



**U.S. Customs and  
Border Protection**

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**INFORMATION BULLETIN NUMBER: 12-003**

**TO:** Importers, Customhouse Brokers and Other Interested Parties

**SUBJECT:** Amendment to Information Bulletin Number 02-001 on Procedures for Merchandise Entered for Consumption or Warehousing at Miami Field Office Ports and Subsequently Refused Admission by the Food & Drug Administration (FDA) under Section 801 of the Food, Drug and Cosmetic Act

This Bulletin amends Information Bulletin Number 02-001, dated October 11, 2001, concerning the disposition of merchandise refused admission under Section 801 of the Food, Drug and Cosmetic Act at the following U.S. Customs and Border Protection (CBP) Ports of Entry (POE): Miami Airport and Seaport; Port Everglades; and the Port of West Palm Beach.

Merchandise that is refused admission by the Food and Drug Administration (FDA) must be exported or destroyed within 90 days from the date of the FDA Notice of Refusal. Refused shipments must remain intact when presented for destruction or exportation.

All shipments of FDA refused merchandise designated for export must be exported via an Immediate Exportation (IE) CBP Form 7512 from the port of entry. The Port Director at the port of entry may authorize the Transportation and Exportation (T&E) CBP Form 7512 of FDA refused goods between ports of entry within the Miami Field Office (MFO). The importer must request, in writing, stating the valid reason for the exception. Upon approval of the T&E, the port of entry must coordinate with the port of export the re-examination and supervision of the exportation. If the re-examination and supervision of the exportation cannot be accomplished, the T&E will not be authorized. The importer must either directly export the merchandise on an IE to another location outside the United States or destroy the merchandise. If the T&E requested is moving to another port outside of the MFO's jurisdiction, FDA must also approve the T&E. FDA will not approve a T&E unless CBP can guarantee that the merchandise will be re-examined and the exportation supervised at the port of departure. If CBP cannot guarantee the re-examination or supervision of the departure, the importer must either directly export the merchandise on an IE to another location outside the U.S. or destroy the merchandise. The refused merchandise must be clearly identified on the CBP Form 7512 or CBP Form 3499 as FDA refused merchandise and include the entry number, quantity and description of the merchandise.



**Please comply with the following Procedures:**

**Miami Airport (5206)**

*Exportations:*

The filer must provide the Carrier Audit Team (CAT) with a package consisting of the following: unprocessed IE (CBP Form 7512), copy of CBP Form 3461 package, invoice(s), air waybill(s), copy of CBP Form 7501, copy of FDA Notice of Refusal, and a copy of the outbound air waybill(s). The package will be submitted to the Inbond/Informal Counter, Attention Carrier Audit Team, at the Cargo Clearance Center (CCC). The Customs and Border Protection Officer (CBP Officer) at the Inbond/Informal Counter will route the package to the CAT. The CAT will review the package to ensure that all paperwork has been submitted. If any paperwork is missing, the filer will be notified via telephone that additional information is required.

Once the documents are reviewed, the CAT will review the CBP Form 3499 address section to determine if the merchandise is located within the airport's jurisdiction. Shipments off the airfield will be referred to the appropriate port. The CAT will then contact the exporting carrier to verify that the refused merchandise is located at its warehouse. The CAT will go to the exporting carrier's warehouse and examine the refused merchandise to ensure that the merchandise and quantity match what is reflected on the FDA Notice of Refusal. The inspection must take place at the exporting carrier's warehouse and the refused merchandise must be exported intact. The examining CBP Officer will complete an Export Verification Worksheet and annotate the finding. The CBP Officer will then perforate the CBP Form 7512.

For compliant examinations, CBP Form 7512 will be stamped "*FDA Refused Merchandise Examination & Exportation Verified.*" The CBP Officer will sign, annotate badge number and date the CBP Form 7512. The original package including the CBP Form 7512 will be placed in the respective broker/miscellaneous box. The broker must then forward a stamped copy to CBP/FDA Joint Team 488. For non-compliant examinations, CBP Form 7512 will not be stamped unless the only discrepancy is the timeliness of the exportation. The CAT will request copies of the exporting manifest and/or air waybills and will annotate the discrepancy on the CBP Form 7512. The CAT will maintain a copy of the entire package and place the original package in the respective broker/miscellaneous box. Additionally, a copy of the entire discrepant package including the Export Verification Worksheet will be forwarded to CBP/FDA Team 488 at the Cargo Clearance Center, Miami International Airport.

