



## Guideline to Importing Into the United States

### ENTRY OF GOODS

- When goods are imported into the customs territory of the United States (the fifty states, the District of Columbia and Puerto Rico), they are subject to certain formalities involving U.S. Customs and Border Protection (CBP) (formerly known as U.S. Customs Service).
- In almost all cases, the goods are required to be “entered,” that is, declared to CBP, and are subject to detention and examination by CBP officers to ensure compliance with all laws and regulations enforced or administered by CBP.
- The entry law, codified at 19 U.S.C. § 1484, limits the right to make entry to the “owner or purchaser” of imported merchandise, or to a licensed “customs broker” who has been appointed by the owner, purchaser, or consignee of the merchandise.
  - As a general rule, an owner or purchaser is someone with a financial interest in the transaction.
- “Financial Interest” in Imported Merchandise
  - Examples of persons with a financial interest in imported merchandise include:
    - The actual owner or purchaser of the goods;
    - A buying or selling agent;
    - A person who imports on consignment;
    - A person who imports under loan or lease;
    - A person who imports for exhibition at a trade fair;
    - A person who imports goods for repair or alteration or further fabrication.
- The formal entry process usually involves two steps.
  - The first is the filing of an entry on Customs Form (CF) 3461, as well as a commercial invoice (or a pro forma invoice when the commercial invoice cannot be produced), packing lists, if appropriate, and such other documentation as is necessary to determine merchandise admissibility. This must be done within 15 calendar days after landing from a vessel, aircraft or vehicle, after receipt under a permit to transfer, or after arrival at the port of destination in the case of merchandise transported in-bond.

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- The second: A follow-up entry summary on CF 7501, with estimated duties attached, must be filed within 10 working days after the time of entry.
  
- Pursuant to the Customs Modernization Act, it is now the responsibility of the importer of record to use “reasonable care” to “enter,” “classify”, and “value” the goods, and provide any other information necessary to enable CBP to properly assess duties, collect accurate statistics, and determine whether all other applicable legal requirements are met.

## **COMPLYING WITH CUSTOMS REQUIREMENTS**

- Only licensed customs brokers may actually prepare and file entry documentation on behalf of others.
  
- Customs brokers are private individuals or firms licensed by the Customs Service to prepare and file the necessary Customs entries, arrange for the payment of duties found due, take steps to effect the release of the goods in Customs custody, and otherwise represent their principals in customs matters.

## **INFORMED COMPLIANCE**

- Informed compliance is a shared responsibility between Customs and the import community wherein Customs effectively communicates its requirements to the trade, and the people and businesses subject to those requirements conduct their regulated activities in accordance with U.S. laws and regulations.

## **ASSESSMENT OF DUTY**

- All goods imported into the United States are subject to duty or duty-free entry in accordance with their classification under the applicable items in the Harmonized Tariff Schedule of the United States.

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## FDA CONSIDERATIONS

- The Food and Drug Administration (FDA) mission is to enforce the Federal Food, Drug, and Cosmetic (FD&C) Act and other laws which are designed to protect consumers' health, safety, and pocketbook. These laws apply equally to domestic and imported products.
- All food, drugs, biologics, cosmetics, medical devices, and electronic products that emit radiation, as defined in the FD&C and related Acts, are subject to examination by FDA when they are being imported or offered for import into the United States.
- All imported products are required to meet the same standards as domestic goods.
- Imported drugs and devices must be safe and effective; cosmetics must be safe and made from approved ingredients; radiation-emitting devices must meet established standards; and all products must contain informative and truthful labeling in English.
- In addition to required entry forms, certain products require specific information to be presented to FDA at time of importation:
  - **Drug and Medical Device Imports**
    - Although it is not a requirement for foreign drug firms to register their establishments, their products must be listed with the FDA.
      - Forms required to obtain a labeler code (FD 2656) and drug list their product (FD 2657) should be requested from the Center for Drug Evaluation and Research, Product Information Management Branch (HFD-058), 5600 Fishers Lane, Rockville, MD 20857.
  - **Drugs are restricted from importation unless** they are covered under an Investigational New Drug Exemption (IND) or by an approved New Drug Application (NDA).
    - Information on regulations covering INDs or NDAs and application forms should be requested from CDER Executive Secretariat (HFD-8), Center for Drug Evaluation and Research, 5600 Fishers Lane, Rockville, MD 20857.
  - **There are several forms that are required to be filed with FDA prior to the importation of medical devices** into the United States.
    - A **premarket notification** or 510(k) submission is required when the following occurs: (a) a foreign manufacturer intends to export a medical device to the U.S. that the firm has never before shipped to the U.S.; (b) either the foreign manufacturer or initial distributor changes the intended uses of devices that are legally being marketed in the U.S.; or (c)

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changes or modifications to a legally marketed device that could significantly affect its safety or effectiveness.

