

FDA News

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Federal Agencies Issue Draft Guidance for Industry Good Importer Practices

Helping importers ensure their products are safe and comply with U.S. requirements

The U. S. Departments of Health and Human Services, Agriculture, Commerce, Homeland Security, and Transportation and the U.S. Consumer Product Safety Commission, the U.S. Environmental Protection Agency, and the Office of the U.S. Trade Representative today issued draft guidance for industry titled "Good Importer Practices." The guidance is designed to provide guidance to importers on steps they can take to help ensure imported products are in compliance with applicable U.S. statutes and regulations.

"This draft guidance provides importers with recommendations to assist them in preventing or detecting potential problems at critical points along the product's life cycle," said Jeffrey Shuren, M.D., J.D., associate commissioner for policy and planning, U.S. Food and Drug Administration. Recommendations in the draft guidance are designed to anticipate potential sources of product hazards and offer preventive controls firms can implement to mitigate such hazards and help ensure imported products are safe and are compliant with U.S. requirements.

These draft Good Importer Practices are broadly organized under four guiding principles:

1. Establishing a product safety management program
2. Knowing the product and applicable U.S. requirements
3. Verifying product and company compliance with U.S. requirements throughout the supply chain and product life cycle
4. Taking corrective and preventive action when the imported product is not in compliance with U.S. requirements

The draft guidance recommends that importers consider instituting practices to identify and minimize risks associated with imported products. The draft guidance also recommends that, in general, importers should know the producer of the foreign products they purchase and any other manufacturers with which they do business, such as consolidators, trading companies, and distributors; understand the products that they import and the vulnerabilities associated with these products; understand the hazards that may arise during the product life cycle, including all stages of production; and ensure proper control and monitoring of these hazards.

The agencies are issuing this draft guidance to implement recommendations outlined in the "Action Plan for Import Safety: A Roadmap for Continual Improvement," issued by the Interagency Working Group on Import Safety, and to help foster a consistent approach by federal agencies and importers in ensuring the safety of products brought into the United States.

For more information:

[Guidance for Industry – Good Importer Practices Action Plan for Import Safety](#)