*Destructions:*

The filer must present an Application & Approval to Manipulate, Exam, Sample or Transfer Goods (CBP Form 3499) to the Chief, Cargo Control Section at the Cargo Clearance Center. The CBP Form 3499 may only be signed at the port of entry. The Chief, Cargo Control Section, must sign the CBP Form 3499. Once the form is signed, the filer will coordinate with FDA for witnessing the destruction of the refused merchandise. The broker must contact the FDA inspector at phone 305-994-3040, option #3, to coordinate the destruction.



## Express Consignment Courier Facilities (ECCFs)

### *Exportations:*

The filer at the courier facility must provide to the Supervisory CBP (SCBP) Officer on site a package consisting of the following: unprocessed IE (CBP Form 7512), copy of FDA Notice of Refusal, and a copy of the inbound and outbound air waybill(s). If a formal was filed, a copy of CBP Form 3461 package, invoice(s) and copy of CBP Form 7501 will be required. The SCBP Officer or his designee will review the package to ensure that all paperwork has been submitted. If any paperwork is missing, the broker will be notified that additional information is required. The refused merchandise must be exported intact. The CBP Officer will examine the refused merchandise. The CBP Officer will complete the Export Verification Worksheet and annotate the findings. The CBP Officer will then validate/perforate the CBP Form 7512. For compliant examinations, the CBP Form 7512 will be stamped "*FDA Refused Merchandise Examination & Exportation Verified*". The CBP Officer will sign, annotate badge number and date the CBP Form 7512. The original package including the CBP Form 7512 will be returned to the broker at the courier facility. If non-compliant, the CBP Form 7512 will **not** be stamped unless the only discrepancy is the timeliness of the exportation. The CBP Officer will annotate the discrepancy on the CBP Form 7512, and return it, along with accompanying documents, to the broker at the courier facility.

The Express Courier Consignment Facility (ECCF) will maintain a copy of the entire package on site. If the findings are discrepant, the CBP Officer will also forward a copy of the package including the Export Verification Worksheet to the CBP /FDA Joint Team 488. Please note that for refusals of merchandise imported through the ECCF, the above procedures **only** apply to Notices of Action signed jointly by CBP and FDA. FDA has internal procedures for refusals not jointly signed at the courier facilities.

### *Destructions:*

The broker at the courier facility must present to the SCBP Officer on site an Application & Approval to Manipulate, Exam, Sample or Transfer Goods (CBP Form 3499). The CBP Form 3499 may only be signed at the port of entry. The SCBP Officer or his designee must sign the form. Once the form is signed, the broker will coordinate with FDA for witnessing the destruction of the refused merchandise. The broker must contact the FDA inspector at phone 305-994-3040, option #3, to coordinate the destruction.

## **Miami Seaport (5201):**

### *Exportations:*

The filer must submit the following to Selectivity at the Seaport Cargo Center (SCC): I.E. (CBP Form 7512) signed by the exporting carrier/shipping line, copy of CBP Form 3461 package, invoice(s), bill(s) of lading, copy of CBP Form 7501, and a copy of the FDA Notice of Refusal. Selectivity will review the package to ensure that all paperwork has been submitted. If any paperwork is missing, the filer will be notified via telephone that additional information is required. Selectivity will issue a "Delivery Authorization: (locally we use a "Stop Stamp") on the CBP Form 7512 and return one copy to the filer. Selectivity will forward the entire package to the Trade Enforcement Team (TET) at CIPS (Customs Inspection Processing Service) or Econocaribe.



Upon arrival of the cargo at CIPS or Econocaribe, TET will examine the refused merchandise to ensure that the merchandise and quantity match what is reflected on the FDA Notice of Refusal. If consolidated with other cargo, the shipment of refused merchandise should be located at the Tail of the container and exported intact. After the cargo is examined, the CBP Officer will place the "FDA Refused Merchandise Examination & Exportation Verified" stamp on the CBP Form 7512 and initial the stamp area in the upper right-hand corner. The CBP Officer will not sign and date the stamp at this time. The CBP Officer will annotate on the CBP Form 7512 the commodity, quantity and any discrepancies found. A CES seal will be placed on the container and the CBP Form 7512 will be validated. Copies of the CBP Form 7512 package will be returned to the filer. The original documents, including the original CBP Form 7512, will be maintained on file by TET.

