

FDA Compliance Checklist

Required documentation and prior notice rules for food, drugs, cosmetics, and medical devices entering the US.

The US Food and Drug Administration (FDA) regulates a wide range of imported goods. Failure to comply can result in shipment refusal, destruction of goods, or detention at the port of entry. This checklist covers the core requirements every importer of FDA-regulated goods should know.

1. Determine If Your Product Is FDA-Regulated

FDA regulates the following categories commonly seen in imports:

- Food, beverages, and dietary supplements
- Prescription and over-the-counter drugs
- Cosmetics and personal care products
- Medical devices (from bandages to MRI machines)
- Radiation-emitting electronics (including phones and microwaves)

2. File Prior Notice

Most FDA-regulated food shipments require Prior Notice submitted electronically before the goods arrive. Prior Notice must include the product description, manufacturer, shipper, and estimated arrival information. Submitting late or inaccurate Prior Notice is one of the most common reasons FDA shipments are held at the port.

3. Register Your Facility (Food Importers)

Foreign facilities that manufacture, process, pack, or hold food for US consumption must register with FDA under the Bioterrorism Act. Registration must be renewed every two years. Aurora can verify your supplier's registration status before you commit to an order.

4. Confirm Device or Drug Listing Status

Medical devices must have an active FDA establishment registration and device listing. Drugs require an NDC (National Drug Code) and may require a New Drug Application or be marketed under an existing monograph. Unlisted devices or drugs are subject to automatic detention.

5. Common Detention Triggers

Trigger	Typical Cause
Missing Prior Notice	Late or absent electronic filing before arrival
Unregistered facility	Foreign manufacturer not FDA-registered
Mislabeling	Missing required English labeling or nutrition facts
Unapproved additives	Ingredients not approved for use in the US
Device/drug not listed	No active FDA listing on file

Aurora coordinates FDA Prior Notice filing, facility registration verification, and labeling review as part of our import clearance service for regulated commodities. Talk to a broker before your first FDA-regulated shipment to avoid costly detentions.