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11/20/98



**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

Public Health Service *m2188n*  
*HFI-35*

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

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

**WARNING LETTER**

FLA-99-07

November 10, 1998

Simon Stern, President  
National Fisheries, Inc.  
P.O. Box 5557  
Miami, Florida 33014

Dear Mr. Stern:

On August 27-28, 1998, the Food and Drug Administration (FDA) conducted an inspection of your seafood processing plant, located at 3880 Gulfview Avenue, Marathon, Florida. The investigator documented serious deviations from the seafood processing regulations in Title 21 Code of Federal Regulations, Part 123 (21 CFR 123) causing the histamine forming fish species, e.g., mahi, being received, processed, stored, and distributed 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 take corrective actions specified in your current HACCP plan when your storage cooler exceeded the temperature critical limit, and when a shipment of mahi was received at 50° F. Your HACCP plan specifies a critical temperature limit of 45° F at both critical control points and specifies the corrective actions to be taken (re-ice four hours, re-take temperature, and inspect for decomposition). No corrective actions were taken by your firm with regard to the seafood products stored in the cooler, and the mahi received at 50° was accepted and placed in storage [21 CFR 123.7(b)].

Failure to maintain sanitation control records [21 CFR 123.11(c)] that document the monitoring and corrections of sanitation conditions specified in the regulations during receiving, processing, and storage. For example, no documentation is available to show that plant water (ice) safety, cleanliness of food contact surfaces, prevention of cross-contamination, maintenance of hand washing, hand sanitizing, and toilet facilities, protection from contaminants, proper labeling, storage, and use of toxic compounds, control of employee health conditions, and exclusion of pests are being monitored [21 CFR 123.11(b)].

Other deviations noted during the inspection include, but are not limited to: no provision in your HACCP plan for calibration of the thermometer used for receiving; no equipment calibration records; frequency of receiving temperature checks (i.e., every shipment) not specified in your plan; operators name/initials are not documented on receiving records; inadequate monitoring of storage, e.g., 2 times/day does not ensure adequate control and the histamine hazard is not identified for storage. Also, your HACCP plan is not signed and dated to signify that the plan has been accepted for implementation by your firm.

The above identification of violations are not intended to be an all-inclusive list of deficiencies at your Marathon seafood processing plant. We note that your firm has previously received three letters from FDA regarding similar violations documented during inspections of other seafood processing plants operated by your firm. It is your responsibility as president to ensure that all fish and fishery products received, stored, processed, and distributed by all of your seafood processing plants are in compliance with the Act and the requirements of the regulations.

You should take prompt action to correct these violations. Failure to correct these violations 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 fish or fishery products received, processed, and stored by any of your firms until full compliance with the seafood regulations is achieved.

We request that you notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct these violations and to prevent their reoccurrence. Your response should include copies of any 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 corrections will be completed.

Your reply should be directed to Jimmy E. Walthall, Compliance Officer, U.S. Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, telephone (407) 475-4731.

Sincerely,



Douglas D. Tolen  
Director, Florida District