



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

HFI-35

1723297

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

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

**WARNING LETTER**

FLA-99-28

January 25, 1999

Gregory A. Albritton, President  
Boca Grande Fishery  
13010 Fishery Rd.  
Placida, FL 33946

Dear Mr. Albritton:

On September 2, 1998, the Food and Drug Administration (FDA) conducted an inspection of your plant located at 13010 Fishery Road, Placida, 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 list appropriate corrective action plans in your current HACCP plan, in that the receiving Critical Control Point (CCP) in your plan lists a critical limit of 41° for receiving from trucks, yet the corrective action states if fish is received up to 45°, it may be re-iced and accepted. The storage CCP of your HACCP plan lists a critical limit of 40°, but the corrective actions listed in your plan focus on correcting the cause of the deviation (temperature in excess of 40°) and do not address the disposition of any product that becomes adulterated as a result of the deviation [21 CFR 123.7(a)(1)].

Failure to maintain sanitation control records [21 CFR 123.11(c)] that document the monitoring and correction of sanitation conditions specified in the regulations [21 CFR 123.11(b)], for example, plant water and ice safety, 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.

In addition, the temperature monitoring records reviewed during the inspection lacked the name and address of the firm [21 CFR 123.9(a)] and the CCP monitoring records are not signed and dated to indicate review by a HACCP trained individual [21 CFR 123.8(a)(3)].

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