



Food and Drug Administration
555 Winderley Place, Suite 200
Maitland, Florida 3275

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-99-54

April 19, 1999

Armando A. Coronel
President
Miavana Wholesale Company
2175 N.W. 23rd Court
Miami, Florida 33142

Dear Mr. Coronel:

On December 3, 1998, the Food and Drug Administration (FDA) conducted an inspection of your fish importing facility, located at 2175 N.W. 23rd Court, Miami, Florida 33142. Investigator Carlos W. Hernandez documented for the second consecutive time, serious deviations from the seafood HACCP regulation in Title 21 Code of Federal Regulations, Part 123 (21 CFR 123). These deviations cause 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 deficiencies were noted:

Failure to adequately perform one or more of the affirmative steps required in 21 CFR § 123.12(a)(2)(ii) to verify that the seafood products imported from [REDACTED] are processed in accordance with the provisions of the HACCP regulations.

Failure to list and implement product specifications that are designed to ensure that the seafood products are not adulterated, as required in 21 CFR § 123.12(a)(2)(i).

We acknowledge that you have attempted to fulfill the affirmative step requirement as specified in 21 CFR § 123.12(a)(2)(ii)(D) by maintaining the foreign processor's HACCP plan. However, the control strategies are different depending on whether the processor receives the fish directly from the harvester or from an intermediate processor. Therefore, the following information is necessary to determine the adequacy of the HACCP plan:

- whether the foreign processor receives the product as a primary or secondary processor,
- whether the processing step needs to be a critical control point; and
- what the critical limits should be.

The above identified deviations are 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 action to correct these and all violations at your firm. Failure to achieve corrective action may result in further regulatory action without further notice. These actions may include seizure, injunction, or removal from the European Union (EU) list. Additionally, until FDA is satisfied that the above deficiencies have been corrected, no EU certificates will be issued. FDA may also detain your imported seafood products without examination until your firm is fully in compliance with the Seafood HACCP regulation.

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,



Douglas D. Tolen
Director
Florida District