



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

9/14/97
519

Food and Drug Administration
7200 Lake Ellenor Drive
Orlando, Florida 32809

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Re: Customs Entry No.: WKV-0002736-2
Product: Fresh Mahi H & G

WARNING LETTER

FLA-97-76

August 11, 1997

Frank J. Marrero, President
International Cargo Brokers, Inc.
10201 N.W. 21st Street
Miami, Florida 33172

Dear Mr. Marrero:

The Food and Drug Administration (FDA) attempted to examine a shipment of fresh mahi offered for import into the United States by your firm on July 1, 1997, under entry number WKV-0002736-2 and found that the shipment was not held intact for FDA examination. Our inspector went to B & V Seafood, 7850 N.W. 72nd Avenue, Miami, Florida 33166, to collect a sample of fresh mahi. The product presented to the FDA inspector was neither in the same numbered cases, nor had the same weight, as declared on the packing list for this entry. In addition, [REDACTED] of the [REDACTED] cases presented appeared to have come from the shipment of July 2, while [REDACTED] of the other cases appeared to have come from some other entry/entries. Of the [REDACTED] cases of mahi declared on the original packing list for this entry, only [REDACTED] case was presented to the FDA inspector.

Regulation, Title 21, Code of Federal Regulations (CFR), Part 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 the 1,742 pounds of fresh mahi which have not been presented to FDA for review (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 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. 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: Paul Bagdikian, Compliance Officer, P.O. Box 59-2256, Miami, Florida 33159-2256.

Sincerely,

A handwritten signature in black ink that reads "Douglas D. Tolen". The signature is written in a cursive style with a long horizontal line extending to the left.

Douglas D. Tolen
Director, Florida District