FDA and Other Agencies Issue a Draft Guidance for Good Importer Practices

January 21, 2009

On January 13, 2009, the FDA, among other federal agencies, issued a draft guidance for good importer practices. The guidance document provides general recommendations for importers on practices and procedures to increase the likelihood that imported products comply with U.S. safety and security requirements. The draft guidance contains general recommendations, including that the importer:

- Confirm the manufacturers of the product and other firms that handle the product;
- Understand the products imported and potential vulnerabilities associated with these products;
- Understand the hazards that may arise during the product life cycle; and
- Ensure proper control and monitor hazards.

The draft guidance also includes recommendations under four guiding principles, including:

- Establishing a product safety management program;
- Knowing the product and applicable U.S. requirements;
- Verifying product compliance with U.S. requirements throughout the supply chain and product life cycle; and
- Taking corrective and preventive action when the imported product or firm is not compliant with U.S. requirements.

The FDA is seeking comments on the draft guidance by April 13, 2009.

For Further Information

If you have questions concerning the draft guidance or would like more information, please contact Frederick R. Ball, any of the other health law lawyers in the Pharmaceutical & Biotechnology industry group or the attorney in the firm with whom you are regularly in contact.