



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

HFI-35 1/18/99
M3158N
MSB

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

Telephone: 407-475-4700
FAX: 407-475-4768

VIA FEDERAL EXPRESS

WARNING LETTER

FLA-00-06

November 10, 1999

Ralph N. Flippo, President
B & B Fisheries, Inc.
715 E. International Speedway Blvd.
Daytona Beach, FL 32118

Dear Mr. Flippo:

On March 9, 1999, the Food and Drug Administration (FDA) conducted an inspection of your facility located at 715 E. International Speedway Blvd., Daytona Beach, 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:

You must have a HACCP plan that lists the Critical Control Points, in order to comply with 21 CFR 123.6(c)(2). However, your firm's HACCP plan for Mahi Mahi and Big Eye Tuna do not list the critical control points of processing and refrigerated storage for controlling the food safety of histamine formation.

You must have a HACCP plan that lists all of the critical control limits that must be met, in order to comply with 21 CFR 123.6(c)(3). However, your firm's HACCP plan for Mahi Mahi lists critical limits of "High Temperature" and "Bad Smell" at the receiving critical control point that is not adequate to control the hazard of histamine formation. These critical limits should include ice or coolant at the time of delivery or the shipment should be accompanied by transportation records showing that the fish were held at temperatures of 40 degrees F or below throughout transport.

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