



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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

Telephone: 407-475-4700
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VIA FEDERAL EXPRESS

WARNING LETTER

FLA-00-20

January 3, 2000

Pedro A. Torres, President
World Trade Foods
5723 N.W. 158th Street
Miami, Florida 33015
CFN: 1059012

Dear Mr. Torres:

On August 16, 1999, the Food and Drug Administration (FDA) conducted an inspection of your fish importing facility located at 5723 N.W. 158th Street, Miami, Florida 33015. Investigator Maria A. Medina documented for the third consecutive time a serious deviation from the HACCP regulations in Title 21 Code of Federal Regulations, Part 123 (21 CFR 123). The existence of this deviation causes the seafood products being imported and distributed by your firm to be in violation of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). The following deficiency was noted:

You must adequately perform one or more of the affirmative steps in order to comply with 21 CFR § 123.12(a)(2)(ii). However, you have not fulfilled the affirmative step requirement for your mahi mahi and tuna in order to verify that these products were processed in accordance with the provisions of the HACCP regulations.

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 this deviation at your firm, or FDA may take regulatory action without further notice. Such action may include seizure and/or injunction of your seafood products. In addition, FDA may detain your imported seafood products without examination and will not approve any request for export or European Union Health Certificates for any of the affected fish and fishery products until your firm is fully in compliance with Seafood HACCP regulations.

Please respond in writing 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 and should be received by this office within three weeks. If corrections cannot be completed within three weeks, state the reason for the delay and the time frame within which the corrections will be completed.

Your written reply should be addressed to the Food and Drug Administration, attention Paul Bagdikian, 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 "Edward R. Atkins". The signature is written in a cursive style with a large initial "E".

Edward R. Atkins
Acting Director, Florida District