

## Chapter 9

**IMPORT OPERATIONS AND ACTIONS**

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## **9-1 Import Procedures**

### **9-1-1 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
- Public Health Service Act, Part F, Subpart 1, Biological Products
- Federal Cigarette Labeling and Advertising Act
- Comprehensive Smoking Tobacco Health and Education Act of 1986
- Title 21 CFR, especially Part 1, Subpart E - Imports and Exports
- Title 19 CFR Customs Duties, especially Part 141, et. seq. dealing with import procedures.

The purpose of this chapter is to provide an overview of import procedures for articles subject to the laws and regulations enforced by the Food and Drug Administration (FDA). The chapter also includes an overview of laws and regulations enforced by U.S. Customs and Border Protection (CBP), as they relate to importation of articles regulated by FDA.

The statements in this chapter represent the Agency's current thinking on the application of the Import Procedures as identified by current law and regulation. It is intended only to provide operating procedures for FDA personnel and does not confer any rights on or for any private person, and does not operate to bind FDA or the public.

### **9-1-2 Division of Authority**

Primary responsibility for administering the nations laws relating to import, export and the collection of duties is given to the United States Customs and Border Protection (CBP), an agency within the Department of Homeland Security. FDA, however, is responsible for determining whether or not an article offered for importation is in compliance with or in violation of the acts enforced by FDA. This includes the responsibility of determining whether or not a violative article may be brought into compliance with the appropriate statute and/or regulations, and authorizing reconditioning in order to bring the article into compliance.

In order to fulfill their respective responsibilities, CBP and FDA must work in close cooperation. For example: the refusal of admission, and subsequent re-exportation, or destruction of merchandise found to be in violation of the Federal Food, Drug, and Cosmetic Act and other Acts enforced by FDA is generally carried out under the direction of CBP, except for drugs that are subject to administrative destruction, which are destroyed by FDA and not by CBP. Additionally, at some ports actual supervision of destruction of violative merchandise may be conducted by FDA pursuant to a local FDA/CBP agreement. In addition, supervision of reconditioning plans is exercised by either FDA or CBP as mutually arranged by district personnel. At ports in reasonably close proximity to an FDA office, such supervision is ordinarily exercised by FDA. At remote ports, such supervision is ordinarily exercised by CBP.

### **9-1-3 ENTRIES**

#### ***Entry Processing***

The FDA district office receives notification from CBP of all formal and informal entries of articles under FDA jurisdiction at ports of entry located in the district's territory. Through the use of CBP's Automated Commercial Environment/International Trade Data System (ACE/ITDS), currently the sole CBP-authorized Electronic Data Interchange (EDI) system for entries that contain FDA-regulated articles and FDA's Operational and Administrative System for Import Support (ACE/OASIS) some electronic entries may be forwarded to off - site districts for processing during certain periods of time, e.g., late night coverage of air carrier hubs. Automated Broker Interface (ABI) Filers using ACE for cargo release are required to provide FDA with information on entries submitted through ACE. The means of receiving notification for paper entries can be arranged through local CBP/FDA District procedures.

The most satisfactory and efficient means for FDA to receive notification is through FDA's electronic entry system-the Operational and Administrative System for Import Support (OASIS). Entries processed through this system will be electronically screened against criteria developed by FDA.

Electronic entries include all required CBP entry information, including entry number, entry date, importer identification, port of entry, vessel/voyage information, filer identification, Harmonized Tariff Schedule (HTS) code(s) for product described in importing documents (tariff code), information on foreign shipper, country of origin quantity, and value. Through the screening process in ACE, CBP determines if the article is subject to FDA jurisdiction.

The CBP ACE uses specific codes within ACE to help it identify which articles are subject to which agency's jurisdiction. These codes are known as "Other Government Agency" (OGA) flags. FDA flags are "FD0", "FD1" and "FD2". FD0 indicates that FDA has determined the article, even though subject to FDA's laws and regulations, is acceptable for CBP release without further presentation of entry information to FDA. For entries flagged FD1, the article may or may not be subject to FDA regulation. The filer

may, based on information received from the importer regarding the intended use of the article, specify that the entry is not subject to FDA regulation and "Disclaim" the entry. Otherwise, information required by FDA laws and regulations must be submitted. FDA will periodically review "Disclaimed" entries to confirm the accuracy of the declaration. Entries covered by an FD2 flag are considered subject to FDA jurisdiction and must include information required by FDA laws and regulations. Note: As of this update additional "Other Government Agency" (OGA) flags have been added. If necessary, additional information on OGA flags can be obtained by contacting the Division of Import Operations (DIO).

FDA's electronic screening of the CBP ABI/ACE entry requires the filer to provide the following additional information: (1) FDA product code (FDA's product code is not the same as the HTS codes used for CBP screening purposes). (2) The MID code of the foreign manufacturer (MIDs are used by Customs as the "Manufacturer's Identification", and it has now been extended to cover all foreign firms). The MID includes, at a minimum, the two- letter identification of the foreign country, the name of the foreign firm (which is generally made up of the first three letters of the first and second names of the firm, where applicable), up to 4 numbers of the firm's address, if present in the address, and the first three letters of the city where the firm is located. This code is subsequently transmitted to FDA's screen as the un-coded name of the identified firm. (3) The MID information of the foreign shipper, including city and country, which may or may not be the same as the foreign manufacturer. (4) The country of origin (which may be different from the country of origin identified for CBP purposes).

FDA has also established Affirmation of Compliance (A of C) codes which provide FDA district employees with information concerning the article offered for import (example: medical device listing number). Use of the A of C is voluntary, and may or may not provide for a more expeditious screening of the entry.

In OASIS, the FDA forms identified as "Notice of Sampling," "Release Notice," "Notice of Detention and Hearing," and "Notice of Refusal of Admission," are no longer issued as specific forms. OASIS will instead generate a "Notice of FDA Action," which will provide more specific information on the actions taken broken down by each entry line (e.g., "sample collected" or "intended for sampling", "detained", "released", or "refused"). As the status changes for a particular line, a new "Notice of FDA Action" will be issued to advise the appropriate individuals of the changes. For non-mail shipments, which includes parcels not received through the International Mail Facilities via the United States Postal Service, the use of the designation "Product Collected by FDA," "Detained," "Released," "Refused," or similar language on the "Notice of FDA Action," should be considered as satisfying the requirements of the law for "giving notice thereof to the owner or consignee." (See 21 USC 381(a).)

For drugs received through the International Mail Facilities that are subject to administrative destruction, the designation "Detained – Subjection to Refusal and Administrative Destruction," and "Refusal of Admission and Administrative Destruction," and the resultant issuance of a notice to the owner or consignee 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).)

For articles received through the International Mail Facilities the use of the designation "Product Collected by FDA," "Detained – Subject to Refusal," "Released," "Refusal of Admission– Return to Sender," or similar language on the "Notice of FDA Action," and the resultant issuance of a notice to the owner or consignee should be considered as satisfying the requirements of the law for "giving notice thereof to the owner or consignee." (See 21 USC 381(a).)

An example of a "Notice of FDA Action" showing various decisions for products in an entry is attached to this chapter as Exhibit 9-6.

OASIS notices will usually be mailed to the addressees listed on the Notice. A copy of each notice is produced for the filer, importer of record, and consignee designated on the entry. (If the same firm fills one or more of those functions, only one copy is produced for the firm.) Notices are official documents communicating FDA decisions on entries. The distribution of the notices should be made by FDA, not the filer, to ensure proper notification to the parties involved (i.e., FAX, express pick-up services, postal service, etc.) The key is for FDA to distribute to the responsible firm directly without an intermediary.

### ***Formal Entries***

All articles offered for import into the U.S. (entries) that have a value greater than \$2500 (or such higher amount as the Secretary of the Treasury may set by regulation) are considered by CBP to be formal entries. Entry procedures for formal entries are set largely by statute, the most important requirement of which is a bond. Under the terms of a formal entry bond, imported articles may be unconditionally released to importers pending a determination of the admissibility and amount of duty to be paid on the articles. The bond requires importers to redeliver the articles to CBP, upon demand of CBP at any time; for example, to allow FDA sampling or for re-exportation following refusal of admission. If the importer fails to redeliver the goods, CBP, after consultation with FDA, may institute proceeding to collect the liquidated damages provided for in the bond. (See 19 CFR 113.62(k) and 21 CFR 1.97.)

Generally, importers notify CBP of an entry by the electronic submission of information to the CBP ACE/ITDS. The information is forwarded to FDA through ACE. FDA can then review the entry on screen to determine if further action is needed, or if additional paper documentation must be submitted. If FDA requires further documents for review, the filer (or importer, where appropriate) will provide FDA with copies of the CBP Entry documents (CBP 3461/33461ALT, or other CBP entry forms) and other documents, such as a copy of the invoice. If an entry is not filed electronically, the accompanying documents will be submitted directly to FDA at the time CBP entry is made in accordance with local port operations. Note: As of July, 2016, all entries of FDA-regulated articles filed electronically are automatically forwarded to FDA through ACE

Note: the FD 700 set (Importers Entry Notice) and FD 720 set (Land Port Entry Notice) are no longer used for FDA notification. In lieu of these forms, CBP entry documents (CBP 3461/3461ALT/7501 or alternate), along with appropriate commercial documents and/or other required documents, will be submitted to FDA.

### ***Informal Entries***

Under current CBP procedures, entries with a value of \$2500 or less (or such higher amount as the Secretary of the Treasury may set by regulation) do not require posting a redelivery bond. All informal entries of articles under FDA jurisdiction that are entered by filers electronically will be forwarded to FDA through the CBP/FDA ACE interface. Informal entries not filed electronically will be processed by FDA for admissibility using the same criteria as non- electronic formal entries.

When informal entries that include articles under FDA jurisdiction are to be sampled, or FDA believes the articles may be in violation of FDA law, FDA may request CBP convert the informal entry into a formal entry, which requires the posting of a redelivery bond. "Section 321 entry" is a term CBP uses for those entries with a value of \$800 or less. These entries have a fair retail value of \$800 or less, as evidenced by the bill of lading (or other document filed as the entry). They pass free of duty and tax, and are imported by one person on one day. The use of the 321 entry process should not apply to multiple shipments covered by a single order or contract, sent separately for the express purpose of securing free entry, and avoiding compliance with pertinent laws or regulations.

### ***Mail/Personal Baggage***

In the case of articles imported by mail or in personal baggage, FDA districts should develop procedures with their local CBP International Mail Office or border crossing office to cover such products. The procedures should set out such information as who is responsible for coverage and when.

CBP is responsible in the first instance for examination of personal baggage. If, in the course of their examination of an individual's personal baggage, CBP determines the individual is entering a product subject to FDA review, the CBP officer will determine if the article should be brought to the attention of the local FDA office. Personal importations meeting the criteria of entry will be processed in accordance with procedures for non-electronic entries. Generally, since most personal importations are small in size and value, procedures have been developed for evaluating these importations. (See RPM subchapter 9-2 "Coverage of Personal Importations.")

## **9-1-4 SAMPLING**

### ***Ports Covered by FDA***

Most ports of entry into the U.S. are covered by FDA personnel, acting in cooperation with CBP. At these ports, where electronic entry submissions are filed, filers receiving a message indicating FDA review is required will provide appropriate additional entry information to the FDA office in whose territory the port of entry is located. For those entries submitted by paper, all appropriate entry documents should be included with the package sent to the local FDA office.

After the entry has been evaluated and a decision for additional documentation is made, FDA will take appropriate action. If FDA decides to collect a sample, it will provide the filer, importer, owner and/or consignee, where appropriate, with a Notice of Sampling and advise: (1) whether the entry is to be held intact for FDA examination or sampling; or, (2) specify only those items that need be held. Generally, when FDA wishes to sample, it will be acting upon its authority in the Customs regulations (19 CFR 151.4) to collect its own samples for examination.

### ***Ports not Covered by FDA***

There are a number of ports where CBP does not maintain its ACE electronic entry process and FDA does not generally cover the port under its normal operating schedule. To cover these ports, the responsible FDA district office will coordinate coverage with the responsible CBP Port manager to ensure FDA notification. If FDA decides to examine or sample articles offered for import through such a port, CBP, the importer, and broker will be notified.

Generally, for these entries, examination and/or sampling can take place at the point of destination. Under certain conditions, however, FDA may ask CBP to collect a sample at the point of entry and forward it to the FDA servicing laboratory. Appropriate information on the entry, sample requirement, and requirements for holding the entry will be provided to the CBP officials and importer by the responsible district.

### ***Entry Sampling***

FDA may request an examination or sample of articles under its jurisdiction. If no examination or sample is requested, FDA will notify CBP and the filer, who is responsible for notifying the importer or other designated parties. This is referred to as a "May Proceed Notice," and indicates that the shipment may proceed without further FDA examination. In the ACE/OASIS process this may occur as a result of the initial FDA/OASIS screening prior to the information being forwarded to the district office, or after the district performs an "On-Screen-Review" of the information provided. (Note: Should the article, at a later time, be found in violation of the law, FDA is not prevented from taking legal action (e.g., seizure, injunction) because it allowed admission of the article without examination at the time of importation.)

If FDA requests an examination or sample, FDA will notify CBP and the broker or filer, importer, or other designated parties through the electronic entry system or other form

of notification (e.g., Notice of FDA Action) of its intent to sample, requesting the relevant party to hold the entry. FDA will indicate the specific articles to be sampled.

### ***Notice of Sampling***

Whenever FDA intends to sample an article offered for import, it issues a Notice of Sampling to the importer of record, consignee, and filer of its intent to sample the article. Where an entry is manually processed, a copy of the Notice of Sampling may or may not be issued to CBP, depending on local FDA/CBP agreement. Where an entry is processed electronically and CBP collects the sample for FDA, the district will input the information of the entry/sample into OASIS and provide the Notice of Sampling to the importer of record, consignee, and filer specifying which articles were sampled.

For those entries where specific entry lines are not sampled or examined, the Notice of FDA Action will be amended to indicate which entry lines are "May Proceeded." (See RPM subchapter 9-21 "Notice of Sampling" for procedures.)

### ***Payment for Samples***

The FDA will pay for all physically sampled articles found to be in compliance with the requirements of the Act and applicable regulations (21 CFR 1.91). In addition FDA will pay for samples collected as FDA audits of private laboratory reports of analysis submitted to FDA in response to a detention when the article is found to be in compliance. FDA does not pay for samples taken in connection with the supervision of a reconditioning.

Where an owner or consignee seeks reimbursement it shall bill the FDA district office in whose territory the shipment was offered for import. FDA will not pay for a sample if the article is initially found to be in violation, even if the article is subsequently released.

### ***Procedure When no Violation is Found***

If the article is found to be in compliance after examination, the importer of record, consignee (where applicable), filer, and CBP are notified by a Notice of Release that the article may be admitted as far as FDA is concerned. (See RPM subchapter "Notice of Release" for procedures.)

### ***Procedure When Products Cannot Be Sampled or Examined***

Under certain circumstances, FDA decides not to sample or examine articles offered for import. In these cases, if the entry is made through ACE/OASIS, the shipment should be "May Proceeded" through OASIS; if a manual (paper) entry, the shipment should be released by issuance of a paper "Notice of Release." The paper "Notice of Release" should be annotated to indicate that the article is "May Proceeded" and that FDA has made no determination as to the article's compliance with the Food, Drug, and Cosmetic Act, or other related acts or regulations.

In the OASIS system, if a notice is issued for the collection or examination of an article and the sample is not collected, or where an examination of the sampled article could not be accomplished, the filer will be so advised through a revised Notice of FDA Action indicating the article is "May Proceeded." The system will print a status of "May Proceeded" in the Line Summary and also print a detail section "Lines Which May Proceed." If the article FDA chose not to sample was part of a multi-line entry where other articles were collected for examination, the Notice of FDA Action automatically updates the status of the other articles not released.

In OASIS, the following are definitions used to describe "May Proceed" or "Release" actions:

May Proceed: "Product may proceed without FDA examination. FDA has made no determination the product complies with all provisions of the Food, Drug, and Cosmetic Act or other related acts. This message does not preclude action should the article later be found violative." (No compliance decision has been made.)

Release: "The product is released after FDA examination. This message does not constitute assurance the product complies with all provisions of the Food, Drug, and Cosmetic Act or other related acts and does not preclude action should the article later be found violative." (A compliance decision has been made.)

Districts will follow the appropriate instruction under each of the above procedures according to their import operations.

#### **9-1-5 PROCEDURES WHEN VIOLATION IS FOUND FOR PRODUCTS THAT ARE NOT SUBJECT TO ADMINISTRATIVE DESTRUCTION**

For the procedures regarding administrative destruction of products determined to be drugs valued at \$2500 or less see sections 9-3 "Notice of FDA Action – Detained for Mail Shipments" and 9-4 "Notice of Refusal of Admission and Administrative Destruction for Mail Shipments".

#### ***"Notice of Detention & Hearing"***

Examination or sampling of an article offered for import may indicate that the article appears to be in violation of the Act (e.g., section 801(a)), or may be subject to refusal of admission under acts and regulations enforced by FDA. If, after examination or sampling detention is the chosen course of action, the filer, owner, and consignee where applicable, are issued a "Notice of FDA Action - Detained" that shall specify the nature of the violation charged. The owner or consignee is entitled to appear before the FDA and have the right to introduce testimony in support of admissibility of the article, in accordance with Section 801(a) of the Federal Food, Drug, and Cosmetic Act and FDA regulation 21 CFR 1.94. As a result, the "Notice of FDA Action - Detained" shall designate a place for the owner or consignee (or authorized representative) to provide testimony as to the admissibility of the article. 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, or email, and does not have to be introduced in person. However, an in-person hearing will be scheduled if requested by the owner or consignee. It has generally been FDA's procedure to give the owner or consignee 10 working days from the date on the notice to provide FDA with testimony or evidence. However, if for some compelling reason the district determines that 10 working days is insufficient, such as inordinate mail delays due to holiday mailings, this time period may be extended. On the OASIS generated "Notice of FDA Action", this date is identified as the date to "Respond By". A copy of this Notice is also sent to CBP. (See RPM subchapter 9-9 "Notice of FDA Action – Detained for Non-Mail Shipment" for procedures.)

### ***Request for Authorization to Relabel or Perform Other Acts***

In addition to presenting evidence as to the admissibility of the article, the importer may propose a manner in which an article, detained under section 801(a)(3), can be brought into compliance with the Act or be removed from coverage under the Act. ("rendered other than a food, drug, device or cosmetic.") As provided for under 801(b) and 21 CFR 1.95, FDA may authorize relabeling or other action upon the timely submission of an "Application for authorization to relabel and recondition" form FDA-766 or another appropriately completed notice (such as a letter), and the execution of a good and sufficient bond ("CBP redeliver bond") by the owner or consignee (see 21 USC 381(b)). The redelivery bond remains on file with the District Director of CBP for the particular importation. The bond applies to any relabeling or other authorized action, and a new bond will not have to be filed.

After review of the application to relabel or recondition, FDA will notify the importer of its approval or disapproval. If approved (see 21 CFR 1.96 "Granting of authorization to relabel and recondition"), the conditions to be fulfilled, and the time limit within which to fulfill them will be noted. The original application will be sent to the applicant. Notification to other parties will be made where appropriate. A copy will be retained in the district files. (See RPM subchapter 9-10 "Response (Hearing) to Notice of FDA Action - Detained", and RPM subchapter 9-12 "Reconditioning" for procedures)

### ***Inspection After Completion of Authorization to Bring Article into Compliance***

After the relabeling or reconditioning operation has been completed, the applicant will submit the "Importer's Certificate" (Form FDA-766) or provide the district with such notification of completion of the reconditioning. At this point FDA may conduct a follow-up inspection and/or sampling to determine compliance with the terms of the authorization, or may accept the statement from the importer with no further follow-up. The follow-up inspection and/or sampling may be made by an officer of FDA or CBP, depending on the location of the reconditioning and agreements between the district and the local CBP office. The "Report of Inspector" (reverse side of FDA-766, or other appropriately completed summary of reconditioning) shall be completed by the inspecting officer and forwarded to the appropriate FDA office.

***Procedure When Conditions of Authorization Have Been Fulfilled***

If the conditions of the authorization to relabel or recondition have been fulfilled, the district will notify the owner or consignee through a Notice of Release indicating that the admissible portion of the article is no longer subject to detention or refusal of admission. This notice is usually identified as "Originally Detained and Now Released." A copy of the Notice is also sent to CBP and the filer. Where there is a non-admissible portion of the article (rejects), the portion must be destroyed, or re-exported under FDA or CBP supervision. A Notice of Refusal of Admission should be issued for the rejected portion, with copies distributed to the same parties receiving the Notice of Release. Normally, FDA will include in its approval of the reconditioning a provision for any non-admissible portions (rejects) of the reconditioned article be destroyed that should not be permitted to be exported.

***Procedure When Conditions of Reconditioning Have Not Been Fulfilled.***

If an importer's initial attempt at relabeling or reconditioning is not successful, FDA should not consider a request for authorization for a second relabeling or reconditioning unless the authorization includes a change or adjustment from the original authorized method, and the applicant provides reasonable assurance that the second attempt will be successful. If the importer fails to fulfill conditions of an authorization, FDA issues a "Notice of Refusal of Admission" to the importer, consignee, where applicable, and the filer, with a copy of the Notice to CBP.

***Procedure After Hearing - "Notice of Release"***

After the hearing on admissibility, the district may determine that the article does not appear to be in violation and should be released. In this situation, the importer of record and consignee are issued a "Notice of Release" for the detained article. The Notice will indicate that the detained article is no longer subject to detention or refusal of admission. The Notice will also be identified "Originally Detained and Now Released" and, where appropriate, explain the reason for the change of action. A copy of the Notice is sent to CBP, and all parties receiving the Notice of Sampling/Notice of Detention. (See RPM subchapter "Notice of Release" for procedures.)

***Procedure After Hearing - "Refusal of Admission"***

If, after consideration of all evidence, the district decides that the articles still appear to be in violation, the articles may be refused admission. In this situation, FDA notifies the importer, owner, and consignee, where applicable, by issuing a "Notice of Refusal of Admission." On this Notice, FDA states the charge(s) exactly as shown on the original (or amended) Notice of FDA Action - Detained. A copy of the Notice is also sent to CBP. (See RPM subchapter 9-11 "Notice of FDA Action - Refusal of Admission" for procedures.)

If an article is refused admission, such article must be destroyed or exported under CBP's supervision within 90 days of receiving the Notice of Refusal (see 21 USC 381), or within such additional time as specified by CBP. The FDA file for the import remains open until the district receives notification, usually from CBP, indicating that the article was either destroyed or exported.

Some districts and their local CBP offices have developed combination Notice of Refusal of Admission and Notice of Redelivery documents. At this time, use of the combined Notice of Refusal of Admission and Notice of Redelivery has not been approved for national applications. Until the format of combined notices is authorized, districts should continue to follow local procedures as instituted.

Under the OASIS procedures for issuing the Notice of Refusal of Admission, the notice will contain language which includes the reference to the requirement for redelivery. The notice will contain all the above required information concerning the product and charge(s) and will also include the following statements

"A request has been made to CBP to order redelivery for all the above product(s), in accordance with 19 CFR 141.113, which were conditionally released to you under terms of the entry bond. Failure to redeliver to CBP custody will result in a claim for liquidated damages under the provisions of the entry bond."

"These products must be exported or destroyed under CBP supervision within 90 days from the date of this notice, or within such additional time as the District Director of CBP specifies. Failure to do so may result in destruction of the products. Distribution of the products may result in their seizure and/or injunction or criminal prosecution of persons responsible for their distribution."

#### **9-1-6 PAYMENT OF COSTS OF SUPERVISION OF RELABELING AND/OR OTHER ACTION**

After completion of the authorized relabeling or other action, FDA will submit to CBP National Finance Center a detailed statement of expenses incurred by officers or employees of the FDA during the supervision of the authorized relabeling or other action. (See 21 USC 801(c).) Expenses include travel, per diem or subsistence, and supervisory charges (Form FD-790 Charges for Supervision, Exhibit 9-12). The expenses shall be computed based on the following:

- Investigator's time
- Analyst's time
- Per diem allowance
- Travel other than by auto - actual cost of such travel
- Travel by auto (mileage, toll fees, etc.)



