

**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Food and Drug Administration
Florida District
Miami Imports Branch
6601 NW 25 St, Ste-241
Miami, FL 33122
Telephone: 305-526-2800
Fax: 305-526-7483

PROCEDURES FOR EXPORTATION/DESTRUCTION

THE MERCHANDISE SUBJECT TO THIS REFUSAL MUST BE EXPORTED OR DESTROYED UNDER U.S. AND BORDER PROTECTION/FDA SUPERVISION WITHIN NINETY (90) DAYS OF THE DAY OF THIS NOTICE. PLEASE COMPLY WITH THE FOLLOWING INSTRUCTIONS:

1. If you intend to **DESTROY** this merchandise imported by air or sea contact the Miami Imports Branch, U.S. Food and Drug Administration by calling (305)526-2800 extension 0 to arrange date and time of destruction.
2. If you intend to **EXPORT** this merchandise by air, contact U.S. Customs and Border Protection (CBP) Cargo Audit Team (CAT) at the Miami Airport by calling (305)869-2740 or (305)869-2759 to schedule a CBP Officer to supervise the lading of this merchandise at the export carrier's location. If you intend to **EXPORT** this merchandise by sea; contact CBP Trade Enforcement Team (TET), Miami Seaport at (305)808-9711/2/3 for CIPS or (305)887-9871 for Econocaribe.

Failure to export or destroy refused merchandise under Customs/FDA supervision will Result in the assessment of liquidated damages.

The documentation verifying exportation or destruction must be immediately submitted to CBP/FDA Joint Team 488, Room 202 of the Cargo Clearance Center for cancellation of the Request of Redelivery. Liquidated damages will be assessed if proof of exportation or destruction under supervision is not timely submitted to Team 488 within ninety (90) days of the date of refusal.

**REFER TO CUSTOMS INFORMATION BULLETIN NO. 08-005
DATED OCTOBER 17, 2007**

SEE NOTICE OF REFUSAL ATTACHED

5601 NW 25th Street
Miami, FL 33122



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

INFORMATION BULLETIN NUMBER: 08-005

TO: Importers, Customhouse Brokers, and Other Interested Parties

SUBJECT: Procedures for Merchandise Refused Admission by the Food & Drug Administration (FDA) Under the Food, Drug, and Cosmetic Act

The purpose of this bulletin is to provide updated information regarding procedures and contact numbers concerning the disposition of FDA regulated merchandise refused admission by the FDA at the following South Florida ports of entry: Miami Airport, Seaport and Express Consignment Courier Facilities (ECCFs), Port Everglades and West Palm Beach.

This bulletin supersedes Information Bulletin No. 02-001, dated October 11, 2001, titled "Amendment to Information Bulletin No. 01-045 on Procedures for Merchandise Entered for Consumption or Warehousing at the Miami Service Port and Subsequently Refused Admission by the Food & Drug Administration (FDA) Under the Food, Drug and Cosmetic Act".

Merchandise that has been refused admission by the FDA must be exported, destroyed or redelivered to Customs & Border Protection's (CBP's) custody for purposes of destruction within 90 days of the date of refusal. The Notice of Refusal of Admission is generated by FDA and includes a CBP request for redelivery. The notice contains language instructing importers and filers on the procedures for complying with the joint Notice of Redelivery/Refusal. Each notice is annotated with the following statement:

"The merchandise subject to this refusal must be exported or destroyed under CBP/FDA supervision within ninety (90) days of the date of this notice."

The current procedures to comply with FDA refused merchandise are noted below for each port:

MIAMI AIRPORT/SEAPORT

To **EXPORT** merchandise from the **Miami Airport (5206)**, present an unprocessed CBP Form 7512/IE (Immediate Exportation) along with copies of the CBP Form 3461, invoice(s), air waybill(s), FDA Notice of Refusal and other related documents to the Inbond/Informal Counter, Attention: Carrier Audit Team, at the Cargo Clearance Center (CCC).

Upon presentation of the documents, the importer must ensure that the refused merchandise is available for examination at the exporting carrier's facility. These documents must be provided a minimum of 24 hours prior to the scheduled exportation. Upon examination, the CBP Officer

(CBPO) will stamp the CBP Form 7512 "FDA REFUSED MERCHANDISE EXAMINATION & EXPORTATION VERIFIED". If compliant, the stamp will be signed and dated by the CBPO. If the exportation is untimely or a partial exportation, the CBPO will still sign and date the stamped CBP Form 7512, but will annotate the discrepancy on the CBP Form 7512. If the CBPO cannot confirm that the merchandise exported is the merchandise that was refused admission, the stamp will not be signed and dated. The discrepancy will be noted on the CBP Form 7512. The package will be placed in the respective broker/miscellaneous box. For further information, contact the Carrier Audit Team at (305) 869-2759 or 2740. **In order to substantiate that supervision of exportation occurred, the importer/broker MUST possess a stamped, signed and dated CBP Form 7512.**

