



U.S. FOOD & DRUG
ADMINISTRATION

Human Drug Imports

FDA protects public health by securing drug supply chain integrity and working to ensure medicines imported to the United States comply with legal and regulatory requirements. Drugs include brand and generic prescription medicines that are approved by FDA, as well as over-the-counter (OTC) medicines and investigational new drugs.

Imported drugs must meet the same standards for quality, safety and effectiveness as drugs made in the United States. To ensure imported drugs meet FDA's standards, the agency reviews shipments of imported drugs to determine whether they are admissible into the United States. If a drug appears to violate any provision of federal law, FDA may refuse the shipment. An imported drug may be refused entry if it appears to be:

- **Adulterated** — Federal law requires manufacturers to comply with quality manufacturing regulations. A drug may be adulterated if, for example, it was not manufactured in compliance with these quality manufacturing requirements.
- **Misbranded** — Proper label information is an important aspect of marketing a drug product, because it gives patients the information they need to take medications correctly. A drug label must comply with FDA regulations. A drug may be misbranded if, for example, its label is false or misleading, it lacks FDA-required information, or otherwise does not follow FDA's label rules. Manufacturers also must register as an establishment and list their drugs with FDA. A drug may be misbranded if a manufacturer has not complied with these requirements.
- **Unapproved** — Drugs must be proven to be safe and effective for use before companies can market them in the United States. A drug that lacks the required FDA-approval is considered to be "unapproved."

FDA examines and analyzes samples of drugs at time of import to ensure they comply with applicable standards and/or label requirements. If missing or inaccurate information is entered and does not match FDA's records, there will be a delay while the agency verifies all requirements have been met. Ensuring the accuracy of data submitted will ensure the timeliness of the shipment release. See the back of this page for details on requirements for various types of imported drugs.

Please see www.fda.gov for more information on the import entry process and the requirements that FDA verifies at the time of import.

Human Drug Imports

Types of imported drugs

- Prescription medicines
- Investigational new drugs
- OTC medicines
- Active pharmaceutical ingredients

Import requirements

FDA verifies compliance with the following requirements as applicable for the imported drug:

- FDA approval
- Registration and listing
- Premarket submission information
- Declared manufacturer
- Declared importer/consignee
- Product description
- Affirmations of compliance
- Intended use codes

Affirmation of compliance codes

Affirmation of compliance codes are three-letter codes that can be provided at the time of import to facilitate FDA review of import requirements. Providing the correct codes reduces the likelihood that shipments will be held for further FDA entry review during FDA's import screening process.

FDA uses these codes to assist in verifying that products meet the appropriate requirements. Affirmation of compliance codes are only mandatory in some instances and are not required for all scenarios. Submitting voluntary affirmation of compliance codes may expedite initial screening and review.

Intended use codes

Intended use codes (IUC) are mandatory for importing drugs. It's important to know the product and why the drug is being imported. See Customs and Border Protection's guidance, "FDA supplemental guidance for the automated commercial environment/international trade data system (ACE/ITDS)," for more information.

Product code builder

The product code builder online tool will guide you through an easy, user-friendly selection process that will assist in locating and building a product code. The product code builder will provide choices for each of the five components of the product code — industry, class, subclass, process indicator code, and product.

Contact

Contact **CDERImportsExports@fda.hhs.gov** with questions about human drug importation. See CBP's guidance, "FDA supplemental guidance for the automated commercial environment/international trade data system (ACE/ITDS)" for more information.