- Administrative support

Charges for the above will be in accordance with existing regulations. (See 21 CFR 1.99 and RPM subchapter 9-11 "Supervisory Charges" for procedures.) CBP, upon receipt of the charges for supervision, will send a notice for payment to the identified importer of record. The expenses shall include charges of supervision of destruction of the article or rejects as provided for by the Tariff Act of 1911, as amended (see 19 U.S.C. 267). The owner or consignee shall remit payment to CBP. Payment of supervisory charges should not be accepted by FDA district offices.

### **9-1-7 EXPORTATION OF MERCHANDISE REFUSED ADMISSION**

As provided under Section 801(a), CBP supervises exportation of refused articles in accordance with regulations which have been or may be prescribed by the Secretary of Treasury. However, if after a reasonable time, FDA has not received notification of exportation or destruction of articles refused admission, the district should investigate the status of disposition. Districts should also consider, under certain conditions, verifying that the refused articles have been held intact pending exportation or destruction. Procedures on refusals to be verified may change based on the reason for detention.

### **9-1-8 BOND ACTION**

Under the provisions of section 801(b) of the Act (21 USC 381(b)) and CBP regulations (19 CFR 113.62), a bond is required for all conditionally released articles offered for importation. This bond provides for relief to the government should the bond holder default on the conditions of the agreements identified by the CBP regulation. Default will result in the payment of liquidated damages in the amount specified in the bond order.

Bond actions are taken when an entry is distributed after the importer receives notification of FDA's intent to examine or sample the article, and the article is distributed and cannot be redelivered. Bond actions also are taken when an article has been detained and refused, and the article is not destroyed or exported in accordance with the requirements of the law.

If FDA has evidence that the entry, or any portion of an entry subject to FDA jurisdiction, was disposed of in violation of the terms of the appropriate act or its regulations, or of the terms of the bond (see 19 CFR 113.62(e)), it should immediately send such evidence to CBP.

If FDA receives evidence that a refused article was not exported or destroyed, it shall immediately investigate the matter and send a detailed statement to CBP. The statement will show the importer's liability under the redelivery bond or other applicable CBP bond. If the facts warrant, when the *article was under detention*, and the Notice of

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 district 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 districts from the Operational and Administrative System for Import Support (OASIS) may also appear differently.)

## **9-2 Coverage of Personal Importations**

### **9-2-1 PURPOSE**

To provide 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 local FDA district office 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 district 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**

Reminder: The statements in this chapter are intended only to provide operating procedures 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 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 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 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 the Division of Import Operations 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 Sec. 120.500))

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

### **9-3-1 PURPOSE**

To provide districts with procedural instructions 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 FD&C Act.
4. Hearing Process
5. Procedure after hearing

The statements in this chapter are intended only to provide operating procedures for FDA personnel and are not intended to create or confer any obligations on or rights for any private person, and do not place any mandatory requirements on FDA personnel. The statements in the procedures are provided to achieve national uniformity in the handling of this import enforcement activity.

### 9-3-2 BACKGROUND

In developing FDA's automated import system, known as the Operational and Administrative System for Import Support (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 Federal Food, Drug, and Cosmetic Act (FD&C Act), Public Health Service Act (PHS Act) or other acts enforced by the Food and Drug Administration. Under the FD&C Act section 801(a) an article subject to the FD&C Act 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 FD&C Act 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 FDA district director 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 FD&C Act 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 FD&C Act. 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 FD&C 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 FD&C Act, 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 district. For example, if the article is being detained for the presence of a particular pesticide residue, the district 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 FD&C Act, 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 district circumstances require a longer time for response) to provide FDA with testimony or evidence. However, if for some compelling reason, the district 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 section 9-10-3, hearings and postponements see 9-10-14, and the conduct of a hearing, including personal appearance of respondent and written reply (mail, fax, etc) from respondent, see Section 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 district 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 FD&C Act, 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 the field with 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. District management 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 FD&C Act (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 FDA district office over the facsimile signature of the Regional or District Director of CBP in accordance with local agreement. Each FDA district shall have a 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 district 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 FD&C Act
- 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 district 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.

### ***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, Districts should contact the Division of Import Operations (DIO) or refer to CBER's Import Compliance Programs (CPGM 7342.007 Imported CBER-Regulated Products; CPGM 7342.007 Addendum, Imported HCT/Ps).

## **9-6 FDA National Import Procedure Regarding Warehouse Entries**

### **9-6-1 PURPOSE**

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

### **9-6-2 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 Sec. 110.200, "Export of FDA Regulated Products From U.S. Foreign Trade Zones."

### **9-6-3 INSTRUCTIONS**

To fulfill its obligation to ensure that regulated products comply with the requirements of the FFDCA, FDA should receive notification either electronically or by paper, no later than the time the warehouse entry is filed with CBP.

## **9-7 Release Notices**

### **9-7-1 PURPOSE**

To provide the field with procedures in releasing imported lots for which a Notice of Sampling has been issued.

### **9-7-2 BACKGROUND**

The Federal Food, Drug, and Cosmetic Act, and its regulations directs that a notice (Notice of Sampling) shall be given to the owner or consignee of imported merchandise sampled or intended to be sampled under the authority of the Act. The regulations also require the issuance of a further notice to advise the owner or consignee of the result of examination of the sample, for which a Notice of Sampling has been issued [21 CFR and 1.90]. The Release Notice advises the owner or consignee that the merchandise need not be further held insofar as the FDA is concerned.

### **9-7-3 GENERAL COMMENTS**

Release Notice Form, or computer generated notice from OASIS, is issued by FDA under the signature of the field compliance officer or designated individual authorized by the district to sign the notice, whenever FDA has no further interest in a lot for which a Notice of Sampling (or computer generated notice from OASIS) has been issued.

The Release Notice is routinely issued to the importer of record with a copy to CBP and the FDA district fiscal office and file. In accordance with local practices, copies may also be sent to the customhouse broker and the consignee when either is not named as the importer of record. In any case, all persons who are issued a Notice of Sampling should also be sent the Release Notice.

To meet the various circumstances surrounding a release, the following variations of the Release Notice are currently used:

1. "Straight" Release
2. Release without Examination
3. Release with Comment
4. Release after Detention

### **9-7-4 "STRAIGHT" RELEASE**

This release form (or the computer generated notice from OASIS) is issued whenever it appears, from sample examination or otherwise, that merchandise, for which a Notice of Sampling has been issued, is in compliance with the law.

Examples of OASIS Release Notices will be provided at a later date.

### 9-7-5 RELEASE WITHOUT EXAMINATION

Whenever a sample cannot be examined, for which a Notice of FDA Action/Sampling has been issued; a Notice of FDA Action/Release Notice form as identified in Exhibit 9-6, "Straight Release" or the computer generated notice from OASIS is issued amended as follows:

"RELEASED WITHOUT EXAMINATION MAY PROCEED WITHOUT FDA EXAMINATION ON THE RESPONSIBILITY OF THE IMPORTER"

This statement is typed in caps following the blocked information on the notice. An example of the OASIS form will be provided at a later date.

### 9-7-6 RELEASE WITH COMMENT

#### ***Background***

It had been the practice when an importation was encountered which did not fully comply with the requirements of the Act, but the violation was not of sufficient importance to warrant detention of the initial importation, to release the shipment with a "Release with Warning" that future similar violative importations might be denied entry. Although these "Releases with Warning" did not necessarily mean that the correction had to be made before the next importation, that frequently was the intent. The brevity of the warning often gave such notices an unintentional air of curtness.

Therefore, the "RELEASE WITH WARNING" and "RELEASE WITHOUT PREJUDICE" has been replaced with a "RELEASE WITH COMMENT" as a more flexible means of handling minor violations.

#### ***Approach***

When an importation is encountered which does not fully comply with the requirements of the Acts which we enforce, but the violation(s) is (are) not sufficient to warrant detention on a first encountered basis, it may be "Released With Comment." The violation(s) must be minor, since a shipment with serious infraction(s) should be detained. For example, if an FPLA violation which is not considered subject to NLEA concerns is encountered in a product this shipment may be "Released With Comment." However, if the importer or country of origin has already received "notice" of our FPLA labeling requirements, the shipment may be *detained*.

A standard Release Notice is used with a notation "Release With Comment" prominently shown immediately following the blocked information on the notice. The comments may be placed directly on the Release Notice if sufficient space is available or, on an attached letter. If a letter is used, it should be stapled to the Release Notice and referred to in the body of the Form, i.e. "Release With Comment, See Attached

Letter of (date)." An example of a "Release With Comment" is shown as [Exhibit 9-6](#) (examples of OASIS Release With Comment notices will be provided at a later date.)

The violations on which the comments are based should be clearly covered by the Acts or regulations which we enforce. The comments should be stated in nonlegal language with reference to the specific sections of the Acts or regulations involved.

Generally, the Release With Comment should not be used if the problem is one commonly existing in domestic commerce and against which no FDA objection has been made. Center non-concurrence of detention recommendations that indicate non-agency support of similar domestic violation and past policy procedures with both domestic and imported products will serve as guide.

If the violation is clearly absent from similar domestic products, prompt correction should be requested by including the statement "Future shipments may be detained unless (nature of violation, i.e. misbranding) is corrected." By omitting this statement, the comments would serve as an information guide to provide a better understanding of the requirements of the law.

Before issuing a Release With Comment that includes a statement that future shipments may be detained we must be in a position to take action. However, other shipments that may be enroute at the time the comment issues or within a time frame established for correction to be completed may be allowed to proceed if otherwise in compliance.

A statement on the Release Notice should be included directing the importer to advise the foreign manufacturer/shipper of our comments when applicable. A copy of this letter should be requested for the FDA file.

#### **9-7-7 RELEASE AFTER DETENTION**

Release after detention is issued in the following situations:

1. After the issuance of the Notice of FDA Action - Detained (or computer generated notice from OASIS) the importer of record or other designated agent may present testimony which shows that the merchandise is in compliance.
2. In response to the Notice of FDA Action - Detained, the importer of record reconditions the merchandise to FDA's satisfaction pursuant to the terms of the Application for Authorization to Relabel or to Perform Other Action (Form FDA-766), or else causes it to be brought outside the jurisdiction of the Act. The latter situation can occur, for example, when an importer diverts insect-adulterated, food-grade starch to industrial uses (paper manufacturing, etc.).

Under these situations, a Release Notice is issued with a notation "ORIGINALLY DETAINED AND NOW RELEASED" prominently shown following the blocked information or as appropriately set from the computer generated notice. If the merchandise has been reconditioned, the fact of this reconditioning should also be



shown on the notice including the loss (if any) during reconditioning, reject material, the disposition of reject material, and amount of acceptable material. If supervisory charges are also involved, the notice should also bear the statement "Subject to bond liability for charges in connection with reconditioning."

## **9-8 Detention without Physical Examination (DWPE)**

### **9-8-1 PURPOSE**

To provide uniform procedures regarding:

- Authority
- Criteria for recommending action
- Procedure for recommending action
- Criteria for recommending removal of action
- Procedure for notification of removal

### **9-8-2 AUTHORITY AND BACKGROUND**

Section 801(a) of the FD&C Act states, "If it appears from the examination of such samples *or otherwise* that (1) such article has been manufactured, processed, or packed under insanitary conditions . . . 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, then such article shall be refused admission."

Congress authorized FDA to refuse admission of regulated articles based on information, *other than the results of examination of samples*, that causes an article to appear to violate the FD&C Act.

Information such as an article's violative history, among other things, may cause an article to appear adulterated, misbranded, or otherwise in violation of the FD&C Act, as described in Section 801(a).

Section 801 of the FD&C Act explicitly authorizes FDA to refuse admission of articles that appear to violate the Act.

That section also provides the importer with the right to "introduce testimony bearing on the admissibility of the articles." To carry out the provisions of Section 801(a), FDA detains an article that appears violative and provides notice to the importer of the nature

of the violation and the right to present testimony regarding the admissibility of the article (21 CFR 1.94). Depending on the information submitted by the importer, the article may either be permitted or refused entry into the United States.

Detention without physical examination, first used by FDA in 1974, is appropriate when there exists a history of the importation of violative products, or products that may appear violative, or when other information indicates that future entries may appear violative. Detention without physical examination has the effect of reminding the importing community that FDA is a regulatory agency, *not* a quality control laboratory. Often, importers wait until the Agency has issued a Notice of FDA Action - Detained to determine whether the articles they are offering for import comply with the FD&C Act. Detention without physical examination properly places the responsibility for ensuring compliance with the law on the importer.

### **9-8-3 GENERAL PROCEDURES**

Any FDA unit may recommend detention without physical examination or removal from detention without physical examination when it believes that such action is warranted. Such recommendations should be in writing and submitted with supporting data and/or information to the Office of Enforcement and Import Operations (OEIO), Division of Import Operations (DIO).

NOTE: Wherever feasible, recommendations should be submitted via electronic means in the appropriate format rather than via hard copy.

Supporting information should include an analytical package and documentation of center concurrence when no direct reference field authority exists.

Detention without physical examination may also be recommended on the basis of analyses performed by state or local agencies where FDA has determined that the sampling and testing conducted by such agencies is accurate, acceptable and representative of the product on which the recommendation is based.

Based upon local district history, District Directors have the discretion to consider placing future shipments coming through their ports from a particular packer, manufacturer or shipper, under detention where a recommendation for detention without physical examination has been made for DIO concurrence, but has not yet been approved. Shipments of this nature do not require additional sampling.

### **9-8-4 RECOMMENDATIONS INVOLVING PESTICIDE RESIDUES**

The Center for Food Safety and Applied Nutrition (CFSAN) will be responsible for review and concurrence of detention without physical examination recommendations involving pesticide residues for which no tolerance has been established. Copies of

recommendations for detentions without physical examination involving this type of violation should be sent concurrently to CFSAN and DIO.

Recommendations for detention without physical examination due to pesticide residues for which there is an established tolerance should be submitted directly to OEIO/DIO.

#### **9-8-5 DIRECT REFERENCE AUTHORITY RECOMMENDATIONS**

Certain recommendations for detention without physical examination are assumed to have appropriate Center concurrence. These detentions include recommendations involving ceramic ware that appears to be contaminated lead or cadmium at levels above those stated in current Agency guidance (CPG Sec. 545.400 and Sec. 545.450); recommendations for detention without physical examination of ready to eat seafood and imported cheeses due to the presence of *Listeria Monocytogenes*; recommendations involving *Salmonella* in ready to eat seafood; recommendations for the detention without physical examination of surgeon's and patient examination gloves; recommendations for the detention without physical examination for salmonella in animal feed; and recommendations for detention without physical examination of latex condoms. This list is not all inclusive.

#### **9-8-6 RECOMMENDATIONS BASED ON EIR'S, OTHER GOVERNMENT AGENCIES, MOUs, ETC.**

When inspections conducted by FDA, or by foreign or other government authorities under a Memorandum of Understanding (MOU) or other agreement, reveal conditions or practices warranting detention of either particular products or all products manufactured by a firm, or in a specific geographic area, the appropriate Center, upon recommendation from either the Office of Food & Feed Operations (OFFO) or Office of Medical Products and Tobacco Operations (OMPTO), and receipt of the Establishment Inspection Report (EIR) or other documentation, should submit a recommendation for detention without physical examination to DIO. DIO will review the recommendation to assure that all necessary supporting information is included prior to issuance of the procedures. When the responsible Center is satisfied that the appearance of a violation has been removed, either by re-inspection or submission of appropriate documentation, the Center will notify DIO of its recommendation to remove the detention without physical examination action.

#### **DIO RESPONSIBILITIES**

When a recommendation for detention without physical examination is received, DIO will review the recommendation including supporting data/information and review national detention data (if necessary) to determine whether detention without physical examination is appropriate (See RPM subchapter 9-8), setting forth procedures for determining whether detention without physical examination is appropriate).

Recommendations, formatted as Import Alerts or revised Import Alerts, will be offered for agency clearance by DIO. (See RPM subchapter 9-15, "Import Information Directives" for clearance procedures).

DIO serves as the central repository for all detention without physical examination information and data. It is also responsible for reviewing detention without physical examination recommendations to ensure that they are timely, and that the Import Alerts are disseminated and revoked as appropriate.

### **9-8-7 DETENTION WITHOUT PHYSICAL EXAMINATION RECOMMENDATIONS**

Detentions without physical examination should be recommended whenever there is information that would cause future shipments of a product or products offered for entry to appear violative within the meaning of Section 801(a). The recommendation may be based on the violative history of a product, manufacturer, shipper, grower, importer, geographic area, or country. The recommendation may also be based on other information, such as information that food offered for entry was harvested from polluted waters, or information that a product was manufactured or held under insanitary conditions, or manufactured in non-compliance with Good Manufacturing Practice (GMPs), pursuant to Section 801(a) of the Act. A detention without physical examination may be recommended for an article with no prior history of detentions if the recommendation is adequately supported by information that indicates that future shipments may be violative.

### **9-8-8 RECOMMENDATIONS BASED ON ONE VIOLATIVE SAMPLE**

Under this circumstance, FDA has evidence that at least one sample has been found violative and the violation represents a potentially significant health hazard. The sample collection and/or analysis may have been conducted by FDA or another reputable Federal, State, or local agency.

In the following instances, one violative sample, collected while a product is in import or domestic status, may support a recommendation for detention without physical examination of products from a specific manufacturer, shipper, grower, or from a specific growing area or country (if information is sufficient to establish an appearance that the violation extends to that area/country):

1. The product may have adverse health consequences. The appropriate Center, in most instances, would conclude that the problem would warrant a Class I or Class II recall.
2. The product (fresh, frozen, or processed) contains actionable levels of a pesticide residue, aflatoxin, or chemical contaminant.
3. The product is a violative low acid canned food, or acidified food. (i.e., failure to have a process on file for a specified product or no registration).

4. The product is violative in a way that is likely to continue due to the product's ingredients or formulation. For example, products which bear or contain undeclared significant ingredients (i.e., human allergen), unapproved colors, or violate their applicable standard of identity, or products that are unapproved new drugs, or unapproved new animal drugs, will continue to appear violative until the manufacturer of such products changes the label or formula for the products or obtains agency approval necessary for legal marketing.
5. The product is a post amendment device that is not subject to an approved 510(k) or premarket approval application. A copy of the recommendation should be sent for concurrence to the Center for Devices and Radiological Health (CDRH), Office of Compliance (HFZ-300).
6. The product's labeling is violative and/or not in accordance with the Nutritional Labeling and Education Act (NLEA) and such violation is likely to continue until said labeling is corrected by the manufacturer. (See CFSAN Compliance Program for specific procedures).

Recommendations for detention without physical examination based on one violative sample should include documentation of Center concurrence, if such concurrence is required.

Center concurrence is not necessary when the action is covered by direct reference authority, as indicated by, among other things, a Compliance Policy Guide. Recommendations should also include a copy of the analytical package.

#### **9-8-9 RECOMMENDATIONS BASED ON INFORMATION AND HISTORICAL DATA**

When there is evidence that a product from a specific geographical area or country could pose a health hazard, the appropriate Center or district should recommend detention without physical examination. In such cases, where there is also information that the product is likely to continue to be violative, it may not be necessary to collect and analyze a physical sample.

Detention without physical examination may be recommended for products offered for import from a manufacturer, shipper, grower, geographical area, or country based on information showing a pattern of importation of articles that violate the FD&C Act. The information in the recommendation establishing a pattern of continuous violations of the FD&C Act should indicate that actions necessary to remove such violations have not been taken. In such cases, the procedures outlined immediately below would not necessarily apply. Center concurrence is, however, necessary in this situation.

### 9-8-10 RECOMMENDATION BASED ON MULTIPLE SAMPLES

Recommendations for detention without physical examination based on multiple samples showing violations of the Act should include documentation of Center concurrence with the recommended detentions, or copies of analytical packages if Center concurrence is not required, i.e., where direct reference authority is applicable. Recommendations for detention without physical examination may be submitted for:

1. Specific product(s) from an individual manufacturer or shipper for violations that do not pose a significant public health hazard, such as decomposition, filth, labeling, etc., when:
  - a. There have been at least three (3) detentions in a recent six-month period or less; and
  - b. These detentions represent at least 25% of the total shipments of that product examined in the applicable time period as known to the recommending district or unit.
2. Specific product(s) from a country or a specific geographic area when:
  - a. There are at least twelve (12) detentions in a recent six-month period or less; and
  - b. These detentions represent at least 25% of the total shipments of that product examined in that time period as known to the recommending district or unit; and
  - c. These detentions represent a significant number of firms that manufacture, ship, or grow the product from the geographic area or country.
3. Multiple products from a manufacturer or shipper when:
  - a. There are at least six (6) detentions in a recent six-month period or less; and
  - b. These detentions represent a variety of products and constitute at least 25% of the total shipments examined from that firm during the applicable time period as known to the recommending district or unit.

FDA may consider additional information in conjunction with sample analysis when considering whether to recommend products from a manufacturer, shipper, geographic area, or country for detention without physical examination, such as the results of foreign inspections and the other types of information discussed in this subchapter.

### 9-8-11 DETENTION WITHOUT PHYSICAL EXAMINATION OF IMPORTERS ENTRIES

Importers bear the primary responsibility for ensuring that products they import comply with all provisions of the FD&C Act. To carry out this responsibility, they may choose to inspect the foreign manufacturers or growers of products that they import, to enter into agreements with foreign exporters, to make arrangements to have products privately examined and analyzed prior to importation, and/or to take other steps to verify proper labeling and compliance of products with the FD&C Act before offering them for distribution into U.S. commerce.

If districts have documented an importer's practice of repeatedly offering violative articles for importation and attempting to recondition such shipments only after FDA detention, or of repeatedly attempting to export shipments or withdraw entries *after* receiving a notice of sampling or other indication of FDA interest (e.g., inquiries regarding product location), detention without physical examination should be recommended covering either specific commodities or all FDA regulated products offered for entry by that importer, as warranted.

Detention without physical examination should also be recommended if there is other persuasive evidence that future shipments by an importer may be violative. For example:

1. Information received from other government agencies (e.g. U.S. CBP) concerning violative practices by the importer or the importer's foreign suppliers that would cause the articles to appear violative under section 801(a) (e.g., misdeclaration of products to avoid detention without physical examination);
2. A documented history of attempted importation of violative articles that has resulted in the issuance of a Warning Letter to the importer with no subsequent response from such importer or which does not result in the correction of such practice;
3. Verifiable information in the form of consumer or trade complaints, or otherwise, that has the effect of causing the articles offered for import to appear adulterated, misbranded, or otherwise in violation of the FD&C Act as specified in Section 801(a). This information may include repeated requests for notices of refusal or attempts to cancel or export an entry after receiving a notice of sampling or other indication of FDA interest.

Based on a review of district detention data, districts may recommend that an importer be placed on detention without physical examination when the importer exhibits a high percentage of violations of a single product, a group of products, or all products. All such recommendations, formatted as Import Alerts, should be submitted to OEIO/DIO for clearance. Each recommendation should include suggested charges; however, final charges to be used will be determined by the appropriate Center with input from the FDA Office of the Chief Counsel as needed.

### **9-8-12 RECOMMENDATIONS BASED ON ESTABLISHMENT INSPECTION**

Establishment inspections of foreign manufacturers of FDA regulated products that reveal significant deviations from Good Manufacturing Practices, insanitary conditions, or other practices that result in the articles manufactured at such facilities appearing to be misbranded, adulterated, or otherwise in violation of the FD&C Act as described in Section 801(a) should result in the recommendation of detention without physical examination of the articles offered for import from such manufacturer. The appropriate Center(s) should review the recommendation and approve the scope of the action based upon review of the establishment inspection report or other evidence.

The detention without physical examination described above may identify one firm, multiple locations of a firm, or specific products from one or more firms as appropriate. The factors to be considered in the determination of whether to place a manufacturer's articles on detention without physical examination may differ from Center to Center and may be revised as Agency priorities and initiatives change. Recommendations following FDA inspections of foreign manufacturers will be made by either the Office of Food & Feed Operations (OFFO) or Office of Medical Products and Tobacco Operations (OMPTO),, to the appropriate Center, with a copy to DIO. The final detention without physical examination decision rests with the Center.

