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VIA FEDERAL EXPRESS

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, FL 32751

WARNING LETTER

FLA-99-88

September 2, 1999

Glen J. Black, President
Inlet Fisheries, Inc.
22 N. Causeway Drive
Ft. Pierce, Florida 34746

Dear Mr. Black:

The Food and Drug Administration (FDA) conducted an inspection of your fresh fish repacking facility on February 2-3, 1999. The investigator documented a serious deviation from the seafood processing regulations in Title 21, Code of Federal Regulations, Part 123 (21 CFR 123) causing the fresh fish products being repacked 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), as follows:

You are required to have a HACCP plan that lists the critical control points, in order to comply with 21 CFR 123.6(b) and (c)(2). However, your firm's HACCP plan for multiple fish species does not list the critical points of receiving and storage (with accompanying critical limits and monitoring procedures) for controlling the food safety hazard of histamine formation in scombroid-toxin forming species of fish.

The above identified violation is not intended to be an all-inclusive list of deficiencies at your repacking and storage facility. It is your responsibility to ensure that all fish products received, stored, and distributed by your firm are in compliance with the Act and the requirements of the regulations.

You should take prompt action to correct this violation. Failure to correct the violation may result in regulatory action, including seizure and/or injunction, without further notice. In addition, failure to correct the violation may affect your firm's ability to obtain European Union (EU) certificates. As a service to the US seafood industry to facilitate the free flow of trade, FDA has voluntarily undertaken to certify that seafood exports meet the EU's food safety requirements. FDA may not issue any EU certificates for export of any fish products repacked and stored by your firm until compliance with the seafood regulations is achieved.

Mr. Glen J. Black
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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 this violation and to prevent its reoccurrence. Your response should include copies of any documentation demonstrating that correction has been made. If the correction cannot be completed within 15 working days, state the reason for the delay and provide a time frame within which the correction will be completed.

You are required to have a HACCP plan which is specific for each kind of fish and fishery product for which a hazard is reasonably likely to occur, as required by 123.6(b)(2). However, your HACCP plan for multiple fish species groups together fish that have different food safety hazards, different critical control points and different critical limits into a single HACCP plan.

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 number (407) 475-4731.

Sincerely,



Douglas D. Tolen
Director, Florida District