offices

FDA is working to establish offices overseas in parts of the world where the agency believes a much closer working relationship with its counterpart regulators will help FDA do its work even better.

"The Beyond Our Borders initiative is transforming the map of our workforce," says FDA Commissioner Andrew C. von Eschenbach, M.D. "The posting of FDA staff in overseas regions will greatly expand our oversight of imported food and medical products."

FDA's in-country offices will allow the agency to

- build or further strengthen a trusted regulator-to-regulator relationship
- learn more about the industries and challenges of how products are regulated in these countries
- more easily inspect manufacturing and processing facilities in these countries or determine how FDA can further leverage inspections already performed by its counterparts in certain regions, such as Europe
- have increased interactions with foreign manufacturers to help ensure that products shipped to the United States meet FDA standards for safety and manufacturing quality
- verify that imported products and the way they are manufactured meet U.S. health and safety requirements

In November 2008, Secretary of Health and Human Services Mike Leavitt and FDA Commissioner von Eschenbach opened FDA's first overseas offices in China. China is a major producer and exporter of FDA-regulated products to the United States. FDA's China offices are set up to accommodate eight FDA experts from the United States and five local Chinese nationals. In addition to senior technical experts in Beijing, the U.S. contingent will include inspectors who will work out of offices in Shanghai and Guangzhou.

Other planned locations for FDA offices are India, Europe, Latin America, and the Middle East. FDA's goal is to have directors in place, as well as some staff hired, in most of these regions by the end of 2008.

"By promoting food and drug safety and quality, and helping to raise standards beyond our borders, we can better protect Americans while they continue to enjoy the benefits of the global marketplace," says Lumpkin, "and more importantly, contribute to the overall public health of our global community." FDA

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