### **9-8-13 OTHER SITUATIONS**

In cases other than those described above, a recommendation may be made for detention without physical examination if there is a reason to believe, and evidence to support, that future shipments of a product or class of products will appear violative within the scope of Section 801(a).

### **9-8-14 PARTY NOTIFICATION OF DETENTION WITHOUT PHYSICAL EXAMINATION DECISION**

The parties notified regarding the issuance of a detention without physical examination will vary depending on the nature and scope of the action. In most instances, a copy of the Import Alert will suffice for notification. The procedures for notification to the appropriate agency, foreign government, association and manufacturer/shipper and the agency units responsible for initiating the notification are as follows:

1. National CBP, or other federal agency enforcement branch (from the Division of Import Operations)
2. Local office of CBP (by each FDA district when necessary)
3. Appropriate foreign embassy or foreign government, (from the International Affairs Staff)



4. Importer/broker associations, as appropriate (from the Division of Import Operations)
5. Specific foreign manufacturers or shippers, as appropriate (from CFSAN - LACF/AF; CDRH - 510(k), PMA, GMPs; CDER - pre-approval NDAs, GMPs; CVM - pre-approval NADAs, GMPs; CBER license revocation) If notification of the specific foreign manufacturer or shipper is deemed impractical or impossible due to incomplete information, distance, communication difficulties, etc., notification should be sent to the importer, requesting transmittal of the notification to the foreign manufacturer and requesting a response to include what steps were taken to correct the conditions which brought about the detention without physical examination.
6. Industry associations as appropriate, (Centers).

### **9-8-15 REMOVAL FROM DETENTION WITHOUT PHYSICAL EXAMINATION**

A product, firm, shipper, etc., is placed on detention without physical examination because information indicates that the product offered for entry appears to be either manufactured, processed or packed under insanitary conditions; forbidden or restricted for sale in the country in which it was produced or from which it was exported; adulterated, misbranded, or in violation of Section 505 (unapproved new drug); or appears violative as set forth in Section 536(a).

FDA decisions to remove a product, manufacturer, packer, shipper, grower, country, or importer from detention without physical examination should be based on evidence establishing that the conditions that gave rise to the appearance of a violation have been resolved and the agency has confidence that future entries will be in compliance with the Act.

Shippers are placed on detention without physical examination when the identity of the manufacturer of the product that appears violative cannot be determined. Since there is no assurance that any subsequent shipments offered for entry are from the same manufacturer, the procedures set forth in RPM subchapter 9-6, below, will not provide the Agency with the information necessary to establish that the appearance of a violation has been removed. Therefore if after a six-month period a shipper on detention without physical examination has not offered for entry any shipment that is violative, AND can provide documentation to FDA indicating what steps the shipper has taken to ensure that he or she does not offer for entry articles that do not comply with the FD&C Act, such shippers may be removed from detention without physical examination. Shippers that are on detention without physical examination may offer evidence that products from specific manufacturers are not violative and should not be subject to detention without physical examination using the procedures set forth in RPM subchapter 9-6. However, if the manufacturer of the violative product is subsequently identified, removal of such product from detention without physical examination should be based on specific information that overcomes the appearance of a violation and should be submitted by the manufacturer, not by the shipper.

If a product has been placed on detention without physical examination because it appears violative under Section 801(a)(1) or (2), analysis of samples from representative shipments will generally not be sufficient to overcome the appearance of the violation and warrant removal from detention without physical examination. An establishment inspection, or other appropriate action, may be required (i.e., documentation that a product is no longer forbidden or restricted for sale from the government of the country in which it was produced or from which it was exported).

For those products automatically detained because they appear to be violative under Section 801(a)(3), a minimum of five (5) consecutive non-violative commercial shipments should be entered before the agency may consider that the appearance of the violation has been overcome, and that it *may* be appropriate to remove the detention without physical examination.

NOTE: At least one of the five (5) non-violative entries should be audited by FDA to ensure the validity of the analysis.

However, depending on the nature of the apparent violation, a proper registration, scheduled process filing, 510(k) substantial equivalence order, Premarket Approval Application (PMA), NDA or NADA, or other documentation may be necessary before the appearance of a violation is overcome and the detention without physical examination is removed. If during the review to determine whether the appearance of a violation has been removed an apparently violative entry is offered, the review process for removal from detention without physical examination may be discontinued until information is submitted to show that the problem leading to the entry of the violative articles has been corrected. *Under some circumstances, more than the minimum number of in compliance consecutive shipments may be necessary to establish that the violative practices or conditions have been fully resolved.* For example, a shipper, grower, etc., who after being removed from detention without physical examination once again begins to ship the same type of violative products, may need to present more than five consecutive non-violative shipments to remove the appearance of a violation and to be considered for removal from detention without physical examination. When there is a continued history of entry of the same non-compliant product(s), documentation showing that the cause of the violation has been fully corrected may also be necessary.

DIO shall consult with the appropriate district regarding a proposal to remove a firm or product from detention without physical examination. An important element of FDA's decision to remove a product, shipper, or importer from detention without physical examination is the extent to which the evidence shows that future shipments will be in compliance with the FD&C Act and implementing regulations. Splitting shipments into several entries or lines should not be considered as a means to increase the number of non-violative shipments. *FDA needs to be confident that articles offered for importation are in compliance not just on one day, but over the course of a reasonable time period. Otherwise such articles will continue to APPEAR violative.* If there is reason to conclude that two or more entries (or lines) represent a single related shipment or lot, these should be considered to be a *single* shipment.

Shipments should represent routine commercial entries, and should not be divided or staged, such that they are presented essentially for the purpose of removing a product, shipper, country, or importer from detention without physical examination. Shipments that consist of less than 10 to 15 cartons, which do not represent normal industry practice (e.g. high value food such as specialty cheese, etc.), may not be considered in the detention without physical examination removal process. FDA needs to be certain that adequate product is available for representative sampling and private laboratory analysis, as well as for possible audit sampling by FDA. (Refer to ORA Laboratory Procedures Manual (LM), Volume III, Section 7 for procedures regarding private laboratories). The Office of Regulatory Science (ORS) should be contacted regarding the acceptance/non-acceptance of laboratory data.

Shipments presented for consideration for removal from detention without physical examination should be in compliance with the FD&C Act or other statutes enforced by the Agency. Special situations may occur in which data presented may not conclusively demonstrate full compliance of the entry with the FD&C Act. In such situations, district staff may have additional information which, while allowing the shipment to be taken off of detention without physical examination, may still preclude the shipment's release.

#### **9-8-16 REMOVAL OF PRODUCTS MANUFACTURERS/COUNTRIES EXCEPT FRESH PRODUCE**

Recommendations for removal from detention without physical examination should be forwarded to DIO for review when the district or other interested parties present documentation which establishes that the appearance of a violation has been removed. This documentation should include the examination records (analytical worksheets) from any private laboratory, foreign government, or from the FDA laboratory that analyzed the product, as well as documentation of the subsequent release of the shipments by FDA. In addition, other documentation may be necessary to verify that violative conditions no longer exist, e.g., product formulation information, information establishing label revisions, information showing a change in the use of food or other chemical additives, etc. The following guidelines should also be met:

1. Specific products from an individual manufacturer - the last five shipments have been documented to be in compliance with the FD&C Act.
2. Specific products from a country or a specific geographic area - the last twelve (12) shipments have been established to be non-violative. These twelve shipments should include a representative number of manufacturers/shippers from the geographic area or country offering the products for entry.
3. Multiple products from a specific manufacturer the last twelve (12) shipments have been established to be non-violative. These twelve shipments should represent the range of products normally entered by the firm or each of the

products covered by the detention without physical examination if only specific products are listed.

**NOTE:**

For detentions without physical examination based on country or geographic problems with a product, *shippers should not be removed from detention without physical examination. Shippers should ensure that the manufacturer of the articles they import is shown on entry documents so that FDA can determine whether the manufacturer has corrected the Problem(s) with the Products.*

## **9-8-17 REMOVAL OF FRESH PRODUCE**

### ***Chemical Contamination:***

Recommendations to remove fresh produce from detention without physical examination for chemical contamination may be made by the district upon consideration of all relevant information and criteria. DIO should be notified of all such recommendations.

### ***Pesticides:***

Once an illegal pesticide residue has been found, past experience has shown that future shipments of the affected food may likely contain the illegal residue(s) throughout the growing and shipping season, or longer. A district, or other interested party, may recommend removal of a grower from detention without physical examination when the grower has entered a minimum of five (5) consecutive recent shipments without violation and when:

1. The grower demonstrates through adequate documentation that the residue problem no longer exists;

OR

2. The country/grower/importer demonstrates through adequate documentation that each lot of produce to be offered for entry originated in fields that were not treated with the pesticide in question;

OR

Information is obtained demonstrating that the produce originated in untreated fields, including documentation on the types of pesticides used in the surrounding fields, the dates and method of pesticide application, and the results of analyses from a representative sampling of the allegedly untreated field or lot (i.e., along borders and mid section) showing that the product from the implicated field is in

compliance;

OR

Information is obtained on the steps that have been instituted to prevent the occurrence of illegal pesticide residues in future shipments.

Recommendations to remove a product or firm from detention without physical examination may be made at any time if supported by information that demonstrates that detention without physical examination is no longer warranted.

A district may request to end the detention without physical examination after one year of the effective date if:

- there is a clearly defined growing season, and
- it is not a recurring problem, and
- there is an adequate program (having government support) set up to monitor and address the problem, and
- evidence has been received which demonstrates that the problem no longer exists. DIO will monitor import alerts concerned with the detention without physical examination of fresh produce to assure that an assessment is made by the districts and/or headquarters as to whether to remove or continue the detention without physical examination of a product/grower after its anniversary date.

### **9-8-18 REMOVAL OF IMPORTERS**

If an importer has been placed on detention without physical examination for the *first time* for a *specific product*, a recommendation for removal may be appropriate after the importer supplies acceptable documentation that the last five (5) shipments of that product from a specific manufacturer entered in full compliance with the FD&C Act.

If the importer has been placed on detention without physical examination for the *first time for multiple products*, a recommendation for removal may be appropriate after that importer supplies acceptable documentation that the twelve (12) most recent entries were in full compliance. The twelve (12) entries should represent the range of products covered by the detention without physical examination and normally entered by the importer.

If an importer is on detention without physical examination and it is not *the first time*, a recommendation for removal may be appropriate after that importer supplies acceptable documentation that the ten (10) most recent entries were in full compliance, *in the case of a specific product, or the last twenty-four (24) entries, in the case of multiple Products.*

In addition, a request from an importer that he or she be removed from detention without physical examination should include in sufficient detail, the steps that he or she has taken to prevent the entry of products that appear violative in the future.

### **9-8-19 REMOVAL BASED UPON AN ESTABLISHMENT INSPECTION**

Firms or products placed on detention without physical examination based on a violative establishment inspection, or because the products appear to have been manufactured in violation of GMPs, may generally be removed from detention without physical examination following a reinspection which in some instances may be performed by a reliable entity other than which performed the initial violative inspection) that confirms that corrective actions have been instituted and after concurrence by the appropriate Center. In some instances, a firm may present information or documentation sufficient to demonstrate that appropriate corrections are in place to overcome the appearance of a violation and, with the appropriate Center concurrence, may be removed from detention without physical examination.

### **NOTIFICATION OF REMOVAL FROM DETENTION WITHOUT PHYSICAL EXAMINATION**

The same FDA units responsible for the initial notification of the imposition of the detention without physical examination, per RPM subchapter 9-8, "Party Notification..." should notify the same parties of the removal of such detention.

## **9-9 Notice of FDA Action - Detained for Non-Mail Shipments**

### **9-9-1 PURPOSE**

To provide districts with information 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.
4. Custody over detained shipments.
5. Detention of illegal products that are not properly identified for further processing and exportation under 801(d)(3).

The statements in this chapter are intended only to provide operating procedures for FDA personnel and are not intended to create or confer any obligations on or rights for any private person, and do not place any mandatory requirements on FDA personnel.

The statements in the procedures are provided to achieve national uniformity in the handling of this import enforcement activity

## **9-9-2 BACKGROUND**

In developing FDA's automated import system, known as the Operational and Administrative System for Import Support (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. The use of the designation "DETAINED" or similar wording should be considered as meeting the requirements of the wording of the law and regulation when applied to "giving notice thereof to the owner or consignee."

The "Notice of FDA Action - Detained" gives notice of the right to a hearing on the detention for appearance of a violation (21 CFR 1.94). and identifies charges that an import entry may violate under the Federal Food, Drug, and Cosmetic Act (FD&C Act), Public Health Service Act (PHS Act) or other acts enforced by the Food and Drug Administration. Under the FD&C Act section 801(a) an article subject to the FD&C Act shall be refused admission if it appears to (1) have 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 or 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 lot.

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 FDA district director shall give the owner or consignee a written notice to that effect.

## **9-9-3 EVIDENCE, ISSUANCE OF NOTICE, AND PREPARATION OF CHARGES**

### ***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

Furthermore, it is not essential that a detention invariably be based upon examination of a sample, as Section 801(a) of the FD&C Act 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.

### ***Issuance of Notice of FDA Action - Detained***

The Notice of FDA Action - Detained which lists articles as being detained 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 apparent violation(s) with which the importation is charged. It should be sufficiently informative and complete for the importer to understand clearly the alleged violation(s) so that the importer can prepare a reply for the hearing.

A separate charge should be made for each apparent violation (see [Exhibit 9-5](#) to this chapter for charges used in OASIS). The charge should cite the section of the FD&C Act violated, quote the pertinent portion of that section, and make a brief statement of the specific way in which the product appears to be in violation. Charges are drafted in accordance with Section 801 of the FD&C Act, as: "The article is subject to refusal of admission pursuant to Section 801(a)(\*\*\*)in that it appears to\*\*\*\*" (\*\*\*) completed as appropriate for charge). Charges are based on the section of the FD&C Act and not the regulations unless the FD&C Act is not specific enough to identify the exact violation.

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 district. For example, if the article is being detained for the presence of a particular pesticide residue, the district 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.



#### **9-9-4 CUSTODY OF DETAINED SHIPMENTS**

Customs and Border Protection regulation and the Food, Drug, and Cosmetic Act [19 CFR Part 113, 21 U.S.C. 381(b)] provide that a bond considered necessary for the protection of the revenue or assurance of compliance with any pertinent law, regulation or instruction be posted for merchandise. The bond includes a requirement that up to 3 times the value of the entry of merchandise be posted to cover cases involving default on the conditions of the bond [19 CFR Part 113.62(m)(1)].

All formal entries of FDA regulated product are considered by CBP to be "Restricted Merchandise" and as such are required to have a bond established prior to conditional release by CBP. Informal entries, those entries whose value is currently less than \$2,500, are usually not imported under bond. Informal entries subject to FDA review may be requested to have a bond established for them in accordance with CBP regulation. Accordingly, *physical possession of a shipment need not be retained by CBP pending FDA examination when the bond (single entry or term bond) is in place (see 19 CFR 12.3)*. However, if there is reason to believe that the shipment will not be held intact, arrangements should be made with CBP officials to maintain physical possession of the shipment. [See procedures under RPM Chapter 9-14 "Priority Enforcement Strategy for Problem Importers"]

#### **9-9-5 DETENTION OF VIOLATIVE PRODUCTS THAT ARE NOT PROPERLY IDENTIFIED FOR FURTHER PROCESSING AND EXPORTATION UNDER 801(D)(3)**

The "FDA Export Reform and Enhancement Act of 1996," referred to as the "Export Reform Act," Public Law 104-134 became law on April 26, 1996. Technical amendments were enacted on August 6, 1996 (Public Law 104-180). The Export Reform Act contains provisions allowing the importation of certain products, including drug and device components, food and color additives, and dietary supplements, which would otherwise be considered non-compliant with the Federal Food, Drug, and Cosmetic Act and be subject to refusal of admission, when intended for further manufacturing into products to be exported.

When a product is imported under the provisions of Section 801(d)(3) of the Act, the statute requires the importer to submit a statement to the Secretary (FDA) at the time of importation that such article is being imported or offered for import with intent to be incorporated by the initial owner or consignee into a drug, biological product, device, food, food additive, color additive, or dietary supplement that will be exported by such owner or consignee from the United States in accordance with Section 801(e) or 802 of the Act, or Section 351(h) of the Public Health Service Act. Failure to provide this information at the time of importation should be viewed by the district as evidence that the product does not meet the conditions of Section 801(d)(3). Therefore, if the information is not provided at the time of importation, and if the product is otherwise subject to refusal of admission pursuant to Section 801(a) of the Act, the district should issue a Notice of FDA Action - Detained in accordance with normal procedures. If no

response is received by the district to the Notice of FDA Action - Detained that the product meets the requirements for notification of intent for import for export, a Notice of Refusal should be issued (see RPM Chapter 9-4 "Notice of Refusal of Admission, Instructions, "When Should the Notice of Refusal of Admission be Issued?"). Once issued, cancellation of the Notice of Refusal should only be considered under unusual circumstances at the discretion of the district (see RPM Chapter 9-11 "Notice of FDA Action - Refusal of Admission", Instructions, "Re-opening of a Case" and RPM chapter 9-17 "Import for Export", for additional information and procedures for import for export entries).

## EXHIBITS

[9-5 Specimen Charges](#)

[9-6 Notice of FDA Action](#)

## 9-10 Response (Hearing) to Notice of FDA Action - Detained

### 9-10-1 PURPOSE

To provide procedures to FDA field offices regarding who can respond to a Notice of FDA Action - Detained; time frames for responding; and conduct of the hearing.

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

### 9-10-2 BACKGROUND

Section 801(a) of the Federal Food, Drug, and Cosmetic Act provides the owner or consignee of FDA regulated imported goods with an opportunity to appear before the Secretary of Health and Human Services to introduce testimony relative to the admissibility of their imported shipment.

21 CFR Section 1.94 provides that if it appears that an imported article may be subject to refusal of admission, the FDA district director shall give the owner or consignee a written notice stating the reasons therefore. This regulation further provides that this notice shall specify a place and period of time during which the owner or consignee shall have an opportunity to introduce testimony, either orally or in writing, as to the admissibility of the shipment.

In developing FDA's automated import system, known as the Operational and Administrative System for Import Support (OASIS) the specific form "**Notice of Detention and Hearing**" has been replaced by the issuance of a "**Notice of FDA Action**," which contains a description of the article(s) and action taken for a specific

entry. The use of the designation "DETAINED," or other similar wording, under the heading of "Current Status," should be considered as meeting the requirements of the wording of the law and regulation when applied to "giving notice thereof to the owner or consignee" (see RPM Exhibit 9-6 for an example of "Notice of FDA Action" for detention).

### **9-10-3 ELIGIBILITY OF RESPONDENTS**

Section 801(a) of the Federal Food, Drug, and Cosmetic Act and FDA regulation 21 CFR 1.94 provide the owner or consignee an opportunity to introduce testimony relevant to the admissibility of the article if it appears that an imported lot may be subject to refusal of admission. However, the regulations are rather complicated as to the definition of "owner or consignee." 21 CFR 1.83(a) defines, for the purpose of the regulation, the owner or consignee as the person who has the right of a consignee under Sections 483, 484, and 485 of the Tariff Act of 1930, as amended (19 U.S.C. 1483, 1484, 1485).

For the purposes of the Tariff Act, only the declared consignee as shown on the bill of lading may be the importer, unless bill of lading endorsements by this consignee confer his rights to other persons. For the purposes of the Tariff Act, the consignee (importer) is to be regarded as the owner of the imported goods. If the consignee (importer) is not the true owner of the goods, the true owner may file with the District Director of CBP a declaration of ownership, which bestows upon the true owner all of the rights of a consignee. Thus, we are obligated by statute to recognize as eligible for the presentation of testimony, the consignee (importer) or the true owner (if the true owner is not the consignee) if there is on file with CBP a declaration of ownership.

In addition to the consignee (importer) and the true owner, we also recognize the eligibility of the importer of record to present testimony. (The importer of record is the person or firm who guarantees, by bond, proper custody and handling of the imported shipment in compliance with the laws governing such shipment. The importer of record may be the broker, consignee, true owner, or whoever owns the bond covering the shipment.) In most cases, it is the importer of record who responds to the "Notice of FDA Action - Detained."

A designated representative of the consignee (importer), true owner, or importer of record may appear in the consignee's (importer's) behalf; however, unless known to be authorized representatives, the district should require proper documentation designating the individual(s) to be a bonafide representative for the purpose of the hearing. Recognition of others may open the way for claims by the consignee (importer), true owner, or importer of record that FDA has denied or abridged the importer's right to be heard, or for complaints that FDA has permitted unauthorized persons to intrude into the case.

#### **9-10-4 HEARINGS AND POSTPONEMENTS**

The "Notice of FDA Action - Detained" provides an opportunity for the introduction of testimony or the filing of a statement in writing within ten days (or longer if district circumstances require a longer time for response) following the date of detention shown on the notice (excluding Saturdays, Sundays, and holidays). This is indicated on the Notice by the reference to a "Respond By" date. The "introduction of testimony" may take many forms, including a telephone conversation, a FAX or mail, and does not have to be introduced in person. However, if the consignee (importer), true owner, or importer of record requests a hearing as such, it should be scheduled for the earliest possible date.

The response period may be extended at the request of the respondent if it is made within the 10-day time-frame shown in the "Notice of FDA Action - Detained," and the requestor provides a reasonable basis for extension, and the requested extension is confirmed in writing. It is preferable for extension requests to be made in writing, but this is not mandatory. Such requests should be answered by the district, in writing. If the request is granted, the new time frame should be clearly stated in the response letter.

Generally speaking, requests for extension for indefinite or excessively long periods should not be granted. This also applies to requests for extensions based upon reasons other than to obtain or prepare evidence pertaining to the specific charges of the detention. However, extensions should only be granted if some type of resolution is actively being pursued.

#### **9-10-5 CONDUCT OF HEARING: PERSONAL APPEARANCE OF RESPONDENT**

The import hearing provided by section 801(a) of the Act is a different procedure from a hearing pursuant to Section 305 of the Act. Under section 801(a), it is the respondent's opportunity to present a defense of the importation and/or to present evidence to show how the importation may be made eligible for entry. This type of hearing may vary from a series of telephone conversations to a more formal 305 type of meeting. Formal memoranda covering import hearings are not required, although a written record should be made for the files.

The hearing officer (generally it is the district compliance officer, however, it may be any individual designated by the district to conduct such a hearing) should avoid any indication of prejudice or pre-judgment until all evidence is submitted and should assure that the respondent has been provided ample opportunity to present all relevant evidence. If the question arises, the respondent should be made aware of their rights of appeal to a higher level of review in the agency, including to the specific Center responsible for the detained article, to the Associate Commissioner for Regulatory Affairs, to the Commissioner of FDA, to the Secretary of Health and Human Services, and to file legal actions with the court.

The hearing should be confined to relevant matters, and the respondent should be required to confine their comments to the submission of relevant evidence and not be permitted merely to attempt to question, probe, or pass judgment on FDA's basis for detention.

If the facts in the case are such that a decision can be reached regarding the validity of the detention charges at the termination of the hearing, the hearing officer should so advise the respondent of the decision with confirmation by the issuance of the appropriate "Notice," (Refusal, Release, etc.). A copy of the appropriate "Notice" should be sent to the importer of record, if this person is not the respondent.

There is no need to dictate a summary of the hearing in the presence of the respondent, as is done during a "Section 305 meeting," nor is it necessary to provide the respondent with a copy of our memorandum covering the hearing.

Occasionally, a respondent at an import hearing attempts to weigh the relative desirability of appealing a refusal of admission against submitting a request for an authorization to relabel, recondition, etc. (Form FDA-766), or reopen the basic question of the shipment's legality if relabeling or reconditioning is unduly burdensome. The respondent should be advised that orderly procedure requires that the respondent first present a view on the validity of the FDA charge(s), and then, if the respondent concludes that the charges are valid, a request for an authorization to relabel or recondition or refusal can be submitted. This should not be taken as preventing a discussion, at the appropriate time, of what is needed to bring the article into compliance. Once the hearing has been held and a Form FDA-766 has been submitted for an authorization to relabel or recondition, the hearing should not be reopened for the purpose of determining whether the article is subject to refusal of admission.

