Refusal of Admission has not been issued, FDA should immediately issue a Notice of Refusal to the owner or consignee, with a copy to CBP.

Upon the receipt of a bond holder's application for relief (appeal for Mitigation or Cancellation of Assessed Liquidated Damages) as provided under CBP regulations, CBP may cancel the liability for liquidated damages incurred under the bond. CBP will do so upon the payment of a lesser amount, or upon such other terms and conditions as shall be deemed appropriate under the law and in view of the circumstances. However, for assessment of liquidated damages involving FDA merchandise, CBP may not act unless the FDA office having jurisdiction at the port of entry is in full agreement with the action. See 21 CFR 1.97(b) and RPM subchapter 9-12 "Bond Actions" for procedures.

Exhibit 9-6 of Notice of FDA Action is a model and should not be considered all inclusive. The format and language in the actual Notice of FDA Action issued by FDA from the OASIS may also appear differently.

9-2 Coverage of Personal Importations

9-2-1 PURPOSE

To provide operating procedures 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.

9-2-2 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. These procedures clarify 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.

9-2-3 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 designated FDA representative when he or she has detected a shipment of an FDA-regulated article intended for commercial distribution (see GENERAL INSTRUCTIONS 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 designated office should use its discretion, on a case-by-case basis, in accordance with the instructions provided under GENERAL INSTRUCTIONS below, in deciding whether to request a sample, detain the article, or take other appropriate action.

9-2-4 MAIL SHIPMENTS

FDA personnel are responsible for monitoring mail importations. Mail importations are parcels received through the International Mail Facilities, via the United States Postal Service. 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 instructions provided under GENERAL INSTRUCTIONS 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 these procedures should be held by CBP until they are either released or refused entry. Attached as help are two specimen letters that may be sent with the Notice of FDA Action - Detained 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, except in the case of drugs that are subject to administrative destruction (e.g. drugs that are valued at $2500 or less which have been refused admission, or have not met the Personal Importation Policy criteria as described in the 9-2-5 General Instructions section below). In these instances the drugs will be destroyed by FDA.

9-2-5 GENERAL INSTRUCTIONS

FDA personnel may allow entry of shipments 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 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 these procedures. 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, Biologics, 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, biologics, 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, biologics, and devices subject to Import Alerts are not amenable to these procedures. 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 Administration (DEA) jurisdiction should be returned to CBP for handling.

In allowing personal shipments of drugs or devices, FDA personnel may consider a more permissive decision 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 evaluating personal importations, 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 OEIO 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 (CPG), 120.500, "Health Fraud - Factors in Considering Regulatory Action."

9-3 “Notice of FDA Action – Detained” for Mail Shipments

9-3-1 PURPOSE

To provide operating procedures for FDA personnel for:

1. The evidence to support a detention.
2. Preparation and issuance of the "Notice of FDA Action - Detained."
3. Charges under Section 801 or other Acts enforced by FDA, and, for administrative destruction, charges under other provisions of the FFDCA.
4. Hearing Process
5. Procedure after hearing

9-3-2 BACKGROUND

In developing FDA's automated import system, OASIS, the specific form "Notice of Detention and Hearing" has been replaced by the "Notice of FDA Action" with the description of the article sampled and the results of the examination indicating "Detained" for the specific article in the entry. For mail shipments, the use of the designation "DETAINED– Subject to Refusal", and for mail shipments containing drugs, “DETAINED – Subject to Refusal and Administrative Destruction," or similar wording may also be used to satisfy the requirements of the law for "giving notice thereof to the owner or consignee." See 21 USC 381(a).

The "Notice of FDA Action" gives notice of the right to a hearing on the detention for appearance of a violation, or for drugs subject to administrative destruction, a violation (21 CFR 1.94). In addition, the notice identifies charges that an import entry appears to violate, or violates the FFDCA, Public Health Service Act (PHS Act) or other acts enforced by FDA. Under the FFDCA section 801(a) an article subject to the FFDCA shall be refused admission if it appears from the examination or otherwise that

(1) such article has been manufactured, processed, or packed under insanitary conditions or, in the case of a device, the methods used in, or the facilities or controls used for, the manufacture, packing, storage, or installation of the device do not conform to the requirements of section 520(f), or

(2) such article is forbidden or restricted in sale in the country in which it was produced or from which it was exported, or

(3) such article is adulterated, misbranded, or in violation of section 505. It also provides the owner or consignee with an opportunity to introduce testimony relative to the admissibility of the article.

