



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

5/5/88
017336

Food and Drug Administration
555 Winderley Place, Suite 200
Maitland, Florida 32751

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ref: Customs Entry No. DP3-0009022-3
Product: Vegetable Margarine & Apetit-Syrup

WARNING LETTER

FLA-98-45

April 9, 1998

Mrs. Galbaud Francois Rose
320 N.E. 3rd Avenue
Miami, Florida 33139

Dear Mrs. Rose:

The Food and Drug Administration (FDA) requested to examine a shipment of vegetable margarine and appetit-syrup offered for entry into the United States by your firm on March 9, 1998, under the above referenced entry number, and determined that the products are not available for FDA examination. Regulation 1.90, Title 21, Code of Federal Regulations, (21 CFR 1.90) requires the importer to hold an entry intact pending receipt of a "May Proceed Notice" or "Release Notice" from FDA. We have requested the U. S. Customs Service (Customs) to order redelivery of these products (copy enclosed).

Failure to promptly correct this violation and prevent future violations may result in regulatory action without further notice such as seizure, injunction, or automatic detention of future shipments. It is your responsibility, as the importer, to ensure that imported products meet all the requirements of the Federal Food, Drug, and Cosmetic Act and the regulations promulgated thereunder.

We request a response in writing within fifteen (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.

Mr. Galbaud Francois Rose
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Your written reply should be addressed to the Food and Drug Administration, Attention:
Carlos I. Medina, Compliance Officer, P. O. Box 59-2256, Miami, Florida 33159-2256.

Sincerely,



Douglas D. Tolen
Director, Florida District

Enclosure

cc: District Director
U. S. Customs Service
P. O. Box 52-3215
Miami, Florida 33152-3215

Customs Brokers, Inc.
2550 N.W. 72nd Avenue
Ste. 300
Miami, Florida 33122