



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service d1492b

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

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ref: Customs Entry Nos: D97-0110014-8
D97-011001809
Fresh Mahi Mahi, H & G

WARNING LETTER

FLA-98-31

March 4, 1998

Donald L. Newell, President
Fish Express, Inc.
7337 N.W. 37th Avenue
Miami, Florida 33147

Dear Mr. Newell:

The Food and Drug Administration (FDA) attempted to examine two shipments of fresh mahi mahi, H & G, offered for entry into the United States by your firm on February 3, 1998, under the above referenced entry numbers, and found that the shipment was not held intact for FDA examination. FDA inspectors visited your firm on February 5, 1998, and observed that the product shown to them was not the product which was covered by the two referenced entry numbers. It was documented that the product, which we asked to examine had already been distributed by your firm without an FDA release. 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. Since the product was not made available to us, we have requested the U. S. Customs Service (Customs) to order redelivery of the fresh mahi mahi which has been distributed without a release from FDA (copy of the request is 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.

Mr. Donald L. Newell
Page 2
March 4, 1998

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 R. Bagdikian, 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