On occasion, a respondent will request that a Notice of Refusal of Admission be issued immediately so the merchandise can be exported. These requests should also be confirmed in writing by the respondent. Requests for issuance of a Notice of Refusal of Admission should be acted upon without delay.

#### **9-10-6 CONDUCT OF HEARING: WRITTEN REPLY (MAIL, FAX, ETC.) FROM RESPONDENT**

The response to a Notice of FDA Action - Detained by mail is no different from a hearing where a verbal response is provided. The hearing officer must consider the evidence developed by FDA and that presented in the written response, and then make a decision as to whether or not the importation is violative as charged in the Notice of FDA Action - Detained. All such responses should be replied to in writing, e.g., appropriate "Notice" with a clear statement of the hearing officer's decision. A copy of this Notice should be sent to the importer of record, if the person is not the respondent.

Questions regarding appropriateness of respondent, procedures for conducting the hearing, or other concerns not specifically identified in these procedures, should be referred to the Division of Import Operations (301-796-0356)

## **9-11 Notice of FDA Action - Refusal of Admission**

### **9-11-1 PURPOSE**

To provide the field with instructions for issuing the Notice of Refusal of Admission. This section covers all articles excluding drugs valued at \$2500 or less. For those products see RPM subchapter 9-4 Notice of Refusal of Admission and Administrative Destruction for Mail Shipments of Drugs.

### **9-11-2 BACKGROUND**

Section 801(a) of the Federal Food, Drug, and Cosmetic Act directs the Secretary of the Treasury to issue a Notice of Refusal when it appears from examination of samples, or otherwise, that an imported shipment is in violation. This Section also orders the destruction of any such shipment refused admission, unless it is exported within 90 days of the date of the notice, or within such additional time as may be permitted pursuant to such regulations.

### **9-11-3 INSTRUCTIONS**

#### ***Who Should Issue the Notice of FDA Action - Refusal of Admission?***

The language of the law places the responsibility for issuing the Notice of FDA Action - Refusal of Admission upon the Secretary of the Treasury who in turn has delegated this responsibility to the CBP. Traditionally, this notice is issued by the FDA district office over the facsimile signature of the Regional or District Director of CBP in accordance with local agreement. Each FDA district shall have a 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 FDA Action - 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.

The name and contact information of the compliance officer or designated district individual who issues the Notice of Refusal of Admission is automatically indicated by OASIS on the notice.

#### ***When Should the Notice of FDA Action - Refusal of Admission be Issued?***

A Notice of FDA Action - Refusal of Admission is issued under the following circumstances:

1. A response to a Notice of FDA Action – Detained is not 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 district operations).
2. Efforts to relabel or recondition the detained shipment pursuant to an approved application (Form FDA-766) have failed.
3. When a detained shipment has been reconditioned pursuant to an approved application (Form FDA-766), and we have agreed to the exportation of the reject material, a Notice of FDA Action - Refusal of Admission is issued covering the rejects.
4. After a hearing relative to the validity of the charges for detention, the hearing officer rules that the charges are valid and a Form FDA-766 has not been submitted.

NOTE: If a detention action is being appealed by the importer do not issue the Notice of FDA Action - Refusal of Admission until the appeal is decided. Districts should notify the CBP office of the delay to assure liquidation of the bond does not occur.

### ***Distribution of the Notice of FDA Action - Refusal of Admission***

The Notice of Refusal of Admission is always issued to the importer of record (who is the same person or firm who was issued the Notice of Sampling). In accordance with local practices, copies may also be sent to the customhouse broker and the consignee when neither is the importer of record. 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.

Two copies of the Notice must also be sent to CBP.

### ***Charges on the Notice of FDA Action - Refusal of Admission***

The individual violations on a Notice of FDA Action - Refusal of Admission should be stated exactly as shown on the Notice of FDA Action – Detained . If it becomes necessary to add new or amended charges on a Notice of FDA Action - Refusal of Admission, 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 or the submission of a Form FDA-766.

An example of the Notice of FDA Action - Refusal of Admission form and examples of the computer generated notice will be forwarded at a later date.

***When to close the Case***

After the Issuance of the Notice of Refusal of Admission, the case should be kept in an open status until the receipt of the return copy of the Notice of Refusal from CBP showing the exportation or destruction of the shipment.

If the return copy is not received from CBP within 100 days, a letter inquiring as to the status of the shipment, or other agreed upon procedure established with your local CBP port, should be made.

It is important to monitor the final disposition of refused shipments, as FDA has encountered the distribution of such merchandise into domestic channels instead of exportation or destruction. Districts should follow the procedures for follow-up to refusals.

***Requests for Extension Beyond the Ninety Day Period***

If request are received for an extension beyond the 90 day period to export or destroy a refused shipment, the requestor should be referred to the appropriate CBP office. Since the Notice of Refusal of Admission is the responsibility of CBP, FDA cannot grant such extensions.

***Reopening of a Case***

Unless a Notice of Refusal of Admission was erroneously issued by FDA, consideration should not normally be given to requests to void the Notice in order to give the requestor an opportunity for a hearing or time to submit an application (Form FDA-766) requesting permission to relabel or recondition. Indiscriminate voiding of this Notice tends to indicate to the importer of record that it is not necessary to respond within the prescribed period to the Notice of FDA Action - Detained and, also, will generate additional paper work by both FDA and CBP. The latter result is counterproductive to our efforts to process all import matters in a timely manner.

If the compliance officer is of the opinion that the voiding of the Notice is advisable, concurrence must be obtained from the CBP office responsible for insuring the exportation or destruction of the shipment. After the receipt of CBP's concurrence, a letter voiding the Notice should be issued to the requestor with copies to CBP and all persons and firms receiving a copy of the Notice of FDA Action - Refusal of Admission. This letter should provide no more than a ten day period (excluding Saturdays, Sundays, and holidays) to afford the opportunity for a hearing or the submission of a Form FDA-766.

Note: Because of the concern for liquidation of the Bond prior to final disposition of a detained entry, some districts have instituted procedures to issue the Notice of Refusal to CBP before a final decision on reconditioning or appeal have been made. Districts



should follow their local procedures established with their CBP offices when such a practice is used.

## **9-12 Reconditioning**

### **9-12-1 PURPOSE**

To provide the districts with procedures for processing applications (Form FDA-766) requesting authorization to bring detained merchandise into compliance.

### **9-12-2 BACKGROUND**

Section 801(b) of the Federal Food, Drug, and Cosmetic Act provides that an importer of record (also the owner or consignee) may submit to the FDA a written application (Form FDA- 766) requesting permission to bring into compliance an article adulterated, misbranded, or in violation of Section 505 by relabeling or other action, or by rendering it other than a food, drug, device, or cosmetic. This Section also provides that the application should be covered by a bond for the payment of liquidated damages in the event of default. The approval of the application is at FDA's discretion.

### **9-12-3 WHO MAY FILE AN APPLICATION**

Generally speaking, the owner or consignee (provided this firm or individual guarantees by a bond, proper custody and handling of the shipment) or their designated agent (i.e. customhouse broker, consultant, etc.) is the only one who has the legal right to submit an application to recondition or render the detained article not a food, drug, device or cosmetic. Under certain circumstances, the Importer (broker) or other designated agent authorized to act on the matter on behalf of the owner, or manufacturer (if it is a Rad. Health item) may also file an application, provided it is covered by a bond in the event of default. However, before approving an application submitted by the owner or consignee, the importer of record should be contacted to insure that he has no objection.

Frequently, applications are received from customhouse brokers or ultimate consignees who have not posted a bond covering the shipment. Such applications should not be considered and should be returned to the applicant with a notation that we can accept applications only from the importer of record, owner, or consignee, provided the application is covered by a good and sufficient bond, unless appropriate authorization to act on behalf of the owner in the matter has been provided to the district.

## 9-12-4 MECHANICS IN PROCESSING APPLICATION

The Form FDA-766 is essentially a four section form. A specimen copy of this form is attached as Exhibit 9-2 (front and back). A description of this form with additional comments is as follows.

### ***Proposal Section***

The applicant fills out the top portion (face page) of the form and submits it in triplicate (or quadruplicate) to the FDA district which issued the Notice of FDA Action - Detained. A detailed description of the method by which the merchandise will be brought into compliance must be given. For example, such proposed methods as "fumigation and cleaning" are not adequate without the identity of the fumigant, method and duration of application, detailed description of cleaning, etc. In addition, the applicant should indicate the disposition of reject material. (Generally the application should provide for all information identified by Regulation 21 CFR Sections 1.95 and 1.96).

### ***Action on Application Section***

The "Action on Application" section of the form is used by FDA in either approving or disapproving the application. The original copy should be returned to the applicant with the first carbon copy to the district file and the second carbon copy forwarded to CBP for their information. If there is a third carbon copy, it should also be sent to the applicant.

If the district questions the adequacy of the proposed method, the matter should be referred to the appropriate headquarters center for evaluation and advice.

If past experience has shown that the proposed method will not succeed, the application should be disapproved. Applications should be approved only if it appears that the relabeling or other action will be successful and result in an acceptable product.

It is suggested that approved applications include the statement "MERCHANDISE SHOULD BE HELD INTACT PENDING THE RECEIPT OF FDA'S RELEASE NOTICE." Past experience has shown that reconditioned merchandise is sometimes distributed prior to FDA's determination of the adequacy of the reconditioning. In such cases, the applicant sometimes represents to CBP that he was not familiar with FDA procedures or that a third party (the actual reconditioner) was unsure of the procedures. Consequently, the inclusion of the aforementioned statement in the application is in FDA's best interest, if it later becomes necessary to recommend a bond action to CBP. It serves to formally advise the applicant of our procedures and his responsibilities and at the same time may discredit his petition in a bond action.

If the proposal involves a reconditioning of an adulterated product where the sanitary condition of the equipment and facilities is a critical factor, the district should *not* approve the application until the condition, that FDA be notified within a specified time before the start of the reconditioning to enable us to inspect the reconditioning firm, is added by the applying party. An example of such a situation would be the reconditioning

of insect contaminated spices where the cleaning of the product under insanitary conditions would adulterate the article under Section 402(a)(4) of the Act.

Applications should *not* be "approved with the following condition." If there are conditions which we feel should be covered in the proposed procedure it should be denied and inform the applicant that we will reconsider another application if the matter is covered. Past experience has shown that on occasion the applicant either does not agree with or fails to see or understand the conditions which results in much confusion and many problems. By denying the application because of the failure to cover all areas and suggesting resubmission of another proposal to resolve it, the applicant can neither say he did not see, understand or agree to it for he is proposing it. For example, an application should be denied when the matter of rejects has not been resolved. If the applicant fails to propose an acceptable disposition of rejects, the application should be denied; inform the applicant of the reason for denial on the Form FDA-766 and suggest that a new application which includes disposition of rejects will be considered. Only minor points, such as date of completion, etc. should be specified under the "approved with the following condition".

### ***Importer's Certificate Section***

The "Importer's Certificate" section of the Form FDA-766 is used by the applicant to advise FDA that the relabeling or other action has been completed and that the goods are ready for inspection/sample collection. In making this certification, the applicant should fill-in the original copy of the application which was returned to him (as described in RPM subchapter 9-10, "Action on Application Section", above) and then submit the application to FDA.

### ***Report of Inspector Section***

This "Report of Inspector" section of the form FDA-766 is used by the examining FDA or CBP official. This section is later used by the designated district office in preparing the charge sheet and the subsequent Release Notice or Notice of FDA Action - Refusal of Admission.

## **9-12-5 AMENDED APPLICATIONS**

Any changes at any time by the applicant in the reconditioning proposal must be made by the filing of an amended application and must be approved by FDA. Granting of verbal requests for changes may result in misunderstandings and may create problems if it becomes necessary to initiate bond action against the applicant at a later date.

## **9-12-6 REQUESTS FOR ADDITIONAL TIME TO COMPLETE RECONDITIONING**

At times the applicant cannot complete the reconditioning operation within the specified time period. Additional time may be granted by the district upon a written request from the applicant and the showing of reasonable grounds.

Requests for extensions of unduly long periods should not be granted, as the possibility of accidental or intentional diversion and additional adulteration of the shipment increases with the time factor. Normally, a second request for an extension of time should not be granted unless the applicant shows compelling reasons to do so.

#### **9-12-7 UNSUCCESSFUL RECONDITIONING OF ADULTERATED MERCHANDISE**

At times the applicant is not successful in the reconditioning of an adulterated shipment, particularly in cases where the product is contaminated with filth (insects, rodent excreta pellets, etc.). Permission should not be granted for a second attempt at reconditioning without the benefit of another application (Form FDA-766).

The applicant may submit a second application if he so desires. However, this application should not normally be approved unless it contains meaningful changes in the reconditioning operation to insure a reasonable chance at success. A second application should not be approved if it merely is a resubmission of the original application.

In approving a second application, the district should include in the "ACTION ON APPLICATION" section of the application the statement "IF THIS ATTEMPT AT RECONDITIONING DOES NOT BRING THE MERCHANDISE INTO COMPLIANCE FUTURE APPLICATIONS TO DO SO MAY NOT BE CONSIDERED."

Request for a third attempt at reconditioning generally should not be granted. It is our opinion that to allow unlimited attempts at reconditioning only encourage importers to import grossly adulterated merchandise into the U.S.

#### **9-12-8 DISPOSITION OF LOTS NOT RECONDITIONED TO FDA SATISFACTION**

If the applicant is not able to recondition a shipment to FDA's satisfaction, a Notice of FDA Action - Refusal of Admission should be issued in the usual manner. See RPM subchapter 9-11 "Notice of FDA Action - Refusal of Admission." If FDA supervisory charges are involved, a Form FD-790 should be issued. See RPM subchapter 9-13, "Supervisory Charges."

#### **9-12-9 RECONDITIONING OPERATIONS**

##### ***Relabeling of New Drugs***

At times an importer of record may desire to bring a drug shipment detained on a new drug charge into compliance by revising the labeling to remove claims which placed the product into the category of a new drug. Sometimes such a drug appears to be composed of harmless ingredients. A typical example is Chinese herbal medications labeled for the promotion of blood circulation, sexual rejuvenation, headaches,

anemophobia, back neuralgia, bone pain, acute or chronic neuralgia and other pain caused by rheumatism.

Do not permit the relabeling of a drug detained on a new drug charge as a means to bring the item into compliance. To do otherwise is not in the best interest of the consuming public. Experience has shown that such drugs may contain undeclared ingredients, such as phenylbutazone and aminopyrine, which present serious hazards to the users. Likewise, it should be noted that any drug seized in domestic commerce on a new drug charge cannot be relabeled and introduced into commerce, but if condemned by the court must be destroyed.

### ***Reconditioning of Green Coffee and Cocoa Beans Due to the Presence of Live and/or Dead Insects***

This procedure was originally instituted for reconditioning green coffee beans detained under Administrative Guideline 7403.01 due to the presence of live and/or dead insect infestation (CPG 510.500). The procedure has now been expanded to include cocoa beans (CPG 515.750).

In the past when green coffee beans were detained for live and/or dead insect infestation, the importer of record submitted an Application for Reconditioning (FDA-766) indicating fumigation and cleaning prior to delivery to the roasting plant. The coffee industry contended that part of the processing of coffee beans at most roasting plants includes a cleaning procedure for removal of dead insects and extraneous material. The cleaning and rebagging before processing purportedly causes duplication of cleaning and results in additional charges for the importer and ultimately for the consumer.

To avoid duplication the following alternate reconditioning procedure can be used if the importer chooses.

After a detention due to live insect infestation is issued, the importer of record or consignee must submit an Application for Reconditioning (FDA-766). The FDA-766 shall identify the procedure for fumigation (including name and amount of fumigant, time of exposure etc.) which is to be used. The application shall also include the name and address of the roasting plant where the cleaning phase will be accomplished; the identity of the equipment to be used in the cleaning operation; the date and time cleaning operations are to begin; and that a signed statement will be submitted to FDA attesting that the reconditioning was properly carried out by the processor when the entire reconditioning has been completed. When it is deemed necessary, for monitoring purposes, the FDA-766 should be approved with the condition that rejects (tailings) are to be held for FDA examination and subsequent destruction under U.S. CBP or FDA supervision.

As part of the approval of this application (FDA-766) the fumigation must be accomplished prior to permitting the lot's movement to the roasting plant. The district, at its discretion, may examine the lot to determine the effectiveness of the fumigation. If

the stated date or time of cleaning has to be changed, the importer should notify the district supervising the reconditioning at least 72 hours prior to the time noted in the application.

At the time of the initial submission of the FDA-766 application under this procedure, the file should be checked to determine if there has been a recent inspection of the cleaning facility. If not, the application should be approved with the condition that the roasting plant will be inspected to determine if it is acceptable to FDA prior to the movement of the beans to that plant. If the plant is found acceptable, the district will advise the importer that the lot may be sent to the roasting plant. Inspections should be made without undue delay to avoid causing importers excessive storage charges.

After the initial inspections the districts, at their discretion, may make follow-up inspections to determine if the plants' cleaning operations are being maintained to properly recondition detained lots.

All time to conduct inspections to determine if the processors plant and equipment is acceptable and those made to check on specific lots after reconditioning shall be included in the supervisory charges issued to the importer of record. All movement of detained lots shall be under CBP's bond and by acceptable conveyances.

The procedure outlined above, is to be used, with the exception of the fumigation procedure, when the detention is for dead insect infestation only. As previously stated this procedure *is not* to be accepted when the detention is for insect damaged and/or moldy coffee beans.

### ***Reconditioning of Biologicals***

Unlicensed biologicals or biologicals without an effective IND which were refused admission are not subject to reconditioning except in the instances where the intended use of the product is changed to render the product a non-biological, non-drug product, and is so reflected in the associated labeling. Center for Biologics Evaluation and Research (CBER) concurrence with any reconditioning application for a biological product is required.

## **EXHIBITS**

[9-2 Form FDA-766 \(Front\)](#)

[9-2 Form FDA-766 \(Back\)](#)

## 9-13 Supervisory Charges

### 9-13-1 PURPOSE

To provide a uniform procedure for charging expenses in connection with the relabeling, or reconditioning of food, drugs, devices, tobacco products, and cosmetics being imported or offered for import, pending FDA's decision as to the admission of the product. The procedure includes documenting those expenses with a [Form FDA-790 "Charges for Supervision,"](#) in conjunction with a [Form FDA-766 "Application for Authorization to Relabel or to Perform Other Action of the Federal Food, Drug, and Cosmetic Act and Other Related Acts."](#)

### 9-13-2 BACKGROUND

Section 801(c) of the Federal Food, Drug, and Cosmetic Act (FD&C Act or "the Act") [21 U.S.C. 381(c)] requires the owner or consignee of FDA-regulated articles being imported or offered for import to pay for all expenses, including travel, per diem or subsistence, and salaries of officers or employees of the United States, in connection with the supervision of the relabeling or other action ("reconditioning") authorized by FDA under the provisions of FD&C Act section 801(b) to bring the articles into compliance with the Act, or to render the articles other than a food, drug, device, or cosmetic. This includes such expenses in connection with the supervision of the destruction or export of rejected articles or portions thereof, as may be specified in FDA's relabeling or reconditioning authorization. The amount of such expenses is determined by regulation (see 21 CFR 1.99).

In 1985, U.S. Customs and Border Protection (CBP) financial management consolidated all billing operations for FDA supervisory charges at their Accounting Services Division (ASD) in Indianapolis, Indiana. Payments of FDA's supervisory charges are deposited into the U.S. Treasury Miscellaneous Receipts account.

### 9-13-3 SUPERVISORY CHARGES

In submitting a [Form FDA-766](#) (or other form of application) requesting authorization to relabel or perform other action to bring an article into compliance with the Act (see [21 CFR 1.95](#)), the applicant agrees to pay for all supervisory costs in accordance with current regulations. [21 CFR 1.99](#) describes the supervisory costs that the applicant must pay.

The [21 CFR 1.99](#) hourly charge rates for the services of FDA supervising officers and FDA analysts are based on the federal General Schedule (GS) pay scale. At the beginning of each calendar year, ORA HQ sends out an email to the ORA field staff to inform the field of the current GS pay scale [21 CFR 1.99](#) hourly charge rates. This email also informs the ORA field staff of the current mileage reimbursement rates, which are used to calculate the charges for the travel expenses of the supervising officer, per [21 CFR 1.99](#). References below to "the current rate as given by Regulation ([21 CFR 1.99](#))" and "the current mileage rate" should be construed as referring to the current

rates as specified in the aforementioned annual email. These rates should be reiterated on the [Form FDA-790](#) in the “charge per unit” column, for the appropriate line item.

[21 CFR 1.99](#) provides that such costs shall include, but not be restricted to, the following:

1. Travel expenses of the FDA supervising officer.
  - If travel is by government vehicle, charges should be for the mileage costs plus any toll charges. Mileage costs for government vehicle travel should be accounted for on the [Form FDA-790](#) under “Automobile Use” and are calculated by multiplying the current mileage rate by the number of miles traveled. Toll charges should be accounted for on the [Form FDA-790](#) on the “Other Transportation Expenses” line.
  - If travel is by public transportation, the charge is for the actual cost of such travel. Public transportation costs should be accounted for on the [Form FDA-790](#) on the “Other Transportation Expenses” line.
  - Supervisory approval should be obtained prior to charging for any transportation expenses other than those described above but, if approved, should be accounted for and itemized on the [Form FDA-790](#) on the “Other Transportation Expenses” line.
2. Per diem in lieu of subsistence of the FDA supervising officer when away from his or her home station, as provided by law/current regulations.
3. Services of the FDA supervising officer, calculated at the current rate as given by Regulation ([21 CFR 1.99](#)).
  - This rate is designed to account for charges for administrative support of the supervising officer and for the supervising officer’s travel time to or from the site of the article, and therefore separate charges should not be assessed for those items.
4. Services of the FDA laboratory analyst, if applicable, calculated at the current rate as given by Regulation ([21 CFR 1.99](#)).
  - This rate is designed to account for administrative support for the laboratory analyst and for the use of FDA laboratories and equipment, and therefore separate charges should not be assessed for those items.

The following costs should not be charged for:

1. Time spent reviewing, approving, denying, modifying, and/or processing the relabeling or reconditioning request and proposal.
2. Services of a compliance officer supporting the supervision (e.g., services such as determining appropriate courses of action, coordinating logistics of the supervision, performing the services described in # 1 above, etc.).



3. Services of any FDA Center personnel or personnel at ORA HQ supporting the supervision. However, charges should include the supervising officer's or FDA laboratory analyst's time spent consulting or otherwise interacting with FDA Center or ORA HQ personnel regarding the supervision, calculated at the current supervising officer or analyst rate as given by Regulation (21 CFR 1.99).

If multiple supervising officers or laboratory analysts are necessary, then charges should include the services of each of those supervising officers and/or laboratory analysts, calculated at the current rate(s) as given by Regulation (21 CFR 1.99).

The minimum total charge for services of each supervising officer and analyst shall not be less than the charge for one (1) hour. Time after the first hour shall be computed in multiples of one (1) hour, rounding down for fractional parts less than 1/2 hour. For example, if a supervising officer provides services of:

- More than 0 minutes, but less than 1 hour and 30 minutes, charge for 1 hour.
- 1 hour and 30 minutes or more, but less than 2 hours and 30 minutes, charge for 2 hours.
- 2 hours and 30 minutes or more, but less than 3 hours and 30 minutes, charge for 3 hours, etc.

21 CFR 1.99 states that the cost of supervision includes, but is not limited to, the charges described above. Other appropriate miscellaneous expenses not accounted for above should be charged for as miscellaneous expenses for the actual cost incurred, and should be itemized on the Form FDA-790 on the "miscellaneous expenses" line. However, miscellaneous expenses are only warranted under very unusual circumstances. Therefore, appropriate supervisory approval should be obtained prior to incurring or charging for any miscellaneous expenses.

Incurred supervisory costs should be charged for each relabeling and reconditioning attempt, regardless of whether the attempt is successful.

#### **9-13-4 PREPARATION AND SUBMISSION OF CHARGE SHEET**

Future enhancements to FDA's electronic import system (currently OASIS) may result in electronic processing of the supervisory charge-sheet (with appropriate identification and accounting information) for districts to use when submitting their charges to the CBP Accounting Services Division. Until these electronic system enhancements are operational, districts should continue to use Form FDA-790.

