



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

MJD
4/2/99

MJD 489m

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

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-98-48

March 25, 1999

Richard C. Nichols, President
Admiral Fish Company, Inc.
1375 N.W. 89th Ct.
Miami, Florida 33172

Dear Mr. Nichols:

On October 26 and 27, 1998, the Food and Drug Administration (FDA) conducted an inspection of your facility located at 1375 N.W. 89th Ct., Miami, FL. The investigator documented deviations from the Seafood HACCP Regulation in Title 21, Code of Federal Regulations, Part 123 (21CFR 123), causing the seafood products processed by your firm to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (The Act), as follows:

Failure to identify a critical control point at storage in the HACCP plans for: the histamine hazard that is reasonably likely to occur with scombroid fish; the pathogen and botulism hazards that are reasonably likely to occur with refrigerated smoked fish and the pathogen hazard that is reasonably likely to occur with pasteurized crabmeat. [21 CFR 123.6(c)(2)]

Failure to maintain records of the monitoring of the receiving critical control point for scombroid fish. [21 CFR 123.6(c)(7)]

Failure to adequately monitor all of the sanitation controls required in 21 CFR 123.11(b), such as prevention of cross-contamination and protection of food from adulteration. During the October 1998 inspection ten perforated plastic baskets of cooked stone crab claws were stored directly on the floor of the cooler near standing water, one basket of cooked claws was stored on top of a basket of raw fish and cooked crab claws spilled on the cooler floor from one basket were replaced in the basket.

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The HACCP plan for fresh scallops collected during the April 1998 inspection was found to have an inadequate corrective action plan, as it did not specify procedures to ensure product that is adulterated or otherwise injurious to health is prevented from entering commerce and the cause of the deviation is corrected. [21 CFR 123.7(b)]

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 measures to correct these deviations. Failure to promptly correct the deviations noted may result in regulatory action without further notice. Such action includes seizure and/or injunction. In addition, FDA will not issue any certificates for export of any of the seafood products processed at your facility 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 Ken Hester, Compliance Officer, U.S. Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, telephone (407) 475-4730.

Sincerely,



Douglas D. Tolen
Director, Florida District