

Chapter 9

IMPORT OPERATIONS AND ACTIONS

Note: Chapter 9 (Rev. 2002) is currently under revision. Editorial revisions made by DIOP in January 2008.

This chapter includes the following sections:

Section	Topic	Page
9-1	Import Procedures	9-1
9-2	Coverage of Personal Importations.....	9-12
9-3	Importation of Biological Products.....	9-15
9-4	FDA National Import Procedure Regarding Warehouse Entries	9-15
9-5	Release Notices.....	9-16
9-6	Detention without Physical Examination (DWPE)	9-18
9-7	Notice of Detention and Hearing.....	9-30
9-8	Response (Hearing) to Notice of Detention and Hearing.....	9-33
9-9	Notice of Refusal of Admission	9-36
9-10	Reconditioning	9-38
9-11	Supervisory Charges	9-43
9-12	Bond Actions.....	9-45
9-13	Import Information Directives	9-50
9-14	Priority Enforcement Strategy for Problem Importers	9-52
9-15	Import For Export.....	9-60
9-16	Importations for Trade Shows/Fairs, Exhibits and Special Events.....	9-67
9-17	Secured Storage (Temporary Removal Due to Pending Revision).....	9-69
9-18	Communication Concerning Assessment of Civil Monetary Penalties by CBP in cases involving Imported Food	9-70
9-19	Notice of Sampling.....	9-71
9-20	Granting and Denying Transportation and Exportation (T&E) Entries.....	9-76
9-21	EXHIBITS	9-79

9-1 Import Procedures

SCOPE AND PURPOSE

The procedures outlined in this document cover imported merchandise subject to, but not limited to, the following Acts/Regulations:

- Federal Food, Drug, and Cosmetic Act as amended
- Fair Packaging and Labeling Act
- Import Milk Act/Filled Milk Act
- Federal Caustic Poison Act
- Radiation Control for Health and Safety Act

9-2 Coverage of Personal Importations

PURPOSE

To provide guidance for the coverage of personal-use quantities of FDA-regulated imported products in baggage and mail and to gain the greatest degree of public protection with allocated resources.

BACKGROUND

Because the amount of merchandise imported into the United States in personal shipments is normally small, both in size and value, comprehensive coverage of these imports is normally not justified. This guidance clarifies how FDA may best protect consumers with a reasonable expenditure of resources.

There has always been a market in the United States for some foreign made products that are not available domestically. For example, individuals of differing ethnic backgrounds sometimes prefer products from their homeland or products labeled in their native language to products available in the United States. Other individuals seek medical treatments that are not available in this country. Drugs are sometimes mailed to this country in response to a prescription-like order to allow continuation of a therapy initiated abroad. With increasing international travel and world trade, we can anticipate that more people will purchase products abroad that may not be approved, may be health frauds or may be otherwise not legal for sale in the United States.

In addition, FDA must be alert to foreign and domestic businesses that promote or ship unapproved, fraudulent or otherwise illegal medical treatments into the United States or who encourage persons to order these products. Such treatments may be promoted to individuals who believe that treatments available abroad will be effective in the treatment of serious conditions such as AIDS or cancer. Because some countries do not regulate or restrict the exportation of products, people who mail order from these businesses may not be afforded the protection of either foreign or U.S. laws. In view of the potential scale of such operations, FDA has focused its enforcement resources more on products that are shipped commercially, including small shipments solicited by mail-order promotions, and less on those products that are personally carried, shipped by a personal non-commercial representative of a consignee, or shipped from foreign medical facility where a person has undergone treatment.

PERSONAL BAGGAGE

FDA personnel are not to examine personal baggage. This responsibility rests with the CBP. It is expected that a CBP officer will notify their local FDA district office when he or she has detected a shipment of an FDA-regulated article intended for commercial distribution (see GENERAL GUIDANCE below) an article that FDA has specifically requested be detained, or an FDA regulated article that appears to represent a health fraud or an unknown risk to health.

When items in personal baggage are brought to FDA's attention, the district office should use its discretion, on a case-by-case basis, in accordance with the guidance provided under GENERAL GUIDANCE below, in deciding whether to request a sample, detain the article, or take other appropriate action.

MAIL SHIPMENTS

FDA personnel are responsible for monitoring mail importations. It is expected that a CBP officer from the CBP Mail Division will examine a parcel and will set it aside if it appears to contain a drug, biologic, or device, an article that FDA has specifically requested be held, or an FDA-regulated article that appears to represent a health fraud or unknown risk to health.

FDA should audit those parcels set aside by CBP in accordance with the guidance provided under GENERAL GUIDANCE below, using the following procedures:

Prepare a Collection Report for each parcel sampled. Generally, a physical sample is not required on mail importations because a documentary sample (for example, labeling, labels and inserts) will be sufficient for most regulatory purposes. If a physical sample is needed, collect only the minimum necessary for analysis by the laboratory. The remaining portion should not be removed from the custody of the CBP Mail Division.

Importations detained in accordance with this guidance should be held by CBP until they are either released or refused entry. Attached as guidance are two specimen letters that may be sent with the Notice of Detention and Hearing when a parcel is detained. (See [Exhibit 9-3](#) for use in general mail importations and [Exhibit 9-4](#) for use in unapproved drug or device mail importations).

On occasion, products detained by FDA will be mixed with non-FDA-regulated products. When we refuse admission of the FDA-regulated portion, any request for the release of the non-FDA-regulated portion should be referred to the CBP Mail Division with a Notice of Refusal of Admission covering the detained article. Final disposition of all merchandise, including the destruction of detained merchandise, is the responsibility of CBP.