Charges should be assessed on the Form FDA-790 and Form FDA-766 only after relabeling or reconditioning of the merchandise is completed. The forms should be filled out and submitted at the same time. The Form FDA-790 "Grand Total" amounts for total time and total charge should be equal to the Form FDA-766 "Time and cost of supervision" amounts.

In addition to the information identified above for supervisory charges, the Form FDA-790 must also include the CBP Entry Number and date of Entry, name of the Importer of Record, carrier, product description, name of the consignee (if different from the importer of record), FDA sample number (if applicable), and FDA district office address.

Scan the completed Form FDA-790 and the FDA Notice of Release, FDA Notice of Refusal, or FDA Notice of Partial Release for each entry and samples covered by the bill, and email a copy of each document to REIMBSVCS@cbp.dhs.gov, addressed to:

U.S. Customs and Border Protection  
Revenue Division - Reimbursable Team  
6650 Telecom Drive Suite 100  
Indianapolis, IN 46278

Contact name:  
Sheri Malicoat  
sheri.malicoat@dhs.gov  
Office 317-614-4490

Maintain the original completed Form FDA-790 and copies of the FDA Notice of Release, FDA Notice of Refusal, or FDA Notice of Partial Release in the FDA district file. By including a copy of the FDA Notice of Release, FDA Notice of Refusal, or FDA Notice of Partial Release with the completed Form FDA-790, there should be no problem identifying the exact entry and samples being covered by the bill.

If submission of these documents by email is not possible, mail the original completed Form FDA-790 and 1 copy of the completed Form FDA-790, along with a copy of the FDA Notice of Release, FDA Notice of Refusal, or FDA Notice of Partial Release to the above address and contact above. Maintain copies of the completed Form FDA-790 and the FDA Notice of Release, FDA Notice of Refusal, or FDA Notice of Partial Release in the FDA district file.

DO NOT send a copy of the completed Form FDA-790 directly to the applicant. It is the responsibility of CBP to contact the applicant to obtain payment of the bill. CBP will also add on to the bill any expenses incurred by their personnel in connection with an entry.

### **9-13-5 PAYMENT OF SUPERVISORY CHARGES**

CBP will instruct the applicant to send payment to CBP, Revenue Division, not to the local FDA office. If the applicant sends payment to FDA, the district office should return the payment to the organization or importer by registered mail with instructions to submit the payment to CBP at the above address.

FDA is not routinely notified by CBP when payment is received. If the applicant refuses to make payment, CBP will take appropriate action against the importer's bond or place a lien against the importer's future importations.

## 9-14 Bond Actions

### 9-14-1 PURPOSE

To increase the effectiveness of FDA's import operations by appropriately utilizing the CBP bond provisions, in conjunction with FDA's enforcement discretion, in an effort to deter the distribution of imported articles prior to FDA release.

### 9-14-2 BACKGROUND

Sections 801(b) and 536(b) of the Federal Food, Drug, and Cosmetic Act and 21 CFR 1.97 provide for the delivery to the owner or consignee of a lot offered for entry into the United States, pending a decision to admit the lot upon the execution of a bond (commonly referred to by FDA as a "redelivery bond"). This bond is filed with the Customs and Border Protection (CBP) and provides for the payment of liquidated damages in the event of default. (The individual or firm posting the bond is referred to as the "Importer of Record.")

This bond contains a condition for redelivery of the lot, or any portion thereof, upon demand of CBP and also a provision for the performance of conditions as may be legally imposed for the relabeling or other action necessary to bring the article into compliance or rendering it other than a food, drug, device, or cosmetic.

FDA district personnel have and may utilize enforcement discretion when evaluating cases of bond violations and penalty recommendations. While it may be accurate to state that FDA "rarely mitigates", it should be pointed out that districts have at their disposal, and may wish to exercise, enforcement discretion when, in their judgment, appropriate circumstances are present. Some examples of appropriate circumstances are stated in *Penalty Recommendation*.

### 9-14-3 BOND VIOLATION

Importers are not specifically required by law to hold a shipment in any given location once a bond has been filed, pending a decision by FDA whether or not to sample. However, in the event FDA decides to collect a sample, CBP can require, under terms of the bond, that the importer return the entire shipment or any portion thereof for sampling, if the shipment has left the port area. If unable to redeliver upon demand by CBP, the importer is subject to assessment of liquidated damages.

In advising importers who inquire about making immediate distribution of any entry, district personnel should recommend that distribution be withheld pending an Agency decision on admissibility. Generally speaking, a bond violation occurs when the importer fails to redeliver merchandise, upon CBP demand, that has been distributed for sale

before sampling and/or release by FDA or before an authorized FDA representative expressed that the merchandise may proceed without FDA examination

Following are examples of situations which may, if the merchandise is not redelivered on Customs demand, result in bond violations:

1. Distribution of a shipment before FDA has decided whether or not to sample;
2. Distribution of a shipment after FDA has elected to sample but before the sample(s) can be collected;
3. Distribution of a shipment that appears to be violative, before or after the receipt of a Notice of FDA Action - Detained;
4. Distribution for sale of a shipment before FDA can inspect and/or sample the merchandise that was relabeled or reconditioned pursuant to an approved Application For Authorization To Relabel Or To Perform Other Action under 801(b) of the Federal Food, Drug, and Cosmetic Act (Form FDA-766);
5. Distribution of a shipment for which a Notice of FDA Action - Refusal of Admission has issued. As soon as it appears that one of the above situations may have occurred, FDA district personnel should report the situation in writing to the CBP Port Director, as an investigation may be initiated by CBP to determine whether a bond violation has occurred. The report to CBP should be strictly factual, with enough background information for CBP to accurately assess the case. The report should, at this point, contain no recommendations nor should it judge the case before the importer of record has had an opportunity to present evidence. The District should offer CBP full cooperation in conducting any investigation that is considered necessary.

If an importer has distributed a shipment before FDA has determined whether to sample or after a Notice of Sampling has issued but before the samples are collected, the written report should ask CBP to require redelivery for sampling purposes.

If, at the time of the aforementioned report to CBP, the shipment had been sampled and a Notice of FDA Action - Detained had already issued on the shipment, a Notice of FDA Action - Refusal of Admission should be issued. The Notice of FDA Action - Refusal of Admission should be executed in the usual manner.

NOTE: A Notice of FDA Action - Detained and Notice of FDA Action - Refusal of Admission are not required in cases where FDA *has not* sampled the shipment.

Where the articles are distributed prior to FDA sampling, FDA should consider following up in domestic channels, for example, by collecting official domestic samples. Where samples have been collected by FDA and are shown to be violative, and the goods are

not redelivered, FDA may consider recommending seizure, or some other action, to remove the violative product from distribution channels.

#### **9-14-4 BOND ACTION PROCEDURES**

If CBP, after review of FDA's report along with any other information, determines that the articles are not entitled to admission, CBP may issue a Notice of Redelivery (CBP Form 4647) to the importer of record. If redelivery is not made within a specified time (currently 30 days) CBP regulations provide for the issuance of a Notice of Penalty or Liquidated Damages Incurred and Demand for Payment (CBP Form 5955A). CBP has amended the amount of liquidated damages to be assessed to three times the value of the restricted merchandise not redelivered (19 CFR 113.62(k)) and increased the amount of the bond required for such entries to three times the value of the merchandise (CBP Directive 3510- 03, 1/14/91). These amounts are current as of the date of the issuance of this RPM. Check CBP regulations for current amounts. The Notice (CBP Form 5955A) will generally request liquidated damages in the amount prescribed by regulation for the *undelivered* merchandise, plus duties. This Notice gives the importer of record an opportunity to object to the action if he or she feels there are extenuating circumstances, and to explain in a written petition why he or she should not be subject to the stated penalties.

The importer of record generally will submit a petition to CBP to either void the Notice of Penalty and Liquidated Damages or will offer to pay a lesser amount. If there are mitigating circumstances, CBP and FDA may agree to the payment of a lesser amount. See 21 CFR 1.97(b).

If the importer of record refuses to pay the amount agreed upon by CBP and FDA, the importer has the option of presenting the case to a CBP Court. Generally, if the Court rules for the government, the importer must pay the original amount of liquidated damages.

#### **9-14-5 RESPONSIBILITY UNDER THE BOND**

When the importer of record is a customhouse broker and not the ultimate consignee, a plea is frequently entered for cancellation of liquidated damages on the basis that the broker had no part in the distribution of the merchandise. It should be emphasized that any importer of record has agreed to the obligations set forth in the bond, most importantly, redelivery. If such bond holders were excused from their obligations, the bond provisions would be unenforceable, and the distribution of imported goods prior to release would be encouraged. It may be pointed out to customhouse brokers that their assumption of the responsibility of importer of record was entirely voluntary. By filing the entry as importer of record, the customhouse broker assumes all obligations under the bond.

### 9-14-6 PENALTY RECOMMENDATION

In evaluating a bond action case, it should be remembered that the bond penalty is intended to make the unauthorized distribution of articles unprofitable. Very often penalties are so small that such penalties, in effect, encourage the illegal distribution of future imported lots.

In the absence of any aggravating factor, the following mitigating factors may be utilized in determining *if* mitigation is warranted. Districts do have enforcement discretion to consider mitigation under other circumstances.

1. The merchandise was exported after detention but prior to the issuance of a Notice of FDA Action - Refusal of Admission because the importer *was not aware* he/she was supposed to wait for the Refusal before exportation. The importer is able to supply documentation that the specific merchandise detained was, indeed, exported.
2. A shipment was released by CBP under an Immediate Delivery Entry (I.D.) and distributed prior to FDA release because it was the initial entry subject to the Federal Food, Drug, and Cosmetic Act by the importer who ***was not aware*** of FDA requirements.
3. Conditions out-of- control of importer - Examples:
  - a. An entry is stored in a public storage warehouse pending FDA clearance but is inadvertently shipped even though the importer has issued instructions to hold the merchandise until further notice. The importer must be able to document the issuance of such instructions, which must be verifiable by FDA.
  - b. A shipment being held pending FDA clearance is stolen or damaged or destroyed in an accident. ***FDA personnel should obtain written documentation of the theft or accident from the importer before considering recommending mitigation.***
4. It is the responsible party's first/only failure to redeliver within two (2) years, and the firm's cooperation with FDA has been positive in providing access to records, initiating recalls, etc.
5. There exists either a non-violative FDA analysis or "acceptable" private laboratory analysis for which audit sample is not available. NOTE: repetitive failure (more than once within two (2) years) to have audit samples available constitutes an *aggravating* factor. (See Aggravating Factors below.)
6. Importer has an excellent compliance history with the district.
  - a. The importer has had only one or two bond offenses since doing business in the FDA district, constituting a small percentage of the importer's total entries which FDA has chosen to examine; and

- b. The importer has an excellent recorded history of entering product in compliance with the Act and has fully cooperated with FDA while in business in the FDA district; and
- c. The importer makes a reasonable attempt to retrieve the entry as soon as it is brought to his/her attention.

Districts are reminded that the enforcement discretion available to you may be utilized when determining whether or not to mitigate bond penalties based on other factors the district deems pertinent.

Although often used by importers in the past as "extenuating circumstances," the following are **not** considered examples of true mitigating circumstances:

1. The amount of merchandise missing;
2. The seriousness of the violation

Note - FDA may consider a firm's history of previous bond violations to show that the importer (e.g. broker serving as importer of record) was aware of FDA and CBP procedures, and that mitigation may not be appropriate.

In addition, there are some *aggravating factors* which would generally *preclude* any mitigation. These factors follow.

1. Attempt to deliberately evade FDA surveillance.
2. Fraud
3. Un-redelivered product has resulted in injury or poses a risk to the public health.

#### 9-14-7 MITIGATION INSTRUCTIONS

The "redelivery bond" is a CBP requirement and the mitigation process is a CBP procedure. Therefore, FDA will not consider mitigation until a mitigation petition is filed with CBP and forwarded to the district for evaluation.

As with the basic decision to mitigate, districts do have enforcement discretion, based on their judgment and evaluation of the facts, to determine the degree of mitigation. The following general procedures should be considered in determining the amount of mitigation:

1. In instances involving the documented exportation of the merchandise, first time importers, and situations out of control of the importer, (see items 1 through 6 in Penalty Recommendation) districts can, based on their evaluation of

the facts in the petition, agree to mitigate the penalty to a nominal amount or recommend no penalty.

2. In all other instances, districts should generally consider mitigating the penalty to the level of the value of the non-redelivered merchandise. The degree of mitigation can vary depending on the district's evaluation of the facts in the petition. However, except for those instances noted in item 1. of this section, mitigation below the value of the non-redelivered merchandise should be considered only in exceptional circumstances.

If the districts have doubts concerning the amount of the penalty recommendation, they should submit the case to the Division of Import Operations, OEIO/DIO for review and advice.

### **9-14-8 TRACKING OF PENALTY ACTIONS**

Until this functionality is available in OASIS, each district shall maintain a log of bond violations and assessment of penalties, in the event that it becomes necessary to check on the past violations of an importer of record. The specific format for such a log is at the district's discretion; however, it should contain at least the following information when available: Name and address of the importer of record; product involved; value of merchandise not recovered; penalty paid; date of action; sample number; reason for the detention; and concise reason for the bond action. It is no longer necessary to send a list of bond actions to DIO.

## **9-15 Import Information Directives**

### **9-15-1 PURPOSE**

To identify and disseminate import information (problems, violative trends, etc.) for providing an effective import coverage program.

To formalize the procedures for initiating, preparing, clearing, issuing, revising, and canceling import information directives (Import Alerts and Import Bulletins).

### **9-15-2 BACKGROUND**

Prior to 1972, FDA had no formal system to disseminate import problem information, although Import Circulars were occasionally issued for that purpose. FDA's coverage of imported products was often conducted on a district-by-district basis, resulting in less effective consumer protection.

A formal system known as Import Alert Procedures was established in 1972. Import Alerts replaced the Import Circulars. Detailed procedures for initiation, preparation,



clearance, issuance, revision, and cancellation of alerts has been added in this latest RPM revision.

The FDA Import Alert Retrieval System (FIARS) was made operational in August 1987. FIARS is a computerized format for Import Alerts and Bulletins, enabling users to search for an alert or bulletin by keyword or full text search. The FIARS program resides on the district VAXs and is updated by Division of Import Operations, (DIO) after new alerts or bulletins are issued by EMS.

### **9-15-3 APPROACH**

Import information directives consist of the following documents issued by the DIO:

- Import Alerts identify problem commodities and/or shippers and/or importers and provide procedures for import coverage. Import Alerts will identify those products or shippers that have met the criteria for detention without physical examination (see RPM subchapter 9-8 for discussion of detention without physical examination).
- Import Bulletins are generally informational only. While the information may identify possible problems, bulletins may not provide policy or coverage procedures, although in some cases sample collections will be advised.

### **9-15-4 IMPORT ALERTS**

Import alerts significantly improve the uniformity of enforcement in import problem areas. Import alerts may have a significant impact on national and international economic and trade matters.

#### ***Initiating an Import Alert***

New import alerts may be proposed by the field, the centers, or any other headquarters unit. Recommendations for import alerts should have the concurrence of the appropriate management of the requesting unit.

Submit recommendations for import alerts to the Division of Import Operations (DIO). Include the following information in the recommendation memorandum:

- Purpose of the import alert.
- All pertinent background information such as sample results, violation rates or trends, etc.
- The national significance of the problem (health hazard, etc.).

- The volume of entries, number of importers, foreign shippers, countries involved, other product information such as whether it is seasonal in nature, etc.
- An accurate and complete description of the product, including its packaging and how it is to be stored.

While not required, the submission of a proposed draft of the import alert with the recommendation is highly recommended. FIARS guideline document #00-05, provides the import alert format.

After review, DIO will prepare a clearance package containing an import alert draft, the form FD-2306 (Clearance Record), and any other pertinent information. If the data is incomplete or insufficient the initiator of the draft will be advised.

### ***Import Alert Clearance Procedures:***

DIO is responsible for proper clearance and issuance of import alerts. The clearance package will be sent to the appropriate center, Office of Operations (OO), and Office of Chief Counsel for clearance and the Office of Regulatory Science (ORS) and the Office of Enforcement and Import Operations (OEIO) as necessary. If revision is necessary, the package should be returned to DIO for correction. Upon clearance, DIO will issue the alert via electronic mail service (EMS), load the alert into the Compliance Management System (CMS) and provide appropriate screening in the national entry database.

### ***Clearance Timeframes:***

Every effort should be made to expedite clearance of import alerts. Each clearance point should attempt to review and clear each alert within 2 days. Import alerts involving health hazards should be hand-carried to the next clearance point and/or telephone clearance should be obtained.

When clearance delays are encountered, clearance units should inform DIO (301-796-0356). Upon approval, DIO will issue the import alert via electronic mail.

### ***Review of Import Alerts***

As conditions permit, all import alerts over two years old will be reviewed semi-annually by DIO to determine whether they are current. This review will include an evaluation of detention activity for the previous one year period, the health significance of the problem, etc. When the evaluation so indicates and the Centers agree the alert will be deleted or revised as needed.

### ***Import Alert Filing Procedure***

Import Alerts will be numbered within industry code (i.e., import alerts dealing with seafood begin with industry code "16")

### **9-15-5 IMPORT BULLETINS (IB)**

DIO will issue Import Bulletins on an as-needed basis. Bulletins are usually advisory only and may not disseminate policy or procedures. They will issue on the responsibility of DIO. They will be numbered chronologically within Industry Code preceded by "B" (16-B01, etc.). Import Bulletins are generally valid for 90 days after issuance. Any information from field or headquarters units which falls into this category may be forwarded for consideration as an Import Bulletin

DIO will review Import Bulletins to see if information has developed which indicates the need for an alert. If districts develop such information they should notify DIO.

## **9-16 Priority Enforcement Strategy for Problem Importers**

### **9-16-1 PURPOSE**

To provide procedures for dealing with importers or other individuals who engage in business practices that appear designed to evade the lawful regulation of imports. The procedures outlined in this chapter should not be considered all-inclusive, nor are they intended to limit local options. Situations that appear to involve criminal activity (e.g. smuggling, falsification of records) should also be referred to the Office of Criminal Investigations for their information and follow-up, as appropriate.

These procedures represent the agency's current thinking on dealing with problem importers. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public.

Priority attention should be given to firms with a history of any of the following actions:

- Distributing imported articles in domestic commerce following receipt of a Notice of FDA Action specifying the intention of Sampling, or the Detention or Refusal of the articles;
- or prior to receipt of a Notice of FDA Action specifying the articles are Released.
- Repeatedly importing violative articles.
- Falsifying documents at time of entry, reconditioning, or re-export, including misdeclaring articles to avoid detention without physical examination or other regulatory action.
- Re-entering previously refused articles into the United States.

- Failing to recall or redeliver to CBP, at its request, an article for which a Notice of FDA Action specifying that the article was refused by FDA has been issued.
- Introducing or delivering for introduction into domestic commerce (after entry) any article which is adulterated or misbranded, or which is a new drug without an approved New Drug Application.
- Committing any prohibited act (see 21 USC 331)

### 9-16-2 BACKGROUND

In developing the Operational and Administrative System for Import Support (OASIS), the specific forms "May Proceed Notice," "Release Notice," "Notice of Sampling," "Notice of FDA Action - Detained," and "Notice of Refusal" have been replaced by the issuing of "Notices of FDA Action," which includes a description of the specific FDA action (May Proceed, Release, Sampling or Intention of Sampling, Detained, or Refusal) identified for the specific line in the entry. The use of the designations "Product May Proceed," "Product Released by FDA," "Product Collected by FDA," "Product Detained by FDA," or "Product Refused Entry by FDA," or similar wording should be considered as meeting the standard, "giving notice thereof to the owner or consignee." (See 21 USC 381(a); 21 CFR 1.94.)

In 1988, the Agency conducted a short-term enforcement operation aimed at determining the disposition of food articles refused admission. Thirteen percent of articles refused admission for non-labeling violations had been distributed in interstate commerce, rather than redelivered for export or destruction.

In 1990, the Agency discovered an importer of ceramic dinnerware circumventing detention without physical examination by declaring the entries as statuary, a non-regulated article.

Between 1990 and 1992, New York District, in conjunction with the CBP, investigated and documented an importer's history of violative practices regarding the importation of frozen seafood products. Practices included repeatedly importing violative articles; falsifying documents and manipulating articles to avoid detention without physical examination; refusing or not permitting timely inspection of entries; importing previously refused articles; and smuggling. As a result of the investigation, in 1992 the firm's president was indicted by the U.S. District Court in New Jersey. He was subsequently convicted on 138 counts for submitting false documents to FDA and for illegally re-importing previously rejected salmonella contaminated seafood. On February 5, 1993, all frozen seafood products imported by the firm were placed on detention without physical examination.

Between 1992 and 1995, Florida District and the Office of Criminal Investigations, in conjunction with CBP, investigated and documented an importer's history of violative

practices regarding the importation and handling of frozen shrimp. Practices included repeatedly importing violative articles; falsifying documents to avoid detention without physical examination; manipulating articles in attempts to have packers removed from detention without physical examination; and laboratory shopping (sending samples of product that is detained without physical examination to different private labs and then submitting to FDA only the analysis which shows the product in compliance, even though the other lab found the product violative). Further, Florida District identified three shipments of shrimp imported by the firm which were seized because of decomposition. Prior to the seizures, the firm attempted to sell the decomposed shrimp, which had been rejected by eight consignees and the National Marine Fisheries Service. The firm also was discovered washing decomposed, imported shrimp with a copper sulfate solution in an attempt to conceal the decomposition. On March 10, 1995, all frozen shrimp imported by the firm was placed on detention without physical examination. As a further result of the investigation, the firm and its top management were indicted by the U.S. District Court in Florida. The firm's vice president was convicted on 12 felony counts, including conspiracy, obstructing justice, violating CBP law, and tainting shrimp and selling it with the intent to defraud and mislead.

### **9-16-3 APPROACH**

The following enforcement approaches have general applicability. They should be considered when dealing with firms engaged in the types of practices listed in the "Purpose" section above, when conventional import coverage and enforcement avenues appear insufficient to address the problem. The approaches include review and approval of reconditioning proposals (FDA-766), the use of Warning Letters (sequential, when appropriate), recall, seizure, injunction, or prosecution.

As always, use of enforcement discretion by the district should be considered in determining the appropriate regulatory response. When egregious actions are encountered, a sequential approach may not be appropriate. Also, situations that appear to involve criminal activity (e.g., smuggling, falsification of records) should be referred to the Office of Criminal Investigations for their information and follow-up, as appropriate.

### **WARNING LETTERS**

Issuance of Warning Letters to remind firms of their responsibilities to import articles that comply with the provisions of the Federal Food, Drug, and Cosmetic Act and other laws enforced by FDA, and to assure that only non-violative articles enter domestic commerce in the United States, is often an appropriate first action. (Refer to RPM Subchapter, "Warning Letters.") Warning Letters may be issued to the importer of record, owner, or consignee (if other than the importer of record) with copies to CBP, and may be issued for the following reasons:

1. Failure to hold an entry intact pending receipt of a Notice of FDA Action specifying that the article was Released by FDA. A copy of the Warning Letter

should be attached to the redelivery request sent to CBP when such a request is made.

2. The first documented attempted entry with misleading information. Misleading information includes, for example, low-acid canned foods from a non-registered plant entered under another processor's Food Canning Establishment (FCE) number; or articles from firms subject to detention without physical examination; or articles declared as non-regulated articles to avoid detention without physical examination or other agency action.
3. The first documented instance of submission of a foreign government certification document or private laboratory analytical report that does not match the entry in question.
4. An importer's failure to provide FDA with information regarding the availability for sampling or location of an entry for which a Notice of FDA Action specifying FDA's intention of sampling has been issued.
5. To inform an importer that FDA has requested that CBP deny it permission to file an entry bond, thus restricting its shipments to CBP's custody until admissibility has been determined.
6. Consistently importing violative articles not already subject to detention without physical examination. The importer should be notified that this practice may result in future entries being detained without physical examination.
7. Any other situation which warrants an official notification to the firm and further opportunity for compliance before other action is taken.

