



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Florida District
555 Winderley Place
Suite 200
Maitland Florida 32751
Telephone: 407-475-4700

VIA FEDERAL EXPRESS

Reference: Customs Entry No. DM4-0085887-2 and DM4-0085886-4
Product: Snow Peas

WARNING LETTER

FLA-02-58

September 10, 2002

Mr. Stanley F. Yu
Transamerica Food Enterprises
11077 NW 36th Avenue
Miami, Florida 33167

Dear Mr. Yu:

On June 1, 2002, your firm offered for import into the United States 246 cartons of snow peas under U. S. Customs Service (Customs) entries DM4-0085887-2 and DM4-0085886-4. On June 20, 2002, the U. S. Food and Drug Administration (FDA) issued a Notice of Refusal because the product contained chlorothalonil.¹

Section 801(a) [21 U.S.C. § 381(a)] of the Federal Food, Drug, and Cosmetic Act ("the 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. Under the Act, the product under entries DM4-0085887-2 and DM4-0085886-4 are subject to refusal of admission pursuant to Section 801(a)(3) in that it appears to contain pesticide chemicals, which is in violation of Section 402(a)(2)(B) [21 U.S.C. § 342(a)(2)(B)].

On July 12, 2002, FDA documented the substitution of the refused product upon examination of the refused merchandise at the South Dade County Landfill, located at 24000 SW 97th Avenue, Homestead, FL 30032. The product offered for destruction was labeled with an air waybill number that did not correspond with the original air waybill number (American Airlines AWB #001-99470615) for the refused entries DM4-0085887-2 and DM4-0085886-4. FDA investigated the history of the air waybills and found that the product offered for destruction actually arrived nine

¹ There is no tolerance for chlorothalonil pursuant to 40 CFR § 180.275.

days after the original FDA refused product (entries DM4-0085887-2 and DM4-0085886-4). On July 16, 2002, you provided FDA with a signed affidavit and supporting invoices demonstrating the sale, into interstate commerce, of at least ~~one~~ cartons of the refused shipment.²

This is a violation of Title 21, Code of Federal Regulations, Section 1.90, which requires the importer to hold an entry intact pending receipt of a May Proceed or Release Notice from FDA. Since the articles were not held and there was an attempt to evade regulation, FDA has requested Customs to increase your bond, and require future entries from your firm to be held in a bonded warehouse until FDA makes a final decision as to admissibility. You will be responsible for all costs incurred at secured storage. In addition, FDA is requesting that Customs assess liquidated damages for failure to redeliver the entry noted above.

It is your responsibility, as the importer, to ensure that imported products meet all requirements of the Act, and the regulations promulgated thereunder. We wish to remind you that making fraudulent misrepresentations or false statements to federal officials are criminal offenses under Title 18, United States Code (18 U.S.C.), sections 542 and 1001. When evidence demonstrates the article presented to FDA for examination is not from the original entry, but was substituted for the entry, the article may be seized under Title 19 section 1595a. Criminal charges of entry contrary to law (18 U.S.C. § 545) may result in addition to the charges mentioned above.

Failure to promptly correct this violation and prevent future violations may result in regulatory action without further notice such as seizure, injunction, or detention without examination of future shipments. Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the violation, including an explanation of each step being taken to prevent the recurrence of the violation. In addition, you should inform Customs and FDA if and when redelivery is accomplished.

Your written reply should be addressed to the Food and Drug Administration, Attention: Christine M. Humphrey, Compliance Officer, 6601 NW 25th Street, P.O. Box 59-2256, Miami, Florida 33159-2256. If you have any questions related to this matter, you may contact Ms. Humphrey at (305) 526-2800, ext. 932.

Sincerely,


for Emma R. Singleton
Director, Florida District

² Invoice # 14722 (copy attached)