Import Alerts on Foods, Drugs, and Medical Devices That May be Detained

July 10, 2018
Sandler, Travis & Rosenberg Trade Report

Food and Drug Administration import alerts on the following have been modified in the past week.

- products from Japan due to radionuclide contamination
- medical instruments from Pakistan
- coconut
- imported food products that appear to be misbranded
- animal feeds other than pet treats
- active pharmaceutical ingredients that appear to be misbranded
- frozen and refrigerated guacamole and processed avocado products
- tamarind products from all shippers from all countries

[Click here for ST&R’s on-demand webinar on how to avoid costs and delays from FDA import alerts.]

Importers of FDA-regulated goods are responsible for ensuring that such imports are in compliance with FDA laws and regulations. Before shipping into the U.S., importers should be aware of whether or not their product is listed on an import alert.

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 FDA laws and regulations to be detained without physical examination at the time of entry. 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.

To get news like this in your inbox daily, subscribe to the Sandler, Travis & Rosenberg Trade Report.