Also under the FFDCA section 801(a), as amended, FDA can destroy a drug that has been refused admission if the drug is valued at $2500 or less (or such higher amount as the Secretary of the Treasury may set) and was not brought into compliance under Section 801(b). In addition, FDA intends to exercise its authority to destroy a drug that meets the statutory criteria for administrative destruction where the drug has also been determined to be adulterated, misbranded, or unapproved in violation of Section 505.

It should be noted that the Act does not provide specifically for the issuance of a notice charging that an entry of imported merchandise appears to be in violation. However, 21 CFR Section 1.94 provides that if it appears that an imported article may be subject to refusal of admission, the responsible FDA office shall give the owner or consignee a written notice to that effect.

Evidence Required for Detention

Every detention must be based upon evidence of a violation of the law(s) enforced by FDA. This does not mean that comprehensive examinations are required as a condition for detention, or that detention cannot be based upon very brief examinations if these are sufficient to furnish evidence creating the appearance of a violation, or a violation.

Furthermore, it is not essential that a detention invariably be based upon examination of a sample, as Section 801(a) of the FFDCA provides for refusal of admission if "it appears from the examination of such samples or otherwise" that the article is violative. However, in those cases in which detention is made without examination, there should be substantial evidence of a documentary type, (i.e., a violation in a previous shipment of the entered product from the same firm-see RPM chapter 9-8 "Detention without Physical Examination" for additional procedures) to warrant a charge of violation.

FDA can destroy drugs refused admission, without the opportunity for export, that are valued at $2500 or less and are adulterated, misbranded, or unapproved in violation of Section 505 of the FFDCA. The evidence supporting this determination must be collected and documented in OASIS by the Investigations Branch for review and evaluation by the Compliance Branch.

Issuance of Notice of FDA Action - Detained

The Notice of FDA Action - Detained provides a list of product being detained, and is addressed to the filer, the importer of record who is legally responsible for assuring compliance with all laws and regulations affecting the importation of the merchandise in question, and consignee (if different from the importer of record). Copies should also be sent to whomever else was sent copies of the "Notice" for the sample collected. See RPM Chapter 9-21 "Notice of Sampling" for specific procedures on issuance of this notice.

Preparation of Charges

The statement of charges on the Notice of FDA Action - Detained issued for a detained product is the only information the importer has regarding the violation(s) or appearance of a violation(s) with which the importation is charged. It should be sufficiently informative and complete for the importer to understand clearly the apparent violation(s), or in the case of drugs subject to administrative destruction, the violation(s), so that the importer can prepare and introduce testimony.

A separate charge should be made for each apparent violation, or violation in the case of drugs subject to administrative destruction. See Exhibit 9-5 to this chapter for charges used in OASIS. The charge should cite the section of the FFDC Act violated, quote the pertinent portion of that section, and make a brief statement of the specific way in which the product appears or has been determined to be in violation. Charges are drafted in accordance with Section 801 of the FFDCA, stating “Examination of the following articles has been made and these articles are subject to refusal of admission into the United States because they do not appear to***” or for articles subject to administrative destruction “The article has been determined to be ***” (*** completed as appropriate for charge).

Under the OASIS procedure for issuing the Notice of FDA Action for a detained product, the individual responsible for the decision as to the compliance of the article will select the appropriate charge from the list of charges available in the OASIS system. The selected charge will be incorporated into the Notice of FDA Action, and the annotation required to specify the particular concern(s), where applicable, will be incorporated by the responsible FDA office. For example, if the article is being detained for the presence of a particular pesticide residue, FDA would annotate the charge provided by OASIS (using the narrative field) with the name of the specific pesticide residue found or alleged to be present.