To **EXPORT** merchandise from the **Miami Seaport (5201)**, present an unprocessed CBP Form 7512/IE (Immediate Exportation) along with copies of the CBP Form 3461, invoice(s), bill(s) of lading, FDA Notice of Refusal and other related documents to the Selectivity Section, Attention FDA Refusals, at the Foreign Trade Zone. Selectivity will issue a "stop stamp" on the CBP Form 7512 and the merchandise will be examined upon delivery to the Centralized Examination Station (CES) – Customs Inspection Processing Service (CIPS) or Econocaribe. Refused merchandise consolidated with other freight **MUST** be placed at the tail of the container. Upon examination, the CBPO will stamp the CBP Form 7512 "FDA REFUSED MERCHANDISE EXAMINATION & EXPORTATION VERIFIED", and will initial in the corner, but will **NOT** sign the stamp at this time. Immediately after delivery (same day of exam) to the exporting carrier, the following documents **MUST** be submitted via fax ((305) 808-9755 for exams at CIPS or (305) 887-9681 at Econocaribe) to the Trade Enforcement Team (TET), Attention FDA Refusals: (1) stamped CBP 7512, (2) export bill(s) of lading, (3) Trailer Interchange Report (IIR) or Delivery Order. The CBPO will review the documentation and if compliant, the stamp will be signed and dated by the CBPO. If the exportation is untimely or a partial exportation, the CBPO will still sign and date the stamped CBP Form 7512, but will annotate the discrepancy on the CBP Form 7512. If the CBPO cannot confirm that the merchandise exported is the merchandise that was refused admission, the stamp will not be signed and dated. The discrepancy will be noted on the CBP Form 7512. The package will be placed in the respective broker/miscellaneous box. For further information, contact the TET at the respective CES: (305) 808-9711, 9712 or 9713 for CIPS or (305) 887-9871 for Econocaribe. **In order to substantiate that supervision of exportation occurred, the importer/broker MUST possess a stamped, signed and dated CBP Form 7512.**

To **DESTROY** merchandise imported through the **Miami Airport/Seaport (5206/5201)**, brokers/filers must present a CBP Form 3499 requesting authorization to destroy FDA refused merchandise along with a copy of the CBP Form 3461, invoice(s), bill(s) of lading or airway bill(s) and the FDA Notice of Refusal to the Chief, Cargo Control Section, MIA at the Cargo Clearance Center (for 5206 entries only) or to the Supervisory CBP Officer of the Warehouse Inspection Team (WIT) at the Seaport (for 5201 entries only) for approval. The CBP Form 3499 must be signed by CBP **PRIOR** to requesting supervision of the destruction by FDA. Once the request is approved, contact the Miami FDA Resident Post at (305) 526-2800 to schedule a supervised destruction. Upon completion of the supervised destruction and if found to be compliant, FDA will stamp the CBP Form 3499 "U.S. FOOD AND DRUG

ADMINISTRATION DESTROYED ON", date and sign it, and place a copy in the respective broker/miscellaneous box. FDA will NOT stamp the CBP Form 3499 if found to be non-compliant. **In order to substantiate that supervision of destruction occurred, the importer/broker MUST possess a stamped CBP Form 3499 signed by FDA and CBP.**
EXPRESS CONSIGNMENT COURIER FACILITIES (ECCF)

To **EXPORT** merchandise from the ECCF, present an unprocessed CBP Form 7512/IE (Immediate Exportation) along with copies of the CBP Form 3461, invoices, air waybills, FDA Notice of Refusal and other related documents "Attention FDA Refusals" to the supervisor at the respective facility. Upon presentation of the documents, the refused merchandise must be available for examination at the exporting carrier's facility. Upon examination, the CBP Form 7512 will be stamped "FDA REFUSED MERCHANDISE EXAMINATION & EXPORTATION VERIFIED". If compliant, the stamp will be signed and dated by the CBPO. If the exportation is untimely or a partial exportation, the CBPO will still sign and date the stamped CBP Form 7512, but will annotate the discrepancy on the CBP Form 7512. If the CBPO cannot confirm that the merchandise exported is the merchandise that was refused admission, the stamp will not be signed and dated. The discrepancy will be noted on the CBP Form 7512. The package will be provided to the exporting carrier at the courier facility. **In order to substantiate that supervision of exportation occurred, the importer/broker MUST possess a stamped, signed and dated CBP Form 7512.**

