003/010	EARL GREY TEA BAGS	4 BX	Released 10-26-2012
003/011	BREAKFAST TEA BAGS	4 BX	Released 10-26-2012

* = 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. CF-3461 or CF-7501) and commercial invoice for these products, annotated to show the ACS/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.

REFUSAL OF ADMISSION

REDELIVERY WITH FDA VERIFICATION REQUESTED

Examination of the following products have been made and you have been afforded an opportunity to respond to a notice of detention. Because it appears that the products are not in compliance, you are hereby notified that they are refused admission.

Line ACS/FDA	Product Description
003/005	PEPPERMINT *

Refused : 32 LB

FD&CA Section 801(a)(3); 403(r)(1)(A)/(B) misbranding
The article appears to be misbranded in that the label or labeling bears an unauthorized nutrient content/health claim. PRODUCT LABEL STATES UNAPPROVED HEALTH CLAIMS:"EASE IRRITABLE BOWEL SYNDROE, NAUSEA, VOMITING, DIARRHEA, HEADACHES AND BABY CHOLIC""CONTROL MILD ASTHMA, WARD OFF COMMON COLD".

003/006	LEMON *

Refused : 32 LB

FD&CA Section 801(a)(3); 403(r)(1)(A)/(B) misbranding
The article appears to be misbranded in that the label or labeling bears an unauthorized nutrient content/health claim. PRODUCT LABEL IS MAKING UNAPPROVED HEALTH CLAIMS: "ANTIBACTERIAL AND ANTIFUNGAL PROPERTIES, REDUCING FEVER, STOMACH CRAMPS, FLATULENCE AND COLIC, EASE

ARTHRICTIC PAIN"..

For the District Director of Customs:

[redacted], Compliance Officer (Region/District)
U.S. Food and Drug Administration
8600 NW 36th Street, Suite 700
Miami, FL 33166

(305) 994-3075
(305) 994-3066 (FAX)
[redacted]

A request has been made to Customs 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 into Customs custody will result in a claim for liquidated damages under the provisions of the entry bond.

These products must be exported or destroyed under Customs supervision within 90 days from the date of this notice, or within such additional time as the District Director of Custom 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.

You are required to have FDA verify the identification, exportation, or destruction of the above products. Contact the individual listed above to arrange for the required verification.

After completion of the exportation or destruction forward the original of the signed CF-7512 or CF3499, along with any other documents required by Customs, and a copy of this notice to:

U.S. Customs and Border Protection
6601 NW 25th Street
Room 202, Team 488
Miami, FL 33122

In addition forward copies of the signed CF-7512 or CF-3499, and any other records which document export or destruction, to the individual listed above.

Notice Prepared For: The District Director, U.S. Food and Drug Administration
Notice Prepared By: LDC

"You are ordered to redeliver this merchandise to CBP's custody. This can be accomplished by exporting or destroying under CBP supervision. Forward the original copy of the signed CBPF7512 or CBPF3499 to the CBP/FDA Joint Team 488 with a copy of this notice. Failure to comply with this notice will result in the assessment of liquidated damages."

(Signature) _____
FDA COMPLIANCE OFFICER

(Signature) _____
for PORT DIRECTOR OF CBP
CBP PORT NO. 5[redacted]
MIAMI INTERNATIONAL AIRPORT

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Miami Resident Post
8600 NW 36 Street Room 700
Miami, FL 33166

Telephone: (305) 994-3040
FAX: (305) 994-3066

PROCEDURES FOR EXPORTATION/DESTRUCTION

THE MERCHANDISE SUBJECT TO THIS REFUSAL MUST BE EXPORTED OR DESTROYED UNDER CUSTOMS AND BORDER PROTECTIONIFDA SUPERVISION WITHIN (90) DAYS OF THE DATE OF THIS NOTICE. PLEASE COMPLY WITH THE FOLLOWING INSTRUCTIONS:

1. If you intend to **DESTROY** this merchandise imported by air or by sea contact the **MIAMI RESIDENT POSTINVESTIGATION BRANCH,** U.S. Food and Drug Administration by calling (305)994-3040 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)869-2766 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 Office at (305)808-9681, for CIPS or (305)808-9708 Extensions 101, 104, 105 or 117 for Econocaribe.

Failure to export or destroy refused merchandise under *CBPIFDA* supervision will result in the assessment of liquidated damages.

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

REFER TO CBP INFORMATION BULLETIN NO. 08-005

SEE NOTICE OF REFUSAL ATTACHED.

6601 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

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.