The Warning Letter should state that any distribution of refused articles or articles sampled or intended for sampling that were distributed prior to release are in violation of the Federal Food, Drug, and Cosmetic Act or other applicable acts enforced by FDA, and may result in domestic seizure or other sanctions, including injunction or prosecution

### ***RECONDITIONING PROPOSALS***

The Federal Food, Drug, and Cosmetic Act provides that when an article is submitted for entry is found to be violative, the importer has the option of exporting it, destroying it, rendering it not subject to the Act, or requesting permission from the agency to attempt to bring it into compliance with the Act.

If the importer of record decides to attempt to recondition a detained article, section 801(b) of the Act (21 USC 381 (a)) provides that the owner or consignee (by practice, FDA also accepts applications from an importer of record, with a properly posted bond, as the agent of the owner or consignee) may submit to the FDA a written application

(Form FDA-766 or other acceptable means) requesting permission to bring into compliance an article that is adulterated, misbranded, or in violation of Section 505 (see 21 USC 381 (a)(3)). The owner or consignee may bring the article into compliance by relabeling or other action, or by rendering it other than a food, drug, device, or cosmetic. (Refer to RPM Subchapter 9-12, "Reconditioning.")

The approval of the reconditioning application is at FDA's discretion. The Agency should require appropriate controls and provisions as a part of any application before it approves the reconditioning. The application is an agreement between the importer (or other appropriate party submitting the application) and the Agency.

If FDA has documented an importer's practice of consistently importing violative articles not already subject to detention without physical examination and only attempting to recondition the articles after detention, the District may require, as part of any reconditioning application, that the importer agree to destroy any article not brought into compliance during reconditioning, in lieu of permitting re-export of the violative article.

Districts should consult and obtain the concurrence of both the OEIO/Division of Import Operations (DIO) and the appropriate Center Compliance Office before initiating a policy requiring a specific importer to destroy rather than re-export violative articles as part of every reconditioning process. The information supplied should include, but not be limited to, the following:

1. Documentation of the firm's pattern of importing violative articles.
2. Documentation of prior warning to the firm of their obligation to import the article in compliance with the Federal Food, Drug, and Cosmetic Act or other acts enforced by FDA.
3. Documentation which may establish that the article can be imported in compliance and thus would not require reconditioning after importation.

### ***REQUESTS FOR VOLUNTARY RECALLS***

Although requests for voluntary recalls duplicate a request for redelivery action to some degree, they also offer definite advantages. Experience indicates that requesting the firm to initiate a voluntary action, such as a recall, may result in a more favorable response by the firm than a demand for redelivery. A recall may occur more promptly because it can be initiated in a matter of days, while redelivery may not take place for 90 days or more. This is especially significant in hazard-to-health situations. A recall may provide FDA with further knowledge of the status of the violative merchandise being returned and usually makes it easier to maintain control of the article. This ultimately leads to improved consumer protection.

District management should very carefully encourage the firm to consider a voluntary recall under the following situations:

1. When a potential health hazard situation exists.
2. When there is evidence of distribution of detained or refused merchandise.

When an importer fails to respond fully or in a timely manner to a Warning Letter, or we are notified by CBP that an Importer has not responded to a Notice of FDA Action Specifying Refusal of the product, it may be an indication the goods are no longer intact. A visit to the importer may be appropriate and, if articles are missing, attempt to determine the firm's intentions with respect to corrective action.

When a potential health hazard situation exists and the article has been illegally distributed, appropriate press coverage may issue naming firm, product, and country of origin. Issuance of all publicity must be in accordance with guidelines.

Import recalls are to be conducted in full accordance with the guidelines in RPM Subchapter, "Recall Procedures." Supervision of the disposition of returned articles may be made either by FDA or CBP. If disposition will be by destruction, it is suggested that FDA provide the supervision. If the articles are to be exported, CBP or FDA may handle the supervision.

## **SEIZURE**

Seizure is another enforcement approach that may be considered to gain control over violative imported articles. Seizure is an action against an article. Consequently, it will be necessary to show, through laboratory analysis or otherwise, that the article seized is actually violative. An importer's history of illegal actions, while relevant, is not itself sufficient to support seizure. Whatever the importer's previous history, it will be necessary to show that the article itself is violative. Seizure may be considered for an article which:

1. Represents a potential hazard to health and has been or is likely to be distributed in domestic commerce following receipt of a Notice of FDA Action specifying that the article is Detained or Refused; or
2. Has been fraudulently identified/represented in documents submitted to the Agency; or
3. Is identified by the Agency as a previously refused article.

When an imported article is seized, and condemned, it is subject to the provisions of section 304(d) (21 USC 334(d)) which may allow for re-exportation of the article, provided specified conditions are met. Under 21 USC 334(d), certain condemned imported articles may be re-exported under limited circumstances. Re-exportation is not available for condemned unapproved new drugs (see 21 USC 355), or foods in



violation of the emergency permit control provision (see 21 USC 344). Such articles must be destroyed.

In order to be able to re-export condemned imported articles, the party seeking re-export must satisfy several threshold conditions:

1. The violation did not occur after the article was imported.
2. The party seeking re-export "had no cause for believing that it was adulterated, misbranded, or in violation before it was released from CBP custody."
3. The party seeking re-export must "establish that the article was intended for export at the time the article entered commerce." An example of where it may be possible to demonstrate that a product was intended for export at the time it entered commerce would be when products are imported for purpose of transshipment to a destination outside the U.S.
4. Compliance with 21 USC 381 (e) (1):
  1. Intended for export.
  2. Accords with the specifications of the foreign purchaser (unless the article is to be exported to the original foreign supplier, in which case there is no need to comply with this requirement).
  3. May not be in conflict with the laws of the country to which it is intended for export (unless the article is to be exported to the original foreign supplier, in which case there is no need to comply with this requirement).
  4. Labeled on the outside of the shipping package that it is intended for export
  5. Not sold or offered for sale in domestic commerce

Therefore, there are circumstances where the seizure of an article may not accomplish more than detention and refusal of the article, other than stricter control over the goods before re-export and compliance with the applicable requirements of Section 801(e) (21 USC 381(e)).

Consequently, in evaluating whether a seizure is an appropriate course of action, a district should consider whether the facts in the case would justify recommending to a court that re-export of the article would be an unsatisfactory resolution. Among the points to consider are:

1. Does a potential health hazard exist?
2. Does the previous history of the person in possession of the articles indicate that the person may attempt to re-enter the articles into the United States at a later date?
3. Did the violation occur after the article was imported?
4. Did the importer have cause to believe that the article was in violation before entry?
5. Does the article meet the legal specifications of the country to which it would be exported?
6. Was any portion of the article sold or offered for sale in domestic commerce?
7. Is the article in violation of 21 USC 342(a)(1), (2), or (6), 344, 351(a)(3), 352(j), 355 or 361(a) or (d)?
8. If the article is a drug will it be re-exported to the original foreign supplier?

Under certain circumstances, the district may recommend seizure of violative articles under 21 USC 334 while the articles are still under import status, rather than allow re-export as provided under 21 USC 381 (a). Generally, seizure of articles while in import status may be appropriate if the articles must be destroyed (pose a serious health hazard or it is likely that the articles will be reintroduced into the United States), or the public health requires that certain conditions be imposed (e.g., conditions in 21 USC 381(e)(1)).

As with citation, prosecution, and injunction, samples collected for seizure consideration should, whenever possible, include a 702(b) portion (see 21 USC 372 (b)). Such samples should be collected, sealed, analyzed, and otherwise handled in accordance with procedures normally applied to domestic samples.

State embargo authority and CBP holds are alternative methods to gain control over violative articles. CBP may also release an article at our request so that an immediate domestic seizure may be conducted. Moreover, if a violative article represents evidence of a crime, it may be seized pursuant to a criminal search and seizure warrant. These avenues should also be considered, especially if an importer is likely to attempt to quickly re-export the article.

### ***INJUNCTION***

If injunction is the action of choice, the case should be developed in accordance with the procedures set forth in RPM Subchapter [6-2](#), "Injunctions." Injunctions may require a pattern of actual violations with some recognizable danger of a recurrence. The

monitoring of an injunction is resource intensive. These facts should be taken into consideration when evaluating this course of action. Also consider that an injunction often results in a hearing more quickly than does a prosecution, particularly if a Temporary Restraining Order (TRO) is requested. This can result in quick corrective action as well as more rapid and efficient redelivery if this response is requested in the injunction. Also, the burden of proof is less in civil cases than in criminal cases, and injunction does not preclude subsequent prosecution for the same violation.

When developing an injunction case against an importer or consignee, there must be a well- documented history of an illegal practice.

A TRO requires a heightened showing of harm. See RPM Subchapter [6-2](#), "Injunctions" regarding the prerequisites for a TRO in conjunction with an injunction action.

### **CITATION/PROSECUTION**

Citation/prosecution should be used when conventional import enforcement approaches are determined to be inadequate to correct violative practices, or the violation is sufficiently egregious to warrant punishment.

When citation/prosecution is the action of choice, refer to RPM Subchapter 6-5, "Citations" and "Prosecution" for the appropriate procedures.

Districts should consider the potential impact of developing citation/prosecution recommendations as the action of choice in the following instances:

1. Where there is repetitive illegal distribution of articles after issuance of a Notice of FDA Action specifying the intention of Sampling or Detention; or
2. Where the importer submits false or misleading entry documents; or
3. Where the importer submits false or misleading private laboratory analytical results or false certifications; or
4. Where the importer submits false or misleading export documents; or
5. Where the importer repeatedly brings previously refused articles into the United States; or
6. Where evidence of other fraud exists.

This list is not all inclusive and there may be other situations where citation/prosecution is appropriate.

Any recommendation for citation, prosecution, or injunction must be supported by fully documented instances of attempts to circumvent normal import procedures. For a felony

prosecution recommendation, there must be a fully documented attempt to do the same, with evidence of the intent to defraud or mislead. It is not necessary, in developing a citation/prosecution recommendation, to show that each specific entry is actually violative. However, physical evidence that documents the violative nature of an entry (or of several entries) would be useful to highlight the likely result of the firm's pattern of behavior.

It is important to remember that sample collection and analytical procedures in these cases, as for seizures and injunctions, should differ from routine import work. The Office of Chief Counsel has consistently advised us that when an import physical sample is collected for use in an anticipated legal action, a sealed 702(b) portion should be available (21 USC 372 (b)). This request is further supported by procedures provided in the RPM. Proper chain of custody should also be maintained for these samples. Ordinarily, check analyses should be conducted on such samples. In instances where Compliance Policy Guides exist and instructions differ for domestic legal actions as opposed to import detention, districts should follow the procedures for domestic legal actions in terms of types of analyses, check analyses, etc.

Importers of articles detained without physical examination should not feel free to distribute and sell such articles without risk of criminal penalty. Criminal action may be possible against importers violating FDA's detention without physical examination actions or who routinely ship articles without a Notice of FDA Action indicating the articles are Released. Refusal to allow inspection is a violation of the Federal Food, Drug, and Cosmetic Act. Subsequent entry pursuant to an inspection warrant may yield evidence providing the basis for a felony violation for refusal to allow inspection. Distribution of an article prior to receipt of a Notice of FDA Action indicating the article May Proceed or is Released should be considered refusal to permit inspection, as authorized by section 704 (21 USC 374).

In addition to charges under the Federal Food, Drug, and Cosmetic Act and CBP law, Title 19 (note especially, 19 USC 1592 and 1595a), and/or Title 18 charges may also be considered. These include 18 USC 1001, false statements; 18 USC 1505, obstruction of justice (when a firm knowingly and willingly interferes with an FDA inspection by distributing imported articles not released by FDA from import status); 18 USC 542, entry by use of a false statement; 18 USC 545, smuggling; and 18 USC 371, conspiracy.

## **9-17 Import For Export**

### **9-17-1 PURPOSE**

This subchapter is to provide procedures to FDA field offices regarding the handling of certain products that are offered for import under section 801 of the Federal Food, Drug, and Cosmetic Act (Act). Those products are those that are offered as "imports for export." The provision of the Act that permits such imports, section 801(d)(3), is referred

to as the "import for export" provision. These procedures are intended to provide uniform procedures for handling such importations by all FDA offices. This chapter represents the Agency's current thinking on the application of the import for export provisions of the Act.

## 9-17-2 BACKGROUND

The FDA Export Reform and Enhancement Act of 1996 (Export Reform Act), Public Law 104-134 amended section 801(d)(3) and d(4) of the Act to allow the importation of certain articles that are unapproved or otherwise do not comply with the Act, provided that those imported articles are further processed or incorporated into products that will be exported from the United States, by their initial owner or consignee in accordance with section 801(e) or section 802 of the Act or section 351(h) of the Public Health Service Act (PHSA). On June 12, 2002, the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act), Public Law 107-188, was signed into law. Section 322 of PL 107- 188 amended section 801(d)(3) of the Act. The amended provision is effective September 9, 2002.

Under the amended provision of the Act, importers wishing to import certain violative articles that are intended for further processing or incorporation into another product and subsequent export must provide FDA with certain information at the time of initial importation. The articles include drugs (or components), devices (or components or accessory of a device or other article of a device requiring further processing, which is ready or suitable for use for health-related purposes), food additives, color additives and dietary supplements. The information includes a statement that confirms the intent to further process such article or incorporate such article into a product to be exported and identifies entities in the chain of possession of the imported article. Importers also must provide certificates of analysis as necessary to identify the article unless the article is a device or an article described in Section 801(d)(4). Section 801(d)(3)(A)(i)(III).

Under section 801(d)(3)(A)(ii), at the time of initial importation and before delivery to the importer, initial owner, or consignee, a bond must be executed providing for liquidated damages in the event of default, in accordance with United States Customs and Border Protection (CBP) requirements.

The initial owner or consignee of the article must maintain records of the use and/or destruction of such imports and must submit the records or a report to FDA upon request. Section 801(d)(3)(A)(iv) and (v). The initial owner or consignee must destroy any article or portion not used in an exported product. Section 801(d)(3)(A)(iii).

The amended section 801(d)(3)(B) provides that FDA may refuse admission of an article that could otherwise be imported under section 801(d)(3)(A) if there is credible evidence or information indicating that such article is not intended to be further processed by the initial owner or consignee or incorporated into a drug, biological product, device, food, food additive, or dietary supplement that will be exported in accordance with section 801(e) or section 802 of the Act or section 351(h) of the PHSA.

The "import for export" requirements for blood, blood components, plasma, and source leukocytes differ from those for drugs and other biological products. The Act allows for the importation of these blood products and components provided they comply with section 351(a) of the PHSA or FDA permits such imports "under appropriate circumstances and conditions" as determined by the Center for Biologics Evaluation and Research (CBER) (section 801(d)(4) of the Act). Tissue products may be imported only if the importation complies with regulations promulgated under section 361 of the PHSA. The Bioterrorism Act did not amend section 801(d)(4). However, if CBER approves a particular request for import under section 801(d)(4), the import must comply with all applicable requirements of the amended section 801(d)(3) of the Act. Section 801(d)(4). The import also must comply with all applicable export requirements when the product is exported. Section 801(d)(3)(A)(i)(I) and (iii). The Bioterrorism Act also amends section 301 of the Act. The amended section 301(w) prohibits the making of a knowingly false statement in any statement, certificate of analysis, record or report required under section 801(d)(3); the failure to submit a certificate of analysis; the failure to submit or maintain records; the release into interstate commerce of any article or portion imported into the United States under section 801(d)(3) or any finished product made from such article or portion, except for export in accordance with section 801(e) or section 802 of the Act, or section 351(h) of the PHSA; and, the failure to export or destroy any articles or portions not incorporated into a finished product. Section 801(d)(3) requires that the imported article or portions must be further processed or incorporated into a drug, biological product, device, food, food additive, color additive or dietary supplement that will be exported.

### **9-17-3 INSTRUCTIONS**

#### **INFORMATION SUBMISSION, ENTRY REVIEW, AND DOMESTIC FOLLOW-UP**

When a drug or device component, food additive, color additive, or dietary supplement is imported under section 801(d)(3), the importer is required to submit a statement to FDA at the time of each importation with the following information:

1. that such article (the components, parts, accessories, or articles) is intended to be further processed by the initial owner or consignee or incorporated by the initial owner or consignee into a drug, biological product, device, food, food additive, color additive, or dietary supplement that will be exported from the United States by the initial owner or consignee in accordance with section 801(e) or section 802 of the Act or section 351(h) of the PHSA; and
2. identification of the manufacturer of such article and each processor, packer, distributor or other entity that had possession of the article in the chain of possession from the manufacturer to such importer of the article.

The statement must be accompanied by such certificates of analysis as are necessary to identify such article unless the article is a device or is an article described in section 801(d)(4). Section 801(d)(3)(A)(i)(III).

In order for FDA to efficiently process such importations, the statement required to be provided to FDA pursuant to section 801(d)(3)(A)(i) must include, pursuant to that section, a declaration that the article is intended to be imported for further processing by the initial owner or consignee into a drug, biological product, device, food, food additive, color additive, or dietary supplement that will be exported in accordance with section 801(e) or section 802 of the Act or section 351(h) of the PHS Act. The statement should include information identifying the article and the initial owner or consignee.

Identification of all entities that had possession of the article in the chain of possession should include information sufficient to accurately identify the entity such as the name of each entity (including business and trade names), complete physical address, transaction dates, and any other information to aid in identification such as telephone and fax number, and e-mail address. The statement should include information sufficient to identify the chain of possession of the article through each entity, which could include information such as product coding, lot, batch, or other identification numbers. For medical devices, device history records required of domestic and foreign manufacturers, pursuant to 21 C.F.R.

820.184, may provide information to assist in meeting this requirement. For imported articles subject to section 801(d)(4), the manufacturer in the chain of possession can be considered to be the initial collection agency, e.g., a blood collection center for purposes of information required under section 801(d)(3).

Certificates of analysis, as are necessary to identify the imported article, must accompany the statement filed pursuant to 801(d)(3)(A)(i). Section 801(d)(3)(A)(i)(III). The submission of such certificates is not required if the imported article is a device or is an article described in 801(d)(4). Certificates of analysis, or equivalent documentation should provide the article's formulation, ingredients, components, or assay, as appropriate to the type of article.

Certificates of analysis could include documents to assure the identity of the substance and its components in the chemical and drug industries. A batch certificate could be a certificate of analysis. A document that establishes a drug ingredient is certified to meet USP requirements could be a certificate of analysis. Documents that provide sufficient information to determine the level, potency, identity, strength, quality and purity of the drug component and whether prohibited material has been used in the imported article could be considered certificates of analysis.

For other products, documents that convey assurance as to the identity of the article and its components or substances could be a certificate of analysis. Sufficient information should be provided to determine if prohibited material has been used in the imported article. For an article of food additive or color additive, a document indicating specification of purity or documents establishing the article is a "certified" color or of "food grade" or "Codex Alimentarius" grade food additive could meet the requirement of a certificate of analysis.

When the initial owner or consignee of the imported article is not the importer, the importer should provide FDA with information identifying the initial owner or consignee with the entry. In cases where the importer is not the initial owner or consignee and the article is intended for multiple owners or consignees, each of whom will serve as the initial owner or consignee for a portion of the article, the importer should submit a separate statement identifying each owner or consignee and indicating the amount of the entry each is to receive. Failure to provide this information at the time of importation may be viewed by the district as evidence that the product does not meet the conditions of section 801(d)(3).

If the information needed to efficiently process importations and to make a “May Proceed” decision is not provided at the time the article is offered for entry, and if the product is otherwise subject to refusal of admission pursuant to section 801(a), the district may issue a Notice of FDA Action - Detained in accordance with normal procedures (see RPM Chapter "Notice of FDA Action – Detained for Non-Mail Shipments"). If a response to the Notice of FDA Action - Detained is not received by the district within the designated time (10 days, excluding Saturday, Sunday, and Holiday, or date requested by on the notice, or additional time as deemed necessary by the district), a Notice of Refusal should be issued (see RPM Chapter 9-11 "Notice of FDA Action - Refusal of Admission" Instructions, "When Should the Notice of FDA Action - Refusal of Admission be Issued?"). Once issued, cancellation of the Notice of Refusal should be considered only under unusual circumstances at the discretion of the district (see RPM Chapter 9-11 "Notice of FDA Action - Refusal of Admission" Instructions, "Reopening of a Case").

If the district has evidence or information indicating that the imported article is not intended to be further processed by the initial owner or consignee, or incorporated by the initial owner or consignee, into a product included in section 801(d)(3) that will be exported in accordance with the Act or the PHSA, the district should contact the Division of Import Operations before any action is taken on the entry. In certain circumstances, application of section 801(d)(3)(B)'s refusal authority may be appropriate

### **Submissions of Entries**

Entries of articles imported pursuant to section 801(d)(3) that are accomplished by electronic submission of information through the CBP Automated Commercial Environment/International Trade Data System (ACE/ITDS) and the FDA Operational and Administrative System for Import Support (OASIS) will necessitate that the filer declare that the imported article is intended for further processing or incorporation into a product that will be exported in accordance with Section 801(d)(3)(A)(i) of the Act. If the filer is not the "importer, initial owner or consignee" responsible for further processing or incorporating the imported article into the product to be exported, the filer of the entry should provide the name of such firm or individual in the FDA consignee field using the appropriate FDA Field Establishment Identifier (FEI) number.



When the article is intended for multiple owners or consignees, a separate FDA line should be created for each owner or consignee as provided for in the ACE/ITDS system. FDA has established an Affirmation of Compliance (A of C), identified by the code "IFE" (Import for Export), that will indicate that the entry is being made under the import for export provisions of the Act. Use of the "IFE" affirmation triggers prompts for the submission of Quantity and Value data. If any of this information is not provided, the notification will be considered incomplete by the system. Such lines with "IFE" (or any Affirmation) will display the Affirmation in the Entry Line Summary and line detail screen. If electronic submission is made, in most cases it is unlikely that all of the information required under section 801(d)(3) will be able to be provided through electronic entry. Districts should request and review the supporting paper entry documents for all "IFE" entries.

Once the district has determined that all of the appropriate information has been submitted, either by the on screen review process or by review of the entry documents, a "May Proceed" should be issued in accordance with OASIS procedures. The filer may be held responsible for the accuracy of the information provided through OASIS for such importations and import for export entries will be included in the FDA's filer evaluation conducted by the district of the broker

For manual entry submissions, or when FDA has requested supporting paper entry documents for an electronic "IFE" entry, all documentation required by section 801(d)(3) should be included in the filer's entry package, including the statement and a certificate of analysis as necessary. When the imported article is intended for multiple owners or consignees, a separate statement and certificate of analysis as necessary should be submitted for each owner or consignee indicating the portion of the entry each is to receive. Districts should reconcile the quantities provided and any product not accounted for should be detained if otherwise subject to refusal of admission pursuant to section 801(a) as noted above. If the district determines that all information provided in the manual or electronic submission is appropriate, then the district should follow their normal procedures for marking the entry "May Proceed".

### **Follow-up**

The district responsible for the entry review should use normal operating procedures to determine whether additional follow-up is necessary for entries made under section 801(d)(3). This can consist of additional contact with the importer or the initial owner/consignee at the time of entry to obtain records to confirm the intended use of the article and the final disposition of the article. The home district of the initial owner or consignee should be provided with a copy of the entry paperwork by the district performing the entry review (where the home district is not the importing district). Entries processed by OASIS will be available to home districts through a Structured Query Language (SQL or Sequel) report.

The imported article will continue to be subject to the Customs Temporary Import Bond or other bond instrument as required by CBP, under the new section 801(d)(3)(A)(ii) and remains subject to section 801(a). Any follow-up regulatory actions regarding the failure

of the initial owner or consignee to meet the requirements of section 801(d)(3) should be referred to the Division of Import Operations for handling.

When a domestic inspection is conducted at a manufacturer's facility where the imported article is being further processed or incorporated into a product intended for export, the inspection should include appropriate review of the domestic manufacturer's compliance with section 801(d)(3). For example, the investigator should request the manufacturer's import, export, and/or destruction records during an inspection. The records/reports should include documentation indicating that the imported article was further processed or incorporated into another product and was exported in accordance with section 801(e) or section 802 of the Act, or section 351(h) of the PHSA, or destroyed. The records should establish that the entire amount of the product or article imported is used or exported or destroyed; that the exported products are labeled in conformance with section 801(e)(1) and meet the other requirements of section 801(e)(1) or section 802 of the Act or section 351(h) of the PHSA, as appropriate. Please note, however, that for drug and medical device products, an initial owner or consignee may be allowed to retain a sample of the imported article in order to comply with good manufacturing process (GMP) regulations concerning sample retention.

