



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

HFI-35

4/27/99
NAB

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

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-99-49

April 5, 1999

Carlos Palomina, President
Seafood Only Company
1375 N.W. 89th Court #7
Miami, Florida 33172

Dear Mr. Palomina:

On December 15, 1998, the Food and Drug Administration (FDA) conducted an inspection of your fish importing facility, located at 1375 N.W. 89th Court, Bay #7, Miami, Florida. The investigator, Carlos W. Hernandez, documented for the second consecutive time, a serious deviation from the seafood HACCP importing regulation in Title 21 Code of Federal Regulations, Part 123 (21 CFR 123). The existence of this deviation causes the fish products being imported and stored by your firm to be adulterated within the meaning of section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act). The following deficiency was noted:

You have failed to establish product specifications that are designed to ensure that the seafood products are not adulterated, as required in 21 CFR § 123.12(a)(2)(i).

The above identified deviation is not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to ensure that all seafood products processed and distributed by your firm are in compliance with the Act and all requirements of the federal regulations.

You should take prompt measures to correct these deviations. Failure to promptly correct the deviations noted may result in regulatory action without further notice including seizure and/or injunction. In addition, FDA may detain your imported seafood products without examination and will not approve any requests for export certificates for any of your seafood products until your firm is fully in compliance with the Seafood HACCP regulations.

Please notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct these violations, including an explanation of each step taken to prevent their reoccurrence. Your response should include copies of any available documentation demonstrating that corrections have been made. If corrections cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed.

Your written reply should be directed to Carlos I. Medina, Compliance Officer, Food and Drug Administration, 6601 Northwest 25th Street (P.O. Box 59-2256) Miami, Florida 33159-2256.

Sincerely,

A handwritten signature in black ink that reads "Douglas D. Tolen". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Douglas D. Tolen
Director
Florida District