Import Refusals vs Import Alerts

What is the Difference?

Import Refusals result from a **single detention.**

Import Refusals occur when FDA inspects a shipment at its port of entry and determines it is non-compliant. That one specific non-compliant shipment is refused entry into the United States. Once a shipment is refused, it *cannot be undone*, so companies should carefully monitor their suppliers and the quality of products they ship.

Import Alerts result in **continuous detentions.**

Import Alerts occur when FDA notices a pattern of non-compliance from a particular company, country, or product type. All shipments of products listed on an Import Alert are subject to Detention Without Physical Examination (DWPE). Companies on Import Alert can *petition for removal.*

Registrar Corp Services

Detention Assistance
Registrar Corp may be able to obtain release of a detained shipment before it is officially refused.

Label Review
Labeling violations are a top reason products are refused by FDA. Having Registrar Corp review a label can help prevent Import Refusals.

Import Alert Petition
Registrar Corp can help companies petition to be removed from a FDA Import Alert.

HACCP Plan Review
Creating a new HACCP plan is often an effective corrective action when petitioning FDA for removal from an Import Alert. Registrar Corp can help create or review your HACCP plan for FDA compliance.

FDA Compliance Monitor
Registrar Corp's FDA Compliance Monitor allows users to monitor whether their own , or any other company, is the subject of an FDA Import Refusal or listed on a FDA Import Alert.

Additional Definitions

Detention

A detention occurs when FDA holds a non-compliant product and does not allow it entry into the U.S. market. FDA may allow the product to be returned to the shipper, have the product destroyed, or allow the shipper to bring the product into compliance while at its location of detainment.

Recall

A recall occurs when FDA discovers non-compliance after a product is already on the U.S. market. The product is typically removed from the market and consumers who purchased the product are able to return it for a refund.

Warning Letter

FDA may issue a warning letter to a company if it identifies compliance issues during an inspection or investigation. Failure to correct violations described in a FDA warning letter within an allotted timeframe (usually 15 days) can lead to severe consequences, including seizure and injunction.

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