#### **9-17-4 TIME FRAME FOR HOLDING IMPORTED PRODUCT**

Section 801(d)(3) allows for the importation of otherwise prohibited products and articles for manufacturing, further processing or incorporation and export. The amended provision does not impose any specific limitations on how long a product can be held in the United States before it must be further processed or incorporated into a product and exported or destroyed. A time limitation may be imposed, however, by CBP through its bond requirements.

#### **9-17-5 IMPORTED FOR FURTHER PROCESSING**

The legislative history of the Export Reform Act indicates that section 801(d)(3) was intended to allow manufacturing and processing activities not previously permitted under the Act, and the legislative history of the Bioterrorism Act does not alter that intent. The terms "further processed" and "incorporated" can cover a wide range of activities. These can include packaging or labeling of finished products and specialized processing (such as sterilization) of a product. FDA recognizes that in some instances, it may be advantageous to manufacture a product in a foreign country and then ship it to the United States for specialized packaging or labeling. Merely storing an article or product in the United States before export is not considered "further processing."

#### **9-17-6 PRODUCTS SUBJECT TO DETENTION WITHOUT PHYSICAL EXAMINATION**

The import for export provision does not preclude the importation of articles that otherwise would be subject to detention without physical examination based on an FDA

examination of previous shipments or a foreign inspection that documented significant good manufacturing practice (GMP) violations, or manufactured by a foreign firm that has refused to permit an FDA GMP inspection [21 CFR 820.1(d)]. Therefore, if these articles are offered for import in compliance with section 801(d)(3) or (4) such articles generally could be allowed unless other grounds exist for refusal of admission. Further procedures on criteria for accepting products for IFE that would otherwise be detained without physical examination products may be issued by each Center.

#### **9-17-7 COMPLIANCE WITH RELEVANT EXPORT PROVISIONS**

At the time of importation, FDA ordinarily will not know if the finished product will be exported under the provisions of section 801(e)(1) or section 802 of the Act or section 351(h) of the PHSA. Importers, initial owners, and consignees of articles imported or offered for import pursuant to section 801(d)(3) or (4) should determine whether the intended finished product meets the requirements of one or more of the export provisions (section 801(e)(1) and section 802 of the Act and section 351(h) of the PHSA). If they do not meet such requirements, they must destroy any products that may not be legally exported under the Act or the PHSA, as applicable. Section 801(d)(3)(A)(i)(I) and (iii).

#### **9-17-8 IMPORTATION OF FINISHED GOODS FOR STORAGE AND EXPORT WITHOUT FURTHER PROCESSING AND OTHER ARTICLES NOT INCLUDED UNDER SECTION 801(d)(3)**

Products and articles imported under section 801(d)(3) must be furthered processed or incorporated into a drug, biological product, device, food, food additive, color additive or dietary supplement that will be exported from the United States. This provision does not allow the import of violative products intended only for storage.

Importers of electronic products subject to performance standards are required by U.S. Customs regulation, 19 CFR 12.91, to file the form FDA 2877. Block A.7 on form FDA 2877 needs to be checked to indicate that the device is for medical device processing under import for export.

Since the wording of the amended section 801(d)(3) specifically identifies only food additives, color additives, and dietary supplements as the only food articles that can be imported for export, districts should not accept notification of import for export of other foods that do not meet the criteria of a food additive, color additive, or dietary supplement. Similarly, cosmetics, as defined by section 201(i) of the Act, do not meet the criteria for import for export under the provisions of section 801(d)(3) and any offers for entry for such importations should be refused admission as appropriate.

The amended section 801(d)(3) also identifies specific products into which articles imported pursuant to the section can be incorporated for export. These are drugs, biological products, devices, foods, food additives, color additives, and dietary supplements. Cosmetics are not listed as a product that falls within this provision.

Therefore, violative color additives intended for processing into a cosmetic product do not fall within the scope of section 801(d)(3), and entries for such importations should be refused admission, as appropriate.

### **9-17-9 IMPORTATION OF VIOLATIVE COMPONENTS FOR FURTHER PROCESSING INTO OTHER COMPONENTS AND UNFINISHED PRODUCTS**

Many manufacturers assemble their products in various stages. These manufacturing steps may include sending partially completed products to firms in the United States for further manufacturing or processing, but not into a finished product. Neither the statutory language of the amended section 801(d)(3) nor the legislative history of the Export Reform Act or the Bioterrorism Act require that violative components allowed to be imported must be incorporated into "finished products." Because components, or "subassemblies," are the finished product of the U.S. manufacturer (although not necessarily a consumer ready product) and would constitute a drug, biological product, device, food additive, color additive, or dietary supplement within the Act's meaning, the agency has concluded that articles imported for use in the manufacture of such products fall within the scope of the import for export provision. Therefore, such products are subject to the requirements of section 801(e) or section 802 of the Act or section 351(h) of the PHSA.

### **9-17-10 IMPORT FOR EXPORT PROVISIONS FOR PRODUCTS MANUFACTURED IN FOREIGN TRADE ZONES**

Foreign Trade Zones are federally sanctioned sites that, only for tariff purposes, are considered outside of the "Customs territory" of the United States. Nevertheless, products stored or manufactured in a Foreign Trade Zone are within the territory of the United States for the purposes of the Act and are expected to meet the same requirements as other products regulated by FDA [see Compliance Policy Guides 110.600 "FDA Authority Over Products of Foreign Origin Located in Foreign Trade Zones, Bonded Warehouses, or on Bonded Carriers", and 110.200 "Export of FDA Regulated Products from U.S. Foreign Trade Zones"]. These include the requirements of section 801(d)(3) and section 801(d)(4).

### **9-17-11 RECORDS AND INFORMATION TO BE PROVIDED TO FDA UPON REQUEST**

The new section 801(d)(3)(A)(iv) requires that the initial owner or consignee maintain records on the use or destruction of the imported articles or portions and to provide records when requested. The initial owner or consignee is also required to submit a report to FDA, upon request, that provides an accounting of the export or destruction of such imported article or portions and the manner in which such owner or consignee complied with the requirements of section 801(d)(3). The records should include the statements and any certificates of analysis required to be submitted at the time of import as described above. Additional records could include documentation with more specific identification of the product such as Customs entry number, date, quantities,

manufacturing process and controls and intent of the importation (i.e., further processing into product intended for exportation). Records on export or other disposition need to be retained (section 801(d)(3)(A)(iv)) and should include information such as quantity, dates, destination, shipping, means of destruction, and any records required under the export record keeping and notification regulation. (21 C.F.R 1.101).

### **9-17-12 AGENCY CONTACTS**

Questions regarding importation of specific products should be referred to the appropriate Center (e.g., biological products, tissues, and procedures for considering requests to import violative blood products under section 801(d)(4) should be referred to Center for Biologics Evaluation and Research, Office of Compliance and Biologics Quality, Division of Case Management, Biological Drug and Device Compliance Branch (HFM-624); unapproved drugs should be referred to the Center for Drug Evaluation and Research, Office of Compliance, or Division of Labeling and Non-Rx Drug Compliance, Import/Export International Drug Team (HFD-316); food additives and color additives should be referred to the Center for Food Safety and Applied Nutrition, Office of Compliance, Division of Enforcement, (HFS-608); medical devices and radiation emitting electronic products or their components should be referred to the Center for Devices and Radiological Health, Office of Compliance, Division of Program Operations (HFZ-305); feed additives, veterinary medical devices, and unapproved animal drugs should be referred to the Center for Veterinary Medicine, Division of Compliance (HFV-230).

Information concerning CBER's review of import for export requests under section 801(d)(4) (blood and blood products) is in CBER's SOPP 8503.2.

Questions regarding the procedures to be followed by districts or industry relating to interaction with CBP should be addressed to the Division of Import Operations (301-796-0356).

## **9-18 Importations for Trade Shows/Fairs, Exhibits and Special Events**

### **9-18-1 PURPOSE**

To provide procedures regarding articles subject to regulation by the Food and Drug Administration (FDA) which are imported as exhibits for trade shows, fairs, and exhibitions and regulated articles which are imported for use by participants in special events such as athletic competitions.

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

## 9-18-2 BACKGROUND

The district offices, as well as the Division of Import Operations, frequently receive inquiries regarding the importation of regulated articles to be used as trade show exhibits to promote business opportunities in the United States. Also, persons who are participating in special events or athletic competitions such as The Olympics, Special Olympics or World Cup ski races, may request that foods, devices, or medications be brought into the United States for the sole use of the participating athlete or team. Although many of the articles have not been approved for use in the United States, and under normal circumstances would be detained, the FDA does not normally restrict foreign visitors from bringing with them native foods or required medications *for their own use or consumption* while in the United States.

Exhibits are usually imported for a short period and may be exported or destroyed following the conclusion of the event. Exportation may be to another trade show in another country or back to the country of origin. Products imported for special events and athletic competitions are usually used in the United States and any remaining products are exported or destroyed after the event is over.

## 9-18-3 CBP REQUIREMENTS

United States Customs regulations, 19 CFR Part 147, "Trade Fairs" govern the entry of merchandise intended for exhibition or for use in constructing, installing or maintaining foreign exhibits at trade fairs which have been so designated by the Secretary of Commerce. The regulations also contain provisions concerning CBP supervision of the merchandise and the disposition of the merchandise after the fair has closed.

A special form, "Entry for Exhibition" is used by CBP for exhibitions under the Trade Fair Act of 1959. Articles are entered under bond and may be permitted immediate delivery to the location where they are intended to be exhibited, placed in public storage for examination and subsequent delivery to the site of the trade fair, or into bonded warehouses for delivery at a later date. Articles are segregated from domestic articles and from imported articles entered under the provisions of the general Customs laws that are released from CBP custody.

Disposition of the articles used in trade fairs takes place under CBP supervision at any time within 3 months of the closing date of the fair.

## 9-18-4 Procedures for Trade Shows, Fairs, and Exhibitions

A Customs regulation, 19 CFR 147.23 (b), addresses the compliance of articles with the Federal Food, Drug, and Cosmetic Act and states, "The entry of food products shall conform to the requirements of the Federal Food, Drug, and Cosmetic Act and the regulations issued thereunder." Therefore, foods entering for exhibits should meet the

requirements of the Act in that they are not adulterated or misbranded, and they should comply with applicable food standards and labeling regulations. Although the Customs regulation addresses food products specifically, the Division of Import Operations interprets this section of the Customs regulation to include all FDA regulated articles. Therefore, medical and radiological devices, pharmaceuticals, cosmetics, biological products, electronics and tobacco products may not be adulterated or misbranded and should comply with FDA regulations applicable to that product line.

In general, articles used as exhibits may be handled in several ways: if all articles comply with FDA regulations, the general importing procedures would apply. However, for non-complying articles, it may be possible for an importer or importer's agent to request release of the entry, through the FDA district office, for the sole purpose of exhibition at the event and providing for the supervised destruction or re-exportation at the conclusion of the event. The request for release is made by the importer of record or agent to the FDA district office where the event is to be held and the local CBP office.

- FDA districts generally will permit release of articles which may not be in full compliance with U.S. laws and regulations where a placard is used at the point of display, advising that the product may not be in compliance with applicable FDA regulations and that FDA should be contacted for further information for procedures to bring the products into compliance.
- When large shipments of non-complying articles that are intended for promotion at a trade function, are encountered by FDA, representative products of the entry may be released for display purposes upon receipt of a request from the importer or agent to the FDA district office. However, release of commercial size shipments of non-compliant products destined to be used for promotion at a trade show will be evaluated by FDA on a case by case basis.
- An example of a model letter for responding to inquiries regarding importation for trade shows or exhibitions is attached as [Exhibit 9-10](#).

#### **9-18-5 SPECIAL EVENTS**

For special athletic events, any foods, medications or devices which are being brought into the U.S. for an individual athlete or team use should be held under the supervision of the team physician or trainer.

The amounts of both foods and medications should be commensurate with the duration of the stay. An inventory of the food items and medications being entered should prevent any undue delays when the team or athletes arrive.

Fans, family members and non-participants are not restricted in bringing in familiar food items or medications for personal use. This would also apply to individual athletes or participants who may be traveling alone. However, it may be advisable to have a prescription or letter from a physician accompany necessary medications. Further

information regarding articles imported for personal use may be found in the chapter, "Coverage of Personal Importation."

A statement for responding to inquiries regarding importation for special events is attached as [Exhibit 9-11](#).

## **9-19 Secured Storage (Temporary Removal Due to Pending Revision)**

Temporary Removal Due to Pending Revision

## **9-20 Communication Concerning Assessment of Civil Monetary Penalties by CBP in cases involving Imported Food**

### **Guidance for Industry and FDA Employees**

This guidance does not create or confer any rights, privileges, or benefits for, or on, any person and does not operate to bind FDA, CBP or the public. This guidance is being distributed in accordance with the FDA's policy for Level 2 guidance documents as set out in the agency's Good Guidance Practices, published in the Federal Register of February 27, 1997 (62 FR 8961).

Comments and suggestions regarding this document should be submitted by [date] to Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr. rm. 1-23, Rockville, MD 20857. After [date] submit comments to Division of Import Operations 12420 Parklawn Drive, ELEM-3109, Rockville, Maryland 20857. For questions regarding this document contact DIO at (301) 796-0356.

U.S. Department of Health and Human Services, Food and Drug Administration Office of Regulatory Affairs, January 2001.

**NOTE:** For the purpose of this subchapter, all references to foods include both human and animal foods.

### **9-20-1 PURPOSE**

To ensure that FDA is aware of the assessment, by CBP, of civil monetary penalties against violators in cases involving unsafe food and that CBP is aware of any events for which civil monetary penalties are an appropriate regulatory action.

### **9-20-2 BACKGROUND**

CBP has enforcement programs under existing statutory authorities that allow for the imposition of civil penalties. Under 19 U.S.C. 1592, CBP may impose a civil penalty against any person who by fraud, gross negligence, or negligence, enters, introduces,



or attempts to enter or introduce, any merchandise into the United States by means of any document or electronically transmitted data or information, written or oral statement, or act which is material and false or by means of any omission that is material. Civil penalties can be assessed in amounts up to the domestic value of merchandise so imported. Under 19 U.S.C 1595a(b), CBP may assess a penalty against any person who directs, assists financially or otherwise, or is in any way concerned with introducing, or attempting to introduce any article into the United States contrary to law. Penalties assessed under 1595a(b) also may be in an amount equal to the domestic value of the merchandise. CBP has assessed penalties against importers that substitute, rather than export merchandise that FDA has refused

While this procedure is currently in operation at CBP, FDA district offices do not always provide adequate information to CBP for assessment of a civil penalty. Conversely, FDA is not always kept aware of CBP's assessment of civil monetary penalties involving importation or exportation of food.

### **9-20-3 INSTRUCTIONS**

FDA districts should alert the local CBP Port Director when a situation is encountered for which assessment of civil monetary penalties may be appropriate under the above authorities. FDA districts should coordinate with their local CBP office to make sure CBP informs the local FDA office of the imposition of civil monetary penalties involving the entry or attempt to enter any FDA-regulated food product. CBP should, in turn, develop procedures to receive recommendations for, and to inform FDA of, the imposition of civil penalties for violative importations of food.

FDA districts should meet with local CBP quarterly to discuss enforcement actions, including civil monetary penalties. FDA districts should provide a quarterly report to DIO identifying jointly conducted enforcement actions and/or assessments of civil monetary penalties against importers of FDA-regulated foods.

## **9-21 Notice of Sampling**

### **9-21-1 PURPOSE**

To provide uniform procedures in the use of the "Notice of Sampling" or "Notice of FDA Action" for collecting samples of imported articles subject to the laws and regulations enforced by the Food and Drug Administration (FDA).

The statements in this chapter represent the Agency's current thinking on the application of the Notice of Sampling as identified by current regulation. It is intended only to provide operating procedures for FDA personnel and does not create or confer any rights on or for any person, and does not operate to bind FDA or the public.

## 9-21-2 BACKGROUND

Sections 536(a) and 801(a) (21 USC 360mm and 381(a)) of the Federal Food, Drug, and Cosmetic Act (the Act) direct that notice of sampling shall be given to the owner or consignee of articles imported or offered for import into the United States. FDA regulation (21 CFR 1.90) defines this requirement, stating that such notice is given not only for samples collected but may also be issued for samples that "will be" collected ("notice of delivery of, or intention to deliver, such sample."). The regulation also requires that the owner or consignee receiving the notice "shall hold such article and not distribute it until further notice from the district director or the collector of Customs of the results of examination of the sample."

In developing FDA's automated import system, known as the Operational and Administrative System for Import Support (OASIS), the specific form "Notice of Sampling" has been replaced by the "Notice of FDA Action." The Notice of FDA Action informs the recipient to the sample collected or of FDA's intention of sampling for each line in the entry. The use of the designation "Product Collected by FDA" or similar language should be considered as meeting the standard "giving notice thereof to the owner or consignee". (see 21 USC 381(a))

## 9-21-3 INSTRUCTIONS

### *Issuing the Notice of Sampling*

Traditionally, the Notice of Sampling was issued by the FDA district office over the facsimile signature of the Regional or District Director of CBP, in accordance with an agreement between FDA and CBP. Under the procedures used in the OASIS system, however, the notice is no longer signed over a facsimile signature. At ports remote from a FDA office, local CBP officials may be re-delegated this responsibility of collecting, sampling and delivering the samples to FDA.

Notices of Sampling issued in OASIS are unsigned. They carry the name, address, phone number of the person creating the Status and Notice (often different individuals will be responsible for this operation for the district).

### *When to Issue the Notice of Sampling*

The law, as cited above, specifies that the Notice must be issued each time a sample is collected. For the purpose of this procedure, a Notice of Sampling or the Notice of FDA Action covering the collection of a sample will issue for each article identified for:

1. Physical collection of article submitted to the laboratory for examination;
2. Documentary collections, including labels, photographs, radiological health articles, mail entries, and personal importations.

When collection data is entered into OASIS a new Notice will be generated.

***Notice of Sampling Terms Used by OASIS For Notification to Filer, Importer, etc. at Entry Level***

Under OASIS, when an entry is filed through the CBP Automated Commercial Environment (ACE) to FDA, the following electronic messages are sent to CBP and the filer to identify the collection of a sample or intent to collect a sample: (wording use to explain the meaning of the OASIS message may not be exactly the same as presented here due to up-dates in the OASIS system)

1. FDA REVIEW: All FDA regulated articles in the entry must be held intact and not distributed, pending receipt of written notice or additional message from FDA.
2. FDA HOLD: Further FDA action is being taken on one or more lines in the entry.
3. FDA DO NOT DEVAN: All containers or trailers comprising this entry must be held unopened pending FDA examination, or receipt of written notice or additional message from FDA. (importer/consignee and/or filer) Notify FDA when the containers or trailers will be available. All FDA regulated articles will be examined or sampled by FDA. Following CBP release, the unopened containers or trailers may be moved to a location approved by FDA.
4. FDA EXAM/SAMPLE: All FDA regulated articles in the entry must be held intact and not distributed, pending receipt of written notice or additional message from FDA. (importer/consignee and/or filer) Notify FDA when the products will be available. The articles will be examined or sampled by FDA. Following CBP release, the article may be moved to a location approved by FDA.

***Notice of Sampling Terms Used by OASIS for Notification to Filer, Importer, etc. at Line Level***

Under OASIS the following terms will be used by the district at the line level to identify the collection of a sample or intent to collect a sample: (wording use to explain the meaning of the OASIS message may not be exactly the same as presented here due to up-dates in the OASIS system)

1. FDA EXAM: Articles must be held intact and not distributed, pending receipt of written notice or additional message from FDA. The article will be examined or sampled by FDA. Following CBP release, the article may be moved to a location approved by FDA.
2. FDA EXAM/NOTIFY: Articles must be held intact and not distributed, pending receipt of written notice or additional message from FDA. The article will

be examined or sampled by FDA when available. (importer/consignee and/ filer) Notify FDA when the article will be available. Following CBP release, the product may be moved to a location approved by FDA.

3. FDA EXAM DO NOT DEVAN: All containers or trailers comprising this entry must be held unopened pending FDA examination or receipt of written notice or additional message from FDA. (importer/consignee and/or filer) Notify FDA when the containers or trailers will be available. All FDA regulated articles will be examined or sampled by FDA. Following CBP release, the unopened container or trailers may be moved to a location approved by FDA.

4. FDA EXAM REDELIVER: Articles must be held intact and redelivered for FDA examination or sampling. (importer/consignee and/or filer) Contact FDA for redelivery instructions. A written notice with specific information regarding this request will be sent to the filer, importer of record, and consignee.

In those situations where the article is identified as subject to detention without physical examination, or where the action being recommended is for the detention of the article and no additional documentary or physical sample is collected, the notice to the filer to HOLD for FDA Review should be considered as satisfying the requirement for giving notice to the importer. This will also meet the requirement for the article to be held intact until final determination on admission has been made.

### ***Distribution of the Notice of Sampling***

For notices issued in OASIS, the firm or person whose name is provided as the Importer of Record in the ACE shall be issued the Notice of FDA Action for the collection of the sample. Copies of the notice generated by OASIS will also be identified for distribution to the filer and consignee, where applicable. Notification to CBP is handled through the FDA/ACE interface. No documents are sent to CBP under OASIS for this notification.

For entries submitted as paper entries, the district will enter the data from the entry documents into the OASIS system, appropriately identify the responsible firm or person shown on the CBP Entry Summary (3461/3461ALT or other appropriate entry document) as the importer of record, and provide them with a Notice of Sampling produced by OASIS. Additional distribution of notices should be made as identified for ACE entries.

Section 801(b) (21 U.S.C. 381(b)) states in part: "Pending decision as to the admission of an article being imported or offered for import, the Secretary of the Treasury may authorize delivery of such article to the owner or consignee upon the execution by him of a good and sufficient bond providing for the payment of such liquidated damages in the event of default as may be required pursuant to regulations of the Secretary of the Treasury." The importer of record, who may or may not be the owner or consignee, is the person or firm that posts the CBP redelivery bond covering the importation of the articles and is legally responsible for assuring compliance with all laws and regulations

affecting the importation. The importer of record may be a custom house broker, filer, bank, or other entity that is not directly involved with the ownership of the entry. The bond is subject to forfeiture, and the importer of record is subject to regulatory action for violation of the laws and regulations pertaining to the shipment (19 CFR 113.62(l) Consequence of Default).

All persons or firms who are sent a Notice of Sampling or Notice of FDA Action for sampling, must also be sent other official documents pertaining to the sample, i.e., Notices of FDA Action for Release, Detention and Hearing, and/or Refusal of Admission.

### ***Failure To Hold Articles Identified for Examination and/or Sampling***

If, after an entry has been filed, electronically or manually, and a Notice of Sampling or Notice of FDA Action has been issued for the entry to be held for examination or sampling, FDA finds that the entry or a portion thereof was not held, and there was disregard of the Notice by the importer, a written request to CBP asking for redelivery of the merchandise should be made. If the distributed article is not returned to CBP for FDA's examination or sample, a bond action should be sought through OASIS or current written procedures (see RPM Bond subchapter 9-1 for procedures on request for redelivery/bond action).

For more information, refer to the Cooperative Agreements Manual, "MOU with U.S. Customs Service to Establish a Working Relationship for Cooperative Enforcement (225-79- 4003)", 10/01/80 (Old designation Compliance Policy Guide (CPG) 7155g.03, new designation Section 2-A General Import Agreements) and "MOU with U.S. Customs Service regarding Identifying Roles and Authority Concerning Electronic Products (225-74-6004), 10/01/88 (Old designation CPG 7155g.01).

### ***Multiport Coverage***

Many importers maintain distribution points throughout the country and will move articles to those locations for immediate distribution upon receipt of their releases from CBP and other agencies. As long as the articles are under the importer's full control and are not further distributed, or has been delivered to their consignee but are still under the full control of the importer, the importer may request the article be examined by the district in whose jurisdiction the article is held. This practice should not be encouraged, nor should importers consider the allowance of such practice to be a license to request all their importations be examined at destination. Allowing movement and requesting foreign district examination/sample should be at the discretion of the district, depending on the article to be examined or sampled.