For further information, contact the supervisor at the respective facility:

DHL, Port 5271, (305) 871-2106
FEDEX, Port 5297, (786) 265-6807
FMC, Port 5206, (305) 474-0174
IBC, Port 5298, (305) 876-9725
UPS, Port 5295, (305) 874-7072

To **DESTROY** merchandise imported through the ECCF, brokers/filers must present a CBP Form 3499 requesting authorization to destroy FDA refused merchandise along with a copy of the CBP Form 3461, invoice(s), bill(s) of lading or airway bill(s) and the FDA Notice of Refusal to the supervisor at the respective facility for approval. The CBP Form 3499 must be signed by CBP PRIOR to requesting supervision of the destruction by FDA. Once the request is approved, contact the Miami FDA Resident Post at (305) 526-2800 to schedule a supervised destruction. Upon completion of the supervised destruction, FDA will stamp the CBP Form 3499 "U.S. FOOD AND DRUG ADMINISTRATION DESTROYED ON", date and sign it, and place a copy in the respective broker/miscellaneous box. FDA will NOT stamp the CBP Form 3499 if found to be non-compliant. **In order to substantiate that supervision of destruction occurred, the importer/broker MUST possess a stamped CBP Form 3499 signed by FDA and CBP.**

For refusals of merchandise imported through the ECCF, the above procedures ONLY apply to Notices of Action signed jointly by CBP and FDA. Contact the Miami FDA Resident Post for procedures regarding any other refusals at (305) 526-2800.

PORT EVERGLADES

To **EXPORT** merchandise from **Port Everglades (5203)**, present an unprocessed CBP Form 7512/IE (Immediate Exportation) along with copies of the CBP 3461, invoice(s), bill(s) of lading, FDA Notice of Refusal and other related documents to the Selectivity Section, Attention FDA Refusals. Selectivity will issue a "stop stamp" on the CBP 7512 and the merchandise will be examined upon delivery to the Centralized Examination Station (CES) - International Warehouse Services. Refused merchandise consolidated with other freight **MUST** be placed at the tail of the container. Upon examination, the CBPO will stamp the CBP Form 7512 "FDA REFUSED MERCHANDISE EXAMINATION & EXPORTATION VERIFIED", and will initial in the corner, but will **NOT** sign the stamp at this time. Immediately after delivery (same day of exam) to the exporting carrier, the following documents **MUST** be submitted to the Carrier Audit Team, Attention FDA Refusals: (1) export bill(s) of lading, (2) Trailer Interchange Report (TIR) or Delivery Order. The CBPO will review the documentation and if compliant, the stamp will be signed and dated by the CBPO. If the exportation is untimely or a partial exportation, the CBPO will still sign and date the stamped CBP Form 7512, but will annotate the discrepancy on the CBP Form 7512. If the CBPO cannot confirm that the merchandise exported is the merchandise that was refused admission, the stamp will **NOT** be signed and dated. The discrepancy will be noted on the CBP Form 7512. The package will be placed in the respective broker/miscellaneous box. For further information, contact the Trade Enforcement Team (TET) at (954) 356-7361 or 7362. **In order to substantiate that supervision of exportation occurred, the importer/broker MUST possess a stamped, signed and dated CBP Form 7512.**

To **DESTROY** merchandise from **Port Everglades**, brokers/filers must present a CBP Form 3499 requesting authorization to destroy FDA refused merchandise along with a copy of the CBP Form 3461, invoice(s), bill(s) of lading or airway bill(s) and the FDA Notice of Refusal to the Supervisory CBPO at the respective facility for approval. The CBP Form 3499 must be signed by CBP **PRIOR** to requesting supervision of the destruction by FDA. Once the request is approved, contact the Port Everglades FDA Resident Post at (954) 527-4239 to schedule a supervised destruction. Upon completion of the supervised destruction and if found to be compliant, FDA will stamp the CBP Form 3499 "U.S. FOOD AND DRUG ADMINISTRATION DESTROYED ON", date and sign it, and place a copy in the respective broker/miscellaneous box. FDA will **NOT** stamp the CBP Form 3499 if found to be non-compliant. **In order to substantiate that supervision of destruction occurred, the importer/broker MUST possess a stamped CBP Form 3499 signed by FDA and CBP.**

PORT OF WEST PALM BEACH

To **EXPORT** merchandise from the **Port of West Palm Beach (5204)**, present an unprocessed CBP Form 7512/IE (Immediate Exportation) along with copies of the CBP Form 3461, invoice(s), bill(s) of lading, FDA Notice of Refusal and other related documents to the Seaport Trade Operations Office, Attention FDA Refusals. Refused merchandise will be examined upon delivery to the Centralized Examination Station (CES) - Tropical Shipping. Refused merchandise consolidated with other freight **MUST** be placed at the tail of the container.

