



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

6/1/98
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Food and Drug Administration
555 Winderley Place, Suite 200
Maitland, Florida 32751

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ref: Customs Entry No. WKV-0005409-2
Fresh Mahi-Mahi

WARNING LETTER

FLA-98-43

May 11, 1998

Carlos Contu, President
Ocean Fresh Seafood, Inc.
473 E. Washington Street
North Attleboro, MA 02760

Dear Mr. Contu:

The Food and Drug Administration (FDA) attempted to examine a shipment of fresh mahi mahi offered for entry into the United States by your firm on March 9, 1998, under the above referenced entry number, and found that the shipment was not held intact for FDA examination. An FDA inspector visited Kaelbel Wholesale, 2501 S.W. 31st Street, Ft. Lauderdale, Florida 33312, on March 11, 1998, and noted that this entry was not held intact for FDA examination. It was documented that at least two cases out of the original entry of 16 cases were missing. Regulation 1.90, Title 21, Code of Federal Regulations (21CFR), Part 1.90, requires the importer to hold an entry intact pending receipt of a "May Proceed Notice" or "Release Notice" from FDA. Since at least two cases were not made available to us, we have requested the U. S. Customs Service (Customs) to order redelivery of the two cases of fresh mahi mahi which were not available for examination. A copy of the redelivery 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. Carlos Contu
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Please notify this office in writing within fifteen (15) working days after receipt of this letter of the specific steps you have taken to correct the violations, including an explanation of each step being taken to prevent recurrence. In addition, you should inform Customs and FDA if and when redelivery is accomplished.

This is the second time within a year that this problem has occurred. In June 1997, an entry of thresher shark was not held for FDA examination by your firm. No response was received to a Warning Letter (FLA-97-75), dated August 11, 1997, issued to Jaime Yukon, General Manager, Ocean Fresh Seafood, Inc., 1177 N.W. 81st Street, Miami, Florida 33150. Continuation of these problems will not be tolerated. Since the previous letter was not directed to you, we are enclosing a copy for your information.

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, telephone no. (305) 536-2800, ext. 929.

Sincerely,



Douglas D. Tolen
Director, Florida District

Enclosure

cc: Mr. Carlos Celi
Ocean Fresh Seafood
2501 S.W. 31st Street
Ft. Lauderdale, Florida 33312

Director, Compliance Branch
Food and Drug Administration
New England District Office
One Montvale Avenue, 4th Floor
Stoneham, MA 02180