Under certain conditions, filers may use various means of filing entries, for example multiport entries for clearing cargo. Under these provisions of CBP, the filer may be in one port location (port A) but enter the cargo in port B. However, the cargo itself may be physically located at port C, and the examination will take place at port D. For FDA

coverage, the examination of the cargo may be dependent on the FDA location where the cargo is entered and/or where it is physically located. District coverage of such importations should be evaluated on a case by case basis. Ultimately, the FDA district responsible for the entry will be that district covering the responsible CBP port for the entry.

### ***Simultaneous Multiple Entries***

The following procedures are being provided to assist districts in the collection of import compliance samples from multiple, simultaneous entries (within a 24 hour period) of the same product(s) from the same manufacturer/grower or shipper:

The district will identify each entry individually for coverage. OASIS does not include provisions for consolidating multiple entries under one number, since all actions are based on individual entry numbers. However, districts may relate one entry to another to show they are making their determination of admission on all associated entries from the one entry sampled/examined.

Documentation **MUST** show a direct relationship between the samples, e.g., date of manufacture, production codes, fields of harvest, etc.

This procedure is *recommended* whenever compliance sample of suspect multiple shipments are collected. It may also be used when multiple entries are made to accommodate different consignees with the same product, such as canned foods.

Under no circumstances where districts receive paper entries should different Importer's Entry Notification for portions of the same entry be accepted or processed. Each notification should represent a unique entry. If this situation is encountered, districts may wish to reject the notifications and request the broker to consolidate the information into one notification. Under the OASIS procedure, where entries are filed through the CBP ACE, this procedure may not be applicable.

Also, under the OASIS screening procedures, if a district notices a trend to separate shipments from the same manufacturer, shipper, or grower in order to receive a favorable "May Proceed" on as many portions of the same product through the screening process, the district may consider requesting, as appropriate, the particular product/manufacturer combinations be screened as "examination" to assure all shipments are provided to the district for review before being may proceeded.

### ***Single Entry of Multiple Commodities***

Under the OASIS procedures, when an entry consisting of multiple food items is presented, the district must issue a single Notice of FDA Action identifying all items in the entry for FDA hold/examination. In the case of paper entries, designate the entire entry to be held as "foodstuffs", or use another appropriate term.

There is no prohibition against issuance of one Notice of FDA Action for collection of samples for an entire multiple commodity entry. In the OASIS procedures, the Notice will indicate the specific lines that are to be covered by the district. The intent of the Notice is to provide the owner/consignee with information as to whether the sample(s) have been collected or will be collected. It may not be possible to know in advance of an examination what problems or conditions will be encountered before the entry is examined. Therefore, Notice of FDA Action identifying all commodities present as "HOLD ALL" pending examination does not conflict with FDA regulation or policy. (See OASIS notice statements under "B", "When to Issue the Notice of Sampling")

Because the exact article to be examined/sampled may not be known until after the vehicle transporting the goods has been unloaded, one Notice is issued to assure that all products are held for examination. FDA has authority to request that the entire entry be held pending examination, and whether numerous individual Notices, or one blanket Notice is issued, the effect is the same: the entire entry must be held.

When the importer advises the district of the location and the availability of articles in the entry, the district personnel will visit the site to perform the examination and/or collection. At this time, a new Notice of FDA Action for the collection of the specific articles is issued. Any article not covered by a specific Notice of FDA Action will be designated as "Released" or "May Proceed."

(Note: See exhibit 9-6 for examples of Notices which include identification of products sampled by FDA.)

## **9-22 Granting and Denying Transportation and Exportation (T&E) Entries**

### **9-22-1 PURPOSE**

To provide uniform procedures regarding circumstances when Transportation and Exportation (T&E) entries will be granted or denied.

This document represents the agency's current thinking on the operating procedures when importers enter articles, subject to FDA's jurisdiction, under CBP's Transportation and Exportation (T&E) entries. It does not create or confer any rights for or on any person, and does not operate to bind FDA or the public.

### **9-22-2 BACKGROUND**

CBP regulation 19 CFR 18.10, "Kinds of Entry", lists the various entries and withdrawals that may be made for merchandise transported in bond. One kind of entry is the

transportation and exportation (T&E) entry. A T&E filed with CBP, allows a party to transport merchandise in bond through the U.S. and export the merchandise intact to a foreign destination without the payment of duties. (See 19 U.S.C. 1553, 19 CFR 18.11, and 19 CFR 18.20.)

T&E entries may be made for products which are being transported through the U.S. to be exported. In addition, articles that have been refused admission may be entered under T&E after the importer requests and receives written authorization from the proper governmental authority and/or complies with any applicable regulations. When FDA receives notice from CBP that articles refused by FDA will move under T&E bond to a distant port to be exported under CBP supervision, FDA generally will not object to movement of the refused articles. In addition, when FDA receives notice from CBP that product regulated by FDA, not offered for import will move under T&E entry to a distant port to be exported under CBP supervision, FDA generally will not object to movement. In most instances FDA may waive the written authority requirement. There may be situations, however, where denial of a request for a T&E entry is appropriate.

FDA has been aware of possible weaknesses in T&E entry procedures for movement of refused merchandise to other ports for exportation. For example, in 1975 an incident involving frog legs demonstrated the potential for diversion into domestic commerce when refused articles are transported under T&E bond.

The frog legs case (*U.S. v. 76,552 pounds of Frog Legs*, 423 F. Supp. 329 (S.D. Texas, 1976)) highlighted the risks of T&E movement of refused articles. In that case, adulterated frog legs, reportedly being exported to Mexico, were in fact being diverted to domestic commerce, thus circumventing FDA authority to prevent violative merchandise from reaching the American public.

In response to this and other incidents of diversion, FDA met with CBP to discuss concerns regarding movement under a T&E entry of violative merchandise. CBP agreed that violative shipments should not be permitted movement under T&E procedures where FDA objected. This approach was taken to prevent the granting of T&Es in a haphazard manner and to eliminate the opportunity for merchandise to become lost, stolen, or diverted.

The availability of T&E entry for "restricted and prohibited merchandise" is described in the CBP regulations. Section 18.21(b) of the CBP regulations authorizes CBP to deny release of this type of merchandise under a T&E entry unless the agency responsible for regulating the article provides written permission. Prohibited articles offered for T&E entry without the requisite written authority may be seized pursuant to 19 CFR 18.21(b). However, it is the practice of CBP and FDA that where FDA has no objection to in-bond movement of violative merchandise through the United States for export to a foreign destination, CBP may issue a T&E entry without FDA written permission. When FDA objects to such movement, it would so notify CBP in writing.



There may also be circumstances where regulatory action such as seizure is appropriate for articles moving under a T&E entry. Often, articles will begin moving under T&E entry prior to FDA receiving notice from CBP or the importer. In the case where a request for T&E is to transport violative articles which FDA believes may be intended for future importations into the U.S., regulatory action against the article, even though it may already be moving under T&E entry, may be appropriate. For example, because of transportation concerns, violative drugs that represent a health risk may be shipped to the U.S. prior to entry into Mexico or other nearby countries. The importer may request a T&E entry from CBP. After receiving notice from CBP or the importer that the articles are moving under T&E entry, if FDA is aware that the drugs may be sold to individuals in the United States, FDA may decide it is appropriate to seize the drugs to prevent them from illegally entering domestic commerce.

In one instance, a quantity of unapproved drugs that was being transported from Romania through the United States under a T&E entry to Tijuana, Mexico was condemned and ordered destroyed by CBP. Section 801(b) of the FD&C Act, involving conditional release for movement of products under CBP redelivery bond, did not apply because that provision does not apply to merchandise that is not eligible for legal import under the FD&C Act. CBP ordered destruction because it was the only way to ensure that the drugs would not be re-imported into the United States. The claimant had stipulated that the drugs were new drugs and that no new drug application had been submitted or approved. (See *U.S. v. 300 oz. Gerovital Lotion, and 25,000 Gerovital Tablets, More or Less*, 492 F. Supp 114 (C.D. Cal. 1980). )

### 9-22-3 INSTRUCTIONS

If an article has been refused admission under the FD&C Act, FDA will consider objecting to T&E entry under the following circumstances:

1. The article presents a definite hazard to the health of the consumer (e.g., article containing toxins or pathogens)
2. There is evidence that the T&E entry procedure is being abused and violative merchandise is being diverted into domestic commerce (e.g. the frog legs case cited previously).
3. The distance that the violative product is to be moved is so great that it might be lost, stolen or diverted, and/or that the movement would be very difficult to control and/or monitor.
4. The importing firm has a history of diverting violative merchandise into domestic commerce. (See RPM subchapter 9-14 "Priority Enforcement Strategy for Problem Importers".)

If the merchandise has been entered as a consumption or warehouse entry, the following statement should appear on the Notices of Detention and Refusal:

"DO NOT ISSUE T&E - PERMISSION AS REQUIRED PURSUANT TO 19 CFR 18.21(b) IS NOT GRANTED FOR THE ISSUANCE OF A TRANSPORTATION AND EXPORTATION ENTRY"

If the merchandise has been entered as a T&E, and CBP has notified FDA of the entry, CBP should be notified in writing that FDA opposes granting of the T&E entry.

**NOTE:** In developing the Operational and Administrative System for Import Support (OASIS) the FDA forms for Notice of Sampling, Release, Detention and Hearing, Refusal, etc., have been replaced by "Notice of FDA Action," with the description of the action identified for the specific article in the entry. See RPM subchapter, Import Procedures.

Until OASIS is modified to issue a T&E statement, districts operating under OASIS should annotate their Notice of FDA Action appropriately and forward a copy of the Notice to the local CBP office and other notified parties.

Decisions to reconsider T&E movement, or submit regulatory actions, where appropriate, are at the discretion of the district.

Questions regarding use of T&Es should be directed to the Division of Import Operations, and appropriate Center.

## 9-23 EXHIBITS

- 9-1 Exhibit 9-1  
Exhibit 9-1 has been deleted. See Exhibit 9-6 instead
- 9-2 Form FDA-766  
Exhibit 9-2 has been removed as an exhibit. Form 766 is available at <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM072766.pdf>
- 9-3 Model Letter For Use in General Mail Importations
- 9-4 Model Letter For User in Detentions of Drugs and Devices
- 9-5 Specimen Charges
- 9-6 Notice of FDA Action
- 9-7 19 CFR 12.21-12.23  
19 CFR 21.21-23 has been removed as an exhibit. 19 CFR Part 21 is available at <http://www.gpo.gov/fdsys/granule/CFR-2011-title19-vol1/CFR-2011-title19-vol1-part12>
- 9-8 21 CFR 601.33  
21 CFR 601.33 has been removed as an exhibit. 21 CFR Part 601 is available at

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=601>

9-9 21 CFR 601.22

21 CFR 601.22 has been removed as an exhibit. 21 CFR Part 601 is available at

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=601>

9-10 Letter Responding to Inquiries Regarding Importation for Trade Shows/Fairs and Exhibitions

9-11 Statement Responding to Inquiries Regarding Importation for Special Events

9-12 Charges for Supervision Form FDA 790

Exhibit 9-12 has been removed. Form 790 is available at exhibit 6-3 of the Inspections Operations Manual at <http://www.fda.gov/downloads/ICECI/Inspections/IOM/UCM127464.pdf>

**EXHIBIT 9-3**

## MODEL LETTER FOR USE IN GENERAL MAIL IMPORTATIONS

(LETTERHEAD)

A mail shipment of an article from a foreign country addressed to you is being detained at the U.S. Post Office. All products of this kind must meet the requirements of the Federal Food, Drug, and Cosmetic Act or other laws enforced by the Food and Drug Administration. These laws are designed to protect you from, among other things, unsafe or misrepresented foods, drugs, biologics, cosmetics, devices, and other articles. The product addressed to you does not appear to comply with the law. Please read the enclosed Notice of FDA Action - Detained carefully since it explains why FDA believes that the product sent to you is in violation. The Notice does not in any manner accuse you of violating any law.

If you have good reason to believe that the product does comply with the law and wish to discuss it with us, you may personally come to this office, telephone, or write to us within the time limit shown on the Notice.

If you do not wish to claim this shipment, you may disregard the Notice and the shipment will be returned to the sender without cost to you. The shipment will be returned to the sender automatically if we do not hear from you within the time limit shown on the Notice.

Sincerely yours,

Enclosure:

## EXHIBIT 9-4

### MODEL LETTER FOR USE IN DETENTIONS OF DRUGS AND DEVICES (LETTERHEAD)

A mail shipment addressed to you of a drug (device) from a foreign country is being detained at the U.S. Post Office. All products of this kind must meet the requirements of the Federal Food, Drug and Cosmetic Act which is designed to protect you from products that have not been shown to be safe and effective and that are not labeled in a truthful, accurate and non- misleading manner.

Please read the enclosed Notice of FDA Action - Detained carefully, since it explains why the product addressed to you appears to violate U.S. law. The Notice does not accuse you in any manner of violating any law.

If the drug is not approved for distribution in the United States, FDA may consider releasing the product to you for your own personal use if you provide a statement containing:

- adequate documentation that the product is for your own use and for treatment of a serious condition, and include the name and address of the doctor licensed to practice in the United States who is responsible for your treatment with this product; or
- adequate documentation that the product is for the continuation of treatment of a serious condition begun in a foreign country.

Send your statement to this office and we will promptly review your submission and consider release of the product.

If you have good reason to believe that the product does comply with the law and you wish to discuss it with us, you may come in person to this office, telephone, or write to us within the time limit shown on the Notice.

If you do not wish to claim this shipment, you may disregard the Notice and the shipment will be returned to the sender without cost to you. The shipment will be returned to the sender automatically if we do not hear from you within the time limit shown on the Notice.

Sincerely yours,

Enclosure:

## **EXHIBIT 9-5**

### **SPECIMEN CHARGES**

Suggested wording for charges under the Acts enforced by FDA may be found on Import Alerts, and as part of reference tables of the OASIS automated system.

Charge codes will no longer be listed in this exhibit. The current list of Violation Codes and the text associated with those codes can be found on FDA's Internet Site at the following link:

<http://www.fda.gov/ForIndustry/ImportProgram/ImportRefusals/ucm144864.htm>

**EXHIBIT 9-6**

## NOTICE OF FDA ACTION

The attached exhibit of Notice of FDA Action is a model and should not be considered all inclusive. The format and wording in the actual Notice of FDA Action issued by districts from the Operational and Administrative System for Import Support (OASIS) may appear different.

## EXAMPLE

**United States Food and Drug Administration  
Los Angeles District Office  
Notice of FDA Action**

Entry Number: 112-9861457-6  
Notice Number: 2  
November 6, 1996

Filer:

FBN Freight Services Attention: George  
500 Canal St.  
New Orleans LA 70130

- Port of Entry: 2704, Los Angeles,  
Carrier: NOL RUBY  
Entry Date: November 2, 1996  
Arrival Date: November 4, 1996
- Importer of Record: Shipley's Donut Shop Inc., Lafayette, LA
- Consignee:
  - a: Shipley's Donut Shop Inc., Lafayette, LA
  - b: Specialty Commodities Inc. Fargo, ND

HOLD DESIGNATED

Documents Required and Notify FDA of Availability

Summary of Current Status of Individual Lines

<u>@ LINE:</u>	<u>ACE/FDA</u>	<u>Product Description</u>	<u>Quantity</u>	<u>Current Status</u>
* a	001/001	PINEAPPLE, DEHYDRATED	500 CT	RELEASED 11-6-96

<u>@ LINE:</u>	<u>ACE/FDA</u>	<u>Product Description</u>	<u>Quantity</u>	<u>Current Status</u>
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\* a 002/001 DEHYDRATED GINGER SLICES 10 KG Collected by FDA  
11-06-96

@ LINE:	ACE/FDA	Product Description	Quantity	Current Status
* b	003/001	PAPAYA, DEHYDRATED	10 KG	Detained 11-06- 96

\* *Status change since the previous notice.* Read carefully the sections which follow for important information regarding these lines.

- @ Consignee id

FDA will not request redelivery for examination or sampling, if the products not released by FDA are moved, following USCS conditional release to a location within the local metropolitan area or to a location approved by the FDA office at the number below.

All products in this entry not listed above may proceed without FDA examination. This notice does not constitute assurance the products involved comply with provisions of the Food, Drug, and Cosmetic Act or other related acts, and does not preclude action should the products later be found violative.

Please provide documentation concerning all products in this entry to the FDA office below. Include the USCS document (e.g. CBP-3461 or CBP-7501) and commercial invoice for these products, annotated to show the ACE/FDA line numbers sent electronically.

Also, advise FDA upon actual availability, and include date, location, and warehouse control number, where applicable, for all lines in this entry.

Jennifer A Thomas, Inspector  
U.S. Food & Drug Administration  
(213) 555-1212  
2nd and Chestnut Streets (HFR-MA100)  
Philadelphia, PA 19106

### DETENTION WITHOUT EXAMINATION

The following products are subject to refusal pursuant to the Federal Food Drug and Cosmetic Act (FD&CA), Public Health Service Act (PHSA), or other related acts in that they appear to be adulterated, misbranded or otherwise in violation as indicated below:

LINE

ACE/FDA	Product Description	Respond By
003/001	Product: PAPAYA, DEHYDRATED	November 26, 1996



## FD&amp;CA Section 402(a)(1), 801(a)(3); ADULTERATION

The article appears to be held in a container containing a poisonous or deleterious substance which may render it injurious to health.

## FD&amp;CA Section 402(a)(2)(B), 801(a)(3); ADULTERATION

The article appears to be a raw agricultural commodity that bears or contains a pesticide chemical which is unsafe within the meaning of Section 408(a). The article appears to contain quinalphos.

You have the right to provide oral or written testimony, to the Food & Drug Administration, regarding the admissibility of the article(s) or the manner in which the article(s) can be brought into compliance. This testimony must be provided to FDA on or before the dates shown above

SAMPLES COLLECTED

## LINE

<u>ACE/FDA</u>	<u>Product Description</u>	<u>Est. Cost</u>
001/001	PINEAPPLE, DEHYDRATED	\$ 15.00

- Sample: 10 KG Collected 1 KG from each of 10 cartons

## LINE

<u>ACE/FDA</u>	<u>Product Description</u>	<u>Est. Cost</u>
002/001	DEHYDRATED GINGER SLICES	\$ .23

- Sample: 1 KG Collected approximately 4 ounces from one carton. LINES RELEASED

## LINE

<u>ACE/FDA</u>	<u>Product Description</u>
001/001	PINEAPPLE, DEHYDRATED

These products are released. This notice does not constitute assurance that the product released complies with all provisions of the Food, Drug, and Cosmetic Act, or other related Acts, and does not preclude action should the product later be found violative

Notice Prepared by: Thomas J DiNunzio (QA5)  
U.S. Food & Drug Administration

## EXHIBIT 9-10

### LETTER RESPONDING TO INQUIRIES REGARDING IMPORTATION FOR TRADE SHOWS/FAIRS AND EXHIBITIONS

(LETTERHEAD)

This is in response to your inquiry regarding importing articles regulated by the Food and Drug Administration (FDA) for use as exhibits in trade shows/fairs or other exhibitions.

With the exception of most meat and poultry products, all food, drugs, biologics, cosmetics, medical devices, electronic products that emit radiation, and tobacco products as defined in the Federal Food, Drug, and Cosmetic (FD&C) Act 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. For example, imported foods must be pure, wholesome, safe to eat, and produced under sanitary conditions; 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.

#### GENERAL PROCEDURES

The Federal Food, Drug and Cosmetic Act (the Act), Section 801, directs FDA to refuse admission of any article that appears to be in violation of the Act.

To ensure that FDA is notified of all regulated products imported into the United States, the importer, or his/her representative, must file an entry notice with U.S. Customs and Border Protection and acquire a bond to allow the importer to take delivery of the goods prior to FDA's decision on the admission of the goods. FDA is notified by Customs of the entry and makes a decision as to the article's admissibility. If FDA does not wish to examine the entry, the product is allowed to proceed into the United States. When a sample of an article offered for import has been requested by FDA, the owner or consignee is required to hold the shipment and not distribute it until further notice is received regarding the results of the examination of the sample.

Generally, if FDA samples an entry, an FDA representative will collect the sample from the shipment and have it analyzed in FDA's laboratory. If the analysis shows the product in compliance, the shipment is released into United States commerce. However, if the analysis shows an appearance of a violation, the product is subject to refusal of admission. If it appears that the article is violative, FDA issues a Notice of FDA Action - Detained to the owner or consignee of the article specifying a place and period of time whereby the individual may introduce testimony either verbally or in writing concerning the detention to prove that the product complies with the law, or can submit a petition to

recondition the product to bring it into compliance. The owner or consignee may submit an application to FDA to relabel or perform other actions to bring the article into compliance, or render the article other than a food, drug, device, or cosmetic.

If the product cannot be brought into compliance, it is refused and the importer is required to either re-export or destroy the article under U.S. Customs or other approved supervision. If the refused product is not destroyed or re-exported, CBP issues a notice for redelivery to the importer of record. Failure to redeliver the refused product may result in CBP assessing liquidated damages equal to the value of the merchandise involved in the default or three times the value of the merchandise if the article is restricted merchandise or alcoholic beverages. All FDA regulated products are considered restricted merchandise by CBP.

#### ARTICLES FOR TRADE SHOWS/FAIRS AND EXHIBITIONS

When articles are being imported where the intent is to display them at an industry or consumer trade show or exhibition and all articles comply with FDA regulations, the general importing procedures as stated above should be followed. However, for non-complying articles, it may be possible for an importer or importer's agent to request release of the entry, through the FDA district office, for the sole purpose of exhibit at a trade function and providing for the supervised destruction or re-exportation of the articles at the conclusion of the function.

FDA districts generally **may** permit release of such articles which may not be in full compliance with U.S. laws and regulations where a placard is used at the point of display, advising that the product may not be in compliance with applicable FDA regulations and that FDA should be contacted for further information for procedures to bring the products into compliance.

When large shipments of non-complying articles, intended for promotion at a trade function, are encountered by FDA, representative products of the entry may be released for display purposes upon receipt of a request from the importer to the FDA district office. However, it will be necessary for importers of commercial size shipments of non-compliant product, if for promotion at a trade show, to request release of these types of products which will be evaluated by FDA on case by case basis.

You should contact the FDA district office where the function is to be held for further information or to submit a request for release of products for trade shows, fairs, or exhibitions.

#### CUSTOMS AND BORDER PROTECTION REGULATIONS

Customs regulations, 19 CFR Part 147, "Trade Fairs" address entry of merchandise for exhibition and your local Customs office should be contacted regarding these requirements.

Sincerely yours,

## EXHIBIT 9-11

### STATEMENT RESPONDING TO INQUIRIES REGARDING IMPORTATION FOR SPECIAL EVENTS

(The example cited below was for use by the Atlanta Committee for the Olympic Games, but a similar statement could be used for any event. A statement of this nature is intended to be made available by the committee or sponsor of the event to team officials, participants, foreign government representatives, media representatives, and fans.)

#### STATEMENT FOR THE USE BY ATLANTA COMMITTEE FOR THE OLYMPIC GAMES

(Sponsor Name) (Name of Event)

In keeping with the spirit of the Olympic games, the Food and Drug Administration (FDA) wants you to be comfortable during your stay in the United States, including having access to personal and familiar necessities. The FDA does not normally restrict foreign visitors from bringing native foods or required medications for their own use or consumption while in the United States. However, any medications or pharmaceuticals which are being brought for team use should be held under the supervision of the team physician or trainer. The amounts of both foods and medications should be commensurate with the duration of your stay. Additionally, an inventory of the food items and medications being entered should prevent any undue delay in your team's arrival.

Fans, family members, and other non-participants are also not restricted in bringing in familiar food items. However, it may be advisable to have a prescription or letter from a physician accompany necessary medications. As mentioned above, the amount of foods and medications brought in should be commensurate with the duration of your stay in the United States.

If you have any questions concerning your food or medications when you are in the United States, please contact the local FDA office