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Consumer Law

E-ALERT

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Draft Guidance on Good Importer Practices

On January 12th, 2009, the Food and Drug Administration (FDA) published draft guidance, providing general recommendations to importers on practices and procedures to increase the likelihood that imported products are in compliance with applicable U.S. safety and regulatory requirements.

The draft guidance was developed jointly with other agencies[1] of the federal government as part of the Interagency Working Group on Import Safety. It is intended to cover a wide range of imported products, including food and feed, drugs and biologics, cosmetics, medical devices, pesticides, chemicals and consumer products. Although primarily directed at importers, the draft guidance states that retailers and manufacturers also should carefully consider the recommendations. The stated principles and non-customs-related recommendations are additionally applicable to help ensure the safety of domestically-produced products.

The draft guidance recommends that importers:

- Know the foreign firms that produce the products they purchase and any other firms with which they do business and through which such products pass (*e.g.*, consolidators, trading companies, 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.

To meet these objectives, the draft guidance describes four "guiding principles" and related implementing actions:

1. **Establishing a Product Safety Management Program** - To ensure that the supply chain for imports receives appropriate oversight, importers should establish a "Product Safety Management Program," including an organizational structure to facilitate implementation of the practices recommended by the draft guidance and to ensure corporate responsibility. The organizational structure should include clearly-defined job functions and responsibilities; documented policies and procedures; adequate training; a process to analyze and evaluate risks during a product's life cycle (including conducting risk assessments), appropriate communication mechanisms; and a quality assurance program.

[1] When finalized, the guidance will represent the current thinking of the U.S. Department of Agriculture, Department of Commerce, Department of Health and Human Services (FDA), Department of Homeland Security, Department of Transportation, Consumer Product Safety Commission, Environmental Protection Agency, and the Office of the United States Trade Representative.

2. **Knowing the Product and Applicable U.S. Requirements** - Importers should have a good understanding of the products they are importing, the applicable regulatory requirements, and the compliance history of the products and the firms involved in the products' design, production and handling. The draft guidance recommends that importers know details of the imported product, such as its use, packaging, size, quantity, quality, composition, specifications, safety concerns; whether the product is intended for commercial sale or use in the U.S. or foreign markets; which regulatory requirements apply; and the risks and compliance status and history of the imported products and of the firms that manufacture, distribute, and transport them.

3. **Verifying Product and Firm Compliance with U.S. Requirements throughout the Supply Chain and Product Life Cycle** - Importers should seek to ensure that the product and producer(s) meet all applicable regulatory requirements. Importers are encouraged to undertake significant efforts to control, monitor, and verify product and producer compliance prior to the arrival of the product in the United States, during entry, and while in U.S. distribution. These steps should include assessment of the supplier, resolution of any gaps in the information the importer receives about the supplier, securing a written guarantee of compliance from the supplier and requiring all those involved in the supply chain to provide evidence of compliance. Importers are also encouraged to deal directly with the supplier or the supplier's authorized agent; periodically inspect and audit the supplier; and consider purchasing from certified firms. Importers should additionally establish procedures to trace products from the source to the destination; isolate and hold products; initiate and conduct recalls; and notify distributors, retailers and customers of harmful or volatile products.

4. **Taking Corrective and Preventive Action When the Imported Product or Firm Is Not Compliant with U.S. Requirements** - The draft guidance encourages importers to establish procedures for developing corrective action plans, and for taking corrective and preventive actions. These should include identifying and investigating the root cause of non-compliance with U.S. requirements; taking steps to remediate and prevent harm from present and future shipments and to ensure non-compliance and safety problems do not recur; and working with a non-compliant firm to meet U.S. requirements (or ceasing to do business with that firm).

The draft guidance acknowledges that not all of the recommendations are necessarily applicable to all imports and that some may be impractical for certain small-scale importers. As guidance, the draft does not establish enforceable requirements and importers may use alternative approaches to satisfy applicable laws and regulations. The agencies that developed the guidance believe, however, that those importers who follow the recommendations in the draft guidance "may be less likely to import products that may be harmful to U.S. consumers, and, as a result, may, in some cases, facilitate admissibility determinations, and, therefore, expedite the entry of their products into the United States."

The full text of the draft guidance can be found at http://www.fda.gov/oc/guidance/goodimportpractice.html. Parties who wish to submit comments are encouraged to do so by April 12, 2009.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our consumer law group:

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