Upon examination, the CBPO will stamp the CBP Form 7512 "FDA REFUSED MERCHANDISE EXAMINATION & EXPORTATION VERIFIED", and will initial in the corner, but will NOT sign the stamp at this time. Immediately after delivery (same day of exam) to the exporting carrier, the following documents MUST be submitted to the Carrier Audit Team Attention FDA Refusals: (1) stamped CBP 7512, (2) export bill of lading, (3) Trailer Interchange Report (TIR) or Delivery Order. The CBPO will review the documentation and if compliant, the stamp will be signed and dated by the CBPO. If the exportation is untimely or a partial exportation, the CBPO will still sign and date the stamped CBP Form 7512, but will annotate the discrepancy on the CBP Form 7512. If the CBPO cannot confirm that the merchandise exported is the merchandise that was refused admission, the stamp will not be signed and dated. The discrepancy will be noted on the CBP Form 7512. The package will be placed in the respective broker/miscellaneous box. For further information, call (561) 844-4393 extension 226. **In order to substantiate that supervision of exportation occurred, the importer/broker MUST possess a stamped, signed and dated CBP Form 7512.**

To **DESTROY** merchandise from the **Port of West Palm Beach**, brokers/filers must present a CBP Form 3499 requesting authorization to destroy FDA refused merchandise along with a copy of the CBP Form 3461, invoice(s), bill(s) of lading or airway bill(s) and the FDA Notice of Refusal to the Supervisory CBPO at the Seaport Trade Operations Office. The CBP Form 3499 must be signed by CBP PRIOR to requesting supervision of the destruction by FDA. Once the request is approved, contact the Port Everglades FDA Resident Post at (954) 527-4239 to schedule a supervised destruction. Upon completion of the supervised destruction and if found to be compliant, FDA will stamp the CBP Form 3499 "U.S. FOOD AND DRUG ADMINISTRATION DESTROYED ON", date and sign it, and place a copy in the respective broker/miscellaneous box. FDA will NOT stamp the CBP Form 3499 if found to be non-compliant. **In order to substantiate that supervision of destruction occurred, the importer/broker MUST possess a stamped CBP Form 3499 signed by FDA and CBP.**

GENERAL REQUIREMENTS FOR FDA REFUSED MERCHANDISE AT SOUTH FLORIDA PORTS OF ENTRY:

If you intend to redeliver the merchandise to Customs custody only, destruction will be arranged at the importer's cost. Failure to export or destroy refused merchandise under CBP/FDA supervision within 90 days will result in the assessment of liquidated damages with an assessed amount of three times the entered value. Additionally, substitution of FDA refused merchandise at the time of exportation or destruction may result in penalty action under 19 U.S.C. 1592.

Refused shipments MUST remain INTACT when presented for destruction or exportation. Refused merchandise must be exported via Immediate Exportation (IE) CBP 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. The importer must submit a written request for authorization from the port of entry including a valid reason for the exception.

The refused merchandise must be clearly identified on the CBP Form 7512 or CBP Form 3499 as FDA refused merchandise and indicate the entry number, quantity and description of the merchandise. The merchandise description and quantity indicated on the exportation and destruction documents must match the information on the FDA Notice of Refusal.

Once merchandise has been exported or destroyed under supervision, the stamped and signed copies of the validated CBP Form 7512 (and proof of the date of exportation) or CBP Form 3499, along with a copy of the FDA Notice of Action, MUST be presented to the CBP/FDA Joint Team 488 (Team 488) for cancellation of the request for redelivery. Team 488 is located in Room 202 in the CCC. Failure to present proof of exportation or destruction under supervision within 90 days of the FDA Notice of Action shall result in the assessment of liquidated damages. For further information, contact Team 488 at (305) 869-2527. If a CBP Form 5955A Notice of Penalty or Liquidated Damages has been issued, contact the Fines Penalties & Forfeitures Office for information regarding the petition process at (305) 869-2870.

DISCLAIMER: This information has been prepared for your convenience by Customs and Border Protection in Miami, Florida. This material is intended to provide guidance. Reliance solely on this information alone may not be considered reasonable care. Importers are referred to Treasury Decision 97-96, which was published in the Customs Bulletin of December 17, 1997, for in-depth information on the concept of reasonable care.

Should you have further questions, please contact Supervisory Import Specialist Magaly Alino at (305) 869-2688.



Christopher D. Maston
Port Director
Miami Service Port

10/17/07
Date