



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office

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60 8th Street, N.E.
Atlanta, Georgia 30309

June 19, 2000

VIA FEDERAL EXPRESS

Eric M. Kyrlyiuk, Vice President
Fresh Fish Management, Inc.
3966 Betsy Kerrison Parkway
Johns Island, SC 29455

Warning Letter
00-ATL-50

Dear Mr. Kyrlyiuk:

On December 16-17, 1999, the Food and Drug Administration (FDA) conducted an inspection of your plant, located at Johns Island, South Carolina. During that inspection, our investigators documented serious deviations from FDA's seafood HACCP regulations (21 CFR Part 123). These deviations cause your MAP¹ fish to be in violation of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The deviations are as follows:

1. You must have a HACCP plan that lists the food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(c)(1). However, your firm's HACCP plan for Fresh and Frozen Whole Fish and Fillets (processed into fillets, steaks, and portions) Modified Atmosphere Packaging does not list the food safety hazard of *Clostridium botulinum* toxin formation.
2. You must have a HACCP plan that lists the critical control points (CCP), to comply with 21 CFR 123.6(c)(2). However, your HACCP plan for Fresh and Frozen Whole Fish and Fillets (processed into fillets, steaks, and portions) Modified Atmosphere Packaging does not list storage (including in-process and finished product storage), as a CCP for controlling the food safety hazard of scombrototoxin (histamine) formation in scombroid fish.
3. You must implement the record keeping system listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, you did not record monitoring

¹ MAP = modified atmosphere packaging

observations at the receiving CCP for fresh scombrotoxic fish to document the amount of ice on the product, as listed in your HACCP plan for Fresh and Frozen Whole Fish and Fillets (processed into fillets, steaks, and portions) Modified Atmosphere Packaging.

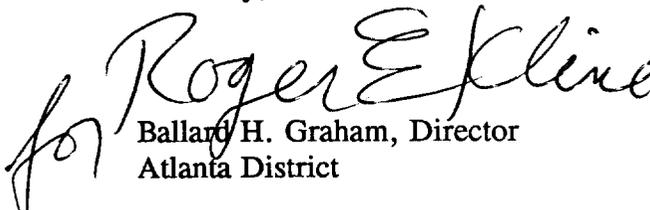
We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating. In addition, we may not provide certificates to your firm for export of your products to European Union (EU) countries if you do not correct these deviations.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as copies of HACCP plans, and HACCP monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations, and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please send your reply to Carlos A. Bonnin, Compliance Officer, U.S. Food and Drug Administration, 60 Eighth Street, N.E., Atlanta, Georgia 30309. If you have questions regarding any issue in this letter, please contact Mr. Bonnin at 404-253-1277.

Sincerely,


for Roger E. Kline
Ballard H. Graham, Director
Atlanta District

cc: Ronnie Wrenn, President
Starboard, Inc.
1714 East Boulevard
Charlotte, NC 28203