Modified Import Alerts on Food and Drug Products

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Sandler, Travis & Rosenberg Trade Report

The Food and Drug Administration has more than 250 active import alerts that prevent potentially violative products from entering U.S. commerce by subjecting them to detention without physical examination. Before shipping into the U.S., importers should be aware of whether or not their product is listed on an import alert.

(Click here to register for ST&R’s upcoming webinar on avoiding costs and delays from FDA import alerts.)

FDA import alerts on the following have been modified in the past week.

- soft cheese and soft ripened cheese from France
- juice processors not in compliance with juice hazard analysis and critical control point regulations
- cosmetics containing illegal colors
- cosmetics due to microbiological contamination
- drugs from firms that have not met drug good manufacturing practices
- active pharmaceutical ingredients that appear to be misbranded
- raw agricultural products and processed foods (pesticides)
- food products containing sulfites
- all vegetable protein products from China for animal or human food use (presence of melamine and/or melamine analogs)

Importers of FDA-regulated goods are responsible for ensuring that such imports are in compliance with FDA laws and regulations. Import alerts inform FDA field staff that the agency has enough evidence or other information to allow a product that appears to be in violation of those laws and regulations to be detained without physical examination at the time of entry (e.g., a product contains illegal colors or food additives or a foreign
firm refused an FDA inspection. Import alerts may cover products from designated countries or areas (including from all foreign countries), manufacturers, or shippers.

Firms and/or products on the “red list” of an import alert are subject to DWPE, while firms and/or products on the “green list” are not because they have met the criteria for exclusion. Some import alerts include a “yellow list” of firms, products, and/or countries subject to intensified surveillance because the nature of the violations may warrant further field examinations of individual entries and/or additional analyses. In addition, depending on the specific import alert, shipments of products subject to DWPE may still be imported into the U.S. if the importer has demonstrated that the shipment is in compliance.

If a product is detained without physical examination the importer has the right to provide evidence to the FDA in an attempt to overcome the appearance of the violation. If no such evidence is submitted, or if the evidence provided is insufficient to overcome the appearance of the violation, the product will be subject to refusal of entry into the U.S.

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