If the merchandise is non-compliant, the CBP OFFICER will submit a copy of the packet to CBP/FDA Team 488. The TET will keep the refusal package in a suspense file for ten business days. The filer must submit the export bill(s) of lading and Trailer Interchange Report (TIR) or a delivery order within this timeframe. Upon receipt of the documents, TET will verify that they correspond to the refusal package. If all of the documents are in order, TET will sign, annotate badge number and date the "FDA Refused Merchandise Examination & Exportation Verified" stamp placed on the CBP Form 7512. The TET will maintain a copy of the entire package, and place the original package in the respective broker/miscellaneous box. If the TET team does not receive further documentation (export verification) from the filer, TET will **not** sign the stamp "FDA Refused Merchandise Examination & Exportation Verified". A copy of the entire package will be forwarded to CBP /FDA Team 488 at the Cargo Clearance Center, Miami International Airport.

#### *Destructions:*

Per 19 CFR 158.43 (Application by importer), "the importer shall file an application for abandonment or destruction of merchandise in bond with the Port Director on CBPF 3499, with the title modified to read "Application and Permit to Abandon (or Destroy) Goods in Bond." When an application is for permission to destroy, the proposed method of destruction shall be stated in the application and be subject to the approval of the Port Director." The filer will present CBP Form 3499 to the Warehouse Inspection Team (WIT) at the SCC. The CBP Form 3499 must be signed at the port of entry. The WIT SCBP Officer, or his designee, will sign the CBP Form 3499 and annotate in the CBP remark section "You must contact FDA inspector at phone 305-994-3040, option #3, to coordinate the destruction." Once the form is signed, the filer will coordinate with FDA for witnessing the destruction of the refused merchandise. The broker must contact the FDA inspector at phone 305-994-3040, option #3, to coordinate the destruction.

#### **Port Everglades (5203):**

#### *Exportations:*

The filer must submit the following to Selectivity: I.E. (CBP Form 7512), copy of CBP Form 3461 package, invoice(s), bill(s) of lading, copy of CBP Form 7501, and a copy of the FDA Notice of Refusal. Selectivity will review the package to ensure that all paperwork has been submitted. If any paperwork is missing, the filer will be notified via telephone that additional information is required. Selectivity will issue a "stop stamp" on the CBP Form 7512 and return one copy to the filer. Selectivity will forward the entire package to the TET team at International



Warehouse Services (IWS). Upon arrival of the cargo at the Container Examination Station (CES), the TET will examine the refused merchandise to ensure the merchandise and quantity match what is reflected on the FDA Notice of Refusal. If consolidated with other cargo, the shipment of refused merchandise **must** be located at the tail of the container and exported intact. The examining CBP Officer will complete the Export Verification worksheet and annotate the findings. If the merchandise is compliant, the CBP Officer will place the *"FDA Refused Merchandise Examination & Exportation Verified"* stamp on the CBP Form 7512 and initial the stamp area in the upper right-hand corner. The CBP Officer will **not** sign and date the stamp at this time. After the examination has been completed, a CBP seal will be placed on the container and the CBP Form 7512 will be validated/perforated. The CBP Form 7512 package will be returned to the filer **via Selectivity**. The remaining paperwork, along with the original CBP Form 7512, will be filed in the Office of the Trade Enforcement Team (TET). The TET will keep the refusal package in a suspense file for ten business days. The filer must submit export bills of lading and the Trailer Interchange Report (TIR) or a delivery order within this time frame. Upon receipt of the documents, the TET will verify that they correspond to the refusal package.

If all of the documents are in order, the TET will sign, annotate badge number and date the *"FDA Refused Merchandise Examination & Exportation Verified"* stamp placed on the CBP Form 7512. The TET will maintain a copy of the entire package, and return the original package to the filer via Selectivity. If the TET does not receive further documentation (export verification) from the filer or if the examination was discrepant, the TET will annotate the discrepancy on the CBP Form 7512. The TET will not sign the stamp *"FDA Refused Merchandise Examination & Exportation Verified"*. However, if the only discrepancy is the timeliness of exportation, the stamp can be signed and the discrepancy annotated on the CBP Form 7512. The TET will maintain a copy of the entire package, and return the original package to the filer via Selectivity. Additionally, a copy of the entire discrepant package including the Export Verification Worksheet will be forwarded to CBP/FDA Team 488 at the Cargo Clearance Center, Miami International Airport.

*Destructions:*

The filer will present an Application & Approval to Manipulate, Exam, Sample or Transfer Goods (the CBP Form 3499) and a copy of the FDA Notice of Refusal to the Cargo Supervisory CBP Officer for review. The Trade Chief will approve the destruction request by signing the CBP Form 3499. Once the form is signed, the filer will coordinate with FDA to schedule a supervised destruction of the FDA refused merchandise. The broker must contact the FDA inspector at phone 305-994-3040, option #3, to coordinate the destruction.