See Exhibit 9-6 example of the "Notice of FDA Action" issued under the OASIS which includes the identification of article(s) for detention.

Hearing Process for Mail Shipments

The owner or consignee is entitled to a hearing before FDA, in order to challenge the decision to refuse and/or destroy an article, as required by section 801(a) of the FFDCA, or to provide testimony in support of admissibility of the article or to contest the administrative destruction of the article, as required by FDA regulation 21 CFR 1.94. It has generally been FDA's procedure to give the owner or consignee 10 working days following the date of detention shown on the notice (or longer if circumstances require a longer time for response) to provide FDA with testimony or evidence. However, if for some compelling reason, the responsible FDA office determines that 10 working days is insufficient, such as inordinate mail delays due to holiday mailings, this time period may be extended. Introduction of testimony by the owner or consignee for Agency review and consideration can be submitted via multiple forms, including a telephone conversation, a facsimile, mail, email, or in person. Regardless of the way the testimony is introduced, the discussion and findings/outcome of the hearing should be sufficiently documented and stored by the Compliance Officer conducting the hearing. For example, the Compliance Officer should upload email correspondence or meeting minutes following a telephone conversation or in person interview into OASIS to support their final decision regarding the article's disposition.

For details on the eligibility of respondents see subsection 9-10-3; for hearings and postponements see 9-10-14; and for the conduct of a hearing, including personal appearance of respondent and written reply (mail, fax, etc) from respondent, see subsections 9-10-5 and 9-10-6.

Procedure After Hearing for Mail Shipments "Refusal of Admission – Return to Sender" or "Refusal of Admission and Administrative Destruction"

If, after consideration of all evidence, the responsible FDA office determines that the articles are violative or appear to be violative, the articles may be refused admission. In this situation, FDA notifies the importer, owner, and consignee, where applicable, by issuing either a "Notice of Refusal of Admission – Return to Sender", or in the case of a drug valued at $2500 or less a "Notice of Refusal of Admission and Administrative Destruction". On this Notice, FDA states the charge(s) exactly as shown on the original (or amended) Notice of FDA Action - Detained. (See RPM subchapter 9-4 "Notice of Refusal of Admission and Administrative Destruction" for procedures.)

After the article is refused admission, FDA has two options depending on the identity and value of the article. If the Compliance Officer has determined that the article 1) is a drug 2) is valued at $2500 or less and 3) is adulterated, misbranded, or an unapproved new drug in violation of section 505 of the FFDCA, the refused product will be destroyed without providing the owner or consignee with the opportunity to export.

For all other articles, the refused article(s) are generally returned to sender. The FDA file for the import remains open until the article is either destroyed or exported.

Under the OASIS procedures for issuing the Notice of FDA Action - Refusal of Admission and Administrative Destruction, the notice will contain language…

> Examination of the following articles has been made and you were given an opportunity to respond to a notice that the articles are subject to refusal of admission into the United States and subject to administrative destruction. FDA has determined that the articles are drugs that are not in compliance with the requirements of the law as indicated below. Further, FDA has determined that each article is valued at $2500 or less. Because these drugs are not in compliance with the requirements of the law and are valued at $2500 or less, you are hereby notified that these articles will be destroyed by FDA in accordance with the FD&CA.

9-4 Notice of Refusal of Admission and Administrative Destruction for Mail Shipments of Drugs

9-4-1 PURPOSE

To provide operating procedures for issuing the Notice of Refusal of Admission and Administrative Destruction when refusing a drug valued at $2500 or less.

At this time, FDA is using its destruction authority on those refused drugs valued at $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation) that are being imported via international mail. However, any refused drug that meets the criteria for administrative destruction may be destroyed regardless of the manner in which it is being imported or offered for import into the U.S. FDA management for the responsible office should be made aware if administrative destruction is appropriate for any such drug that is not being imported via international mail.