- Detailed information regarding the premarket notification process can be obtained from the following documents: Premarket Notification: 510(k), Regulatory Requirements for Marketing a Device, and 510(k) Review Program.
- All Foreign firms are **required to both register their establishments, and individually list their devices before they may import them into the United States.**
  - Establishment registration is accomplished by submitting a properly completed form FDA 2891 (Initial Registration of Device Establishment).
  - In order to list their devices, establishments must submit a properly completed form FDA 2892 (Device Listing) for each medical device that they are importing into the United States. In addition, establishments must designate a U.S. Agent when submitting their FDA 2891 and 2892 forms.
  - Complete information on registration and listing requirements and processes can be obtained from the [Registration & Listing](#) website, or by contacting DSMICA as described below. Form FDA 2877 (Declaration for Radiation Standard) is required for radiation-emitting electronic products entering the United States.
  - To obtain these above forms, or information concerning premarket notification, radiation control standards, or Device Listing and Establishment Registration contact the Center for Devices and Radiological Health, Division of Small Manufacturers, International and Consumer Assistance ([DSMICA](#)), HFZ-220, 1350 Piccard Drive, Rockville, MD 20850-4307, (800) 638-2041. Manufacturers outside the U.S. should call: (301) 443-6597.

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## **SUGGESTIONS TO THE EXPORTER, FOR FASTER CUSTOMS CLEARANCE**

- Include all information required on your Customs invoices.
- Prepare your invoices carefully. Type them clearly. Allow sufficient space between lines.
- Keep the data within each column.
- Make sure that your invoices contain the information that would be shown on a well prepared packing list.
- Mark and number each package so it can be identified with the corresponding marks and numbers appearing on your invoice.
- Show a detailed description on your invoice of each item of merchandise contained in each individual package.
- Mark your goods legibly and conspicuously with the country of origin unless they are specifically exempted from country-of-origin marking requirements, and with such other marking as is required by the marking laws of the United States.
- Comply with the provisions of any special laws of the United States that may apply to your goods, such as laws relating to food, drugs, cosmetics, alcoholic beverages, radioactive materials, and others.
- Observe the instructions closely with respect to invoicing, packaging, marking, labeling, etc., sent to you by your customer in the United States. He or she has probably made a careful check of the requirements that will have to be met when your merchandise arrives.
- Work with U.S. Customs to develop packing standards for your commodities.
- Establish sound security procedures at your facility and while transporting your goods for shipment. Do not give narcotics smugglers the opportunity to introduce narcotics into your shipment.
- Use carrier participating in the Automated Manifest System.
- If you use a licensed customs broker for your transaction, be sure firm uses the Automated Broker Interface.

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## ADDITIONAL INFORMATION

The web address of U.S. Customs and Border Protection is <http://www.cbp.gov>

For information regarding FDA: [www.fda.gov/ora/import/ora\\_import\\_systems.htm](http://www.fda.gov/ora/import/ora_import_systems.htm)

Customs Regulations are available in the current edition of Customs Regulations of the United States, a loose-leaf, subscription publication available from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402; telephone (202) 512-1800. A bound, 2003 edition of Title 19, Code of Federal Regulations, which incorporates all changes to the Regulations as of April 1, 2003, is also available for sale from the same address. All proposed and final regulations are published in the Federal Register, which is published daily by the Office of the Federal Register, National Archives and Records Administration, and distributed by the Superintendent of Documents. Information about on-line access to the Federal Register may be obtained by calling (202) 512-1530 between 7 a.m. and 5 p.m. Eastern time. These notices are also published in the weekly Customs Bulletin described below.

The Customs Bulletin and Decisions ("Customs Bulletin") is a weekly publication that contains decisions, rulings, regulatory proposals, notices and other information of interest to the trade community. It also contains decisions issued by the U.S. Court of International Trade, as well as customs-related decisions of the U.S. Court of Appeals for the Federal Circuit. Each year, the Government Printing Office publishes bound volumes of the Customs Bulletin.

Importing Into the United States is a publication which provides an overview of the importing process and contains general information about import requirements. The February 2002 edition of Importing Into the United States contains much new and revised material brought about pursuant to the Customs Modernization Act ("Mod Act"). The Mod Act has fundamentally altered the relationship between importers and U.S. Customs and Border Protection by shifting to the importer the legal responsibility for declaring the value, classification, and rate of duty applicable to entered merchandise.

Other Resources: [What Every Member of the Trade Community Should Know About: Customs Brokers](#), US Department of Homeland Security, January 2005. [Importing into the United States, A Guide for Commercial Importers](#), U.S. Customs Service, February 2002.

**Disclaimer: The Nath Law Group provides this guideline for informational purposes only. It should not be relied upon in any way nor does it constitute legal advice regarding the topics covered. Be sure to consult appropriate experts or research these issues independently.**

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