



**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

Food and Drug Administration  
Atlanta District Office

g1639d

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

August 1, 2001

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

Robert D. White, President  
Frog Island Seafood, Inc.  
P.O. Box 2107  
Elizabeth City, NC 27906-2107

**Warning Letter**  
01-ATL-68

Dear Mr. White:

On July 9, 2001, the Food and Drug Administration (FDA) conducted an inspection of your plant, located at 434 Esclip Road, Elizabeth City, North Carolina. During that inspection, our investigators documented serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations cause your fresh histamine-forming fish (e.g. Spanish mackerel and bluefish) 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](http://www.fda.gov).

The deviation of concern is as follows:

You must have and implement a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(b). However, your firm does not have a HACCP plan for histamine-forming fish to control the food safety hazard of histamine formation.

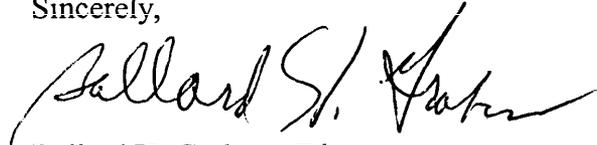
We may take further action if you do not promptly correct this violation. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

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 this deviation. 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 and the FDA 483 issued to Janice W. Freeman, Secretary/Treasurer, at the end of the inspection 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,

A handwritten signature in black ink, appearing to read "Ballard H. Graham". The signature is fluid and cursive, with a long horizontal stroke