**West Palm Beach (5204):**

*Exportations:*

The filer must submit the following to Selectivity: unprocessed Immediate Exportation (the CBP Form 7512), copy of the CBP Form 3461 package, invoice(s), bill(s) of lading, copy of the CBP Form 7501, and a copy of the FDA Notice of Refusal. Selectivity will review the package to ensure that all paperwork has been submitted. If any paperwork is missing, the filer will be notified via telephone that additional information is required.



Selectivity will issue a “stop stamp” on the CBP Form 7512 and return one copy to the filer. Selectivity will forward the entire package to the CES -Tropical Shipping. Upon arrival of the Cargo at the CES, CBP Officer will examine the FDA refused merchandise to ensure the merchandise and quantity match what is reflected on the FDA Notice of Refusal. If consolidated with other cargo, the shipment of refused merchandise should be located at the tail of the container and exported intact. The examining CBP Officer will complete the Export Verification worksheet and annotate the findings. If the merchandise is compliant, the CBP Officer will place the “*FDA Refused Merchandise Examination & Exportation Verified*” stamp on the CBP Form 7512 and initial the stamp area in the upper right-hand corner. The CBP Officer will **not** sign and date the stamp at this time. After the examination has been completed, a CBP seal will be placed on the container and the CBP Form 7512 will be validated/perforated. The CBP Form 7512 package will be returned to the filer. One copy of the CBP Form 7512 package will be filed at the Cargo Processing Center (CPC).

The CPC will retain the refusal package in a suspense file for five business days. The filer must submit export bills of lading and Trailer Interchange Report (TIR) or a delivery order within this time frame. Upon receipt of the documents, the CPC will verify that they correspond to the refusal package. If all of the documents are in order, the CBP Officer will sign, annotating badge number and date the “*FDA Refused Merchandise Examination & Exportation Verified*” stamp placed on the CBP Form 7512. The CPC will maintain a copy of the entire package, and place the original package in the brokers/miscellaneous box.

If the Trade team does not receive further documentation from the filer or if the examination was discrepant, the CBP Officer will annotate the discrepancy on the CBP Form 7512. The CBP Officer will **not** sign the “*FDA Refused Merchandise Examination & Exportation Verified*” stamp. However, if the only discrepancy is the timeliness of exportation, the stamp can be signed and the discrepancy annotated on the CBP Form 7512. The CPC will maintain a copy of the entire package, and place the original package in the brokers/miscellaneous box. Additionally, a copy of the entire package including the Export Verification Worksheet will be forwarded to CBP/FDA Team 488.

#### *Destructions:*

The filer will present an Application & Approval to Manipulate, Exam, Sample or Transfer Goods (CBP Form 3499) and a copy of the FDA Notice of Refusal to the CPC. The CBP Form 3499 must be submitted at the port of entry. The Trade SCBP Officer will sign the CBP Form 3499 and assign a CBP Officer to witness the destruction of the merchandise. For compliant examinations, the CBP Form 7512 will be stamped “*FDA Refused Merchandise Examination & Exportation Verified*”, signed and dated by the CBP Officer. The CBP Officer will cross out the words “Exportation Verified” and annotate “Destruction Verified” on the CBP Form 3499. The CBP Form 3499 will be placed in the respective broker/miscellaneous box. A copy of the CBP Form 3499 package will be filed in the CPC Office. If the merchandise is non-compliant, the CBP Officer will not stamp the CBP Form 3499 unless the only discrepancy is the timeliness of destruction. The CBP officer will annotate the discrepancy on the CBP form 3499. The CBP Form 3499 will be placed in the respective broker/miscellaneous box. A copy of the CBP Form 3499 package will be filed in the CPC office.

If you have any questions concerning this Information Bulletin, please contact Dawn Jones, Supervisory Import Specialist, at (305) 869-2683.

**DISCLAIMER:** This Information Bulletin has been prepared for your convenience by U.S. Customs and Border Protection, Field Operations, Miami Field Office. This material is intended to provide guidance to the trade community and may not be relied upon satisfying any legal obligation to CBP. Reliance solely on this information may not be considered reasonable care (see Treasury Decision 97-96 Dec 1, 1997).

A handwritten signature in blue ink, appearing to read "Vernon T. Foret". The signature is fluid and cursive, with the first name "Vernon" and last name "Foret" clearly distinguishable.

Vernon T. Foret  
Director, Field Operations, Miami  
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