GENERAL GUIDANCE

The statements in this chapter are intended only to provide operating guidance for FDA personnel and are not intended to create or confer any rights, privileges, or benefits on or for any private person.

FDA personnel may use their discretion to allow entry of shipments of violative FDA regulated products when the quantity and purpose are clearly for personal use, and the product does not present an unreasonable risk to the user. Even though all products that appear to be in violation of statutes administered by FDA are subject to refusal, FDA personnel may use their discretion to examine the background, risk, and purpose of the product before making a final decision. Although FDA may use discretion to allow admission of certain violative items, this should *not* be interpreted as a license to individuals to bring in such shipments.

Commercial or Promotional Shipments

Commercial and promotional shipments are not subject to this guidance. Whether or not a shipment is commercial or promotional may be determined by a number of factors including, for example, the type of product, accompanying literature, size, value, and/or destination of the shipment. FDA personnel may also consider whether an importation of drugs or medical devices is a commercial shipment by evaluating whether the article appears to have been purchased for personal use or whether the quantity suggests commercial distribution (i.e., the

supply exceeds what one person might take in approximately three months). Commercial shipments generally include shipments other than those products that are personally carried, shipped by a personal non-commercial representative of a consignee, or shipped from a foreign medical facility where a person has undergone treatment.

Products Other than Drugs and Devices

Many products other than drugs, biologics, and devices that individuals seek to import in personal quantities do not pose a significant health risk although they appear to be violative and may be the subject of an import alert or detention without physical examination based on standards violations, filth, and/or labeling problems. When such items are brought to FDA's attention by CBP, it may be appropriate for FDA personnel to use their discretion to "Release with Comment" and advise the importer of the agency's concerns. FDA personnel should be alert to and should detain those products that do pose a significant health risk.

Drugs, Biologics, and Devices

When personal shipments of drugs and devices that appear violative are brought to FDA's attention by CBP, FDA personnel will use their discretion to decide on a case by case basis whether to detain, refuse, or allow entry of the product. Generally, drugs and devices subject to Import Alerts are not amenable to this guidance. Devices to be used by practitioners for treating patients should not be viewed as personal importations subject to this chapter. Drugs subject to Drug Enforcement Agency (DEA) jurisdiction should be returned to CBP for handling.

In deciding whether to exercise discretion to allow personal shipments of drugs or devices, FDA personnel may consider a more permissive policy in the following situations:

1. when the intended use is appropriately identified, such use is not for treatment of a serious condition, and the product is not known to represent a significant health risk; and
2. when a) the intended use is unapproved and for a serious condition for which effective treatment may not be available domestically either through commercial or clinical means; b) there is no known commercialization or promotion to persons residing in the U.S. by those involved in the distribution of the product at issue; c) the product is considered not to represent an unreasonable risk; and d) the individual seeking to import the product affirms in writing that it is for the patient's own use (generally not more than 3 month supply) and provides the name and address of the doctor licensed in the U.S. responsible for his or her treatment with the product, or provides evidence that the product is for the continuation of a treatment begun in a foreign country.

If there are any questions about the application of these factors to any product, the product should be detained and FDA personnel should consult with the appropriate headquarters office.

When a shipment is not refused entry, FDA personnel may consider issuing a "Release with Comment" and, as appropriate, advise the recipient that 1) the drug (or device) that has been obtained for personal use appears to be unapproved in the United States; 2) the drug (or device) should be used under medical supervision; 3) FDA may detain future shipments of this product; and 4) the patient's physician should consider for example, enrolling the patient

in an Investigational study or applying for Investigation New Drug (IND), Compassionate IND, or Treatment IND exemption.

IMPORT ALERTS

FDA personnel should recommend to the Division of Import Operations and Policy (HFC-170) the issuance of an import alert if they encounter:

1. personal importation of products that represent either a direct or indirect health risk; or
2. the promotion of unapproved foreign products for mail order shipment; or repeated importation of products that represent fraud*.

*(See Compliance Policy Guides Manual, Section 120.500, "Health Fraud - Factors in Considering Regulatory Action" (CPG 7150.10))

9-3 Importation of Biological Products

RPM Subchapter 9-3, Importation of Biological Products was removed in January, 2008 per CBER request. For guidance regarding the importation of biological products, Districts should contact DIOP (HFC-170).

9-4 FDA National Import Procedure Regarding Warehouse Entries

PURPOSE

To provide districts with guidance regarding submission of entry notification to FDA by Customs for importers filing warehouse entries.

BACKGROUND

When a product is imported into the United States, the Importer of Record (Importer) must file entry paperwork with the U.S. Customs and Border Protection (CBP). The importer may choose to file a consumption entry, pay any applicable duty, and introduce the product into domestic commerce. Alternatively, the importer may file a warehouse entry, store the product in a bonded warehouse for up to five years, and pay duty only when the product is withdrawn for domestic commerce (withdrawal for consumption). If the importer exports the product while it is under bond, no duty is incurred.

There have been several instances where importers have questioned FDA's authority over, or right to see paperwork for, FDA regulated product covered by warehouse entries and intended for later export rather than domestic consumption.

Any product brought into the United States from a foreign country is "imported" and, therefore, subject to the import provisions set forth in section 801 of the Federal Food, Drug, and Cosmetic Act (FFDCA). Thus, all importers, including those filing warehouse entries, are subject to section 801 procedures, regardless of whether the intent is to later export the imported products. See also Compliance Policy Guide 7150.11 (Sec. 110.200), "Export of FDA Regulated Products From U.S. Foreign Trade Zones."

GUIDANCE

To fulfill its obligation to ensure that regulated products comply with the requirements of the