9-4-2 BACKGROUND

In 2012, Congress amended section 801(a) of the FFDCA (21 U.S.C. 381(a)) to provide FDA with the authority to destroy a refused drug valued at $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation) after providing the drug's owner or consignee with notice and an opportunity to present testimony to the Agency prior to the drug's destruction. This authority allows FDA to destroy such a drug without providing the owner or consignee with the opportunity to export the drug. The agency has decided to exercise this authority only after FDA makes a determination that a drug that has been refused admission is valued at $2500 or less and is adulterated, misbranded, or unapproved in violation of Section 505 of the FD&CA, and was not brought into compliance as described in Section 801(b).

9-4-3 ISSUANCE OF NOTICES

Who Should Issue the Notice of Refusal of Admission and Administrative Destruction?

The language of the law places the responsibility for issuing the Notice of Refusal of Admission upon the Secretary of the Treasury who in turn has delegated this responsibility to the CBP. Traditionally, the Notice of Refusal of Admission is issued by the responsible FDA office over the facsimile signature of the Regional or District Director of CBP in accordance with local agreement. Each FDA office shall have the pertinent facsimile stamp of the signature of the Regional or District Director of CBP prepared for this purpose and supplied to the appropriate personnel, or have written delegation of authority from the District Director of CBP to issue the Notice of Refusal of Admission under FDA personnel signature. A new stamp should be prepared each time there is a change of personnel in the Regional or District Director of CBP position.

When Should the Notice of Refusal of Admission and Administrative Destruction be Issued?

The Notice of Refusal of Admission and Administrative Destruction should be issued after an owner or consignee is given the opportunity to introduce testimony in response to a Notice of FDA Action – Detained and, after a hearing relative to the validity of the charges for detention, the hearing officer decides that the articles are in violation, or when no response to a Notice of FDA Action - Detained is received within the specified ten day time frame (excluding Saturdays, Sundays, and holidays) and an extension of time for responding has not been granted. Additional time may be noted due to circumstances affecting FDA operations.

A Notice of Refusal of Admission and Administrative Destruction should only be issued when:

- The product is a drug
- The product is valued at $2,500 or less
- The product is adulterated, misbranded, or an unapproved new drug in violation of Section 505 of the FFDCA

  AND

- A response to a Notice of FDA Action - Detained is not received within the specified 10 day time frame (excluding Saturdays, Sundays, and holidays) and an extension of time for responding has not been granted. (Additional time may be noted due to circumstances affecting FDA operations), or
- After a hearing relative to the validity of the charges for detention, the hearing officer decides that the articles are in violation.

Distribution of the Notice of Refusal of Admission and Administrative Destruction

The Notice of Refusal of Admission and Administrative Destruction is issued to the importer of record (who is the same person or firm who was issued the Notice of Sampling). All persons or firms who are sent copies of the Notice of Sampling and Notice of FDA Action - Detained must also be sent a copy of the Notice of Refusal of Admission and Administrative Destruction.

CBP and USPS will be periodically notified by FDA of all lines of drugs valued at $2500 or less which are subject to refusal and destruction pursuant to section 801(a) of the Act, as amended. For additional procedures see the International Mail Facility (IMF) SOP, available on the OEIO/DIO Intranet page.

Charges on the Notice of Refusal of Admission and Administrative Destruction

The individual violations on a Notice of Refusal of Admission and Administrative Destruction should be stated exactly as shown on the Notice of FDA Action - Detained. If it becomes necessary to include new or amended charges on a Notice of Refusal of Admission and Administrative Destruction, an amended Notice of FDA Action - Detained must first be issued providing another ten day period (excluding Saturdays, Sundays and holidays or additional time when appropriate) for an opportunity for hearing.

When to close the entry

After issuance of the Notice of Refusal of Admission and Administrative Destruction, the entry should be kept in an open status until the final disposition takes place at the IMF and the product is placed into a locked drum for destruction. The Drum ID # should be entered into OASIS before the entry is closed.

9-5 Importation of Biological Products

RPM subchapter 9-3, Importation of Biological Products was removed in January, 2008 per CBER request. For procedures regarding the importation of biological products, FDA staff responsible for imports of biological products should contact OEIO or refer to Importing CBER-Regulated Products into the United States for links to CBER's Import Compliance Programs (CPGM 7342.007 Imported CBER-Regulated Products; CPGM 7342.007 Addendum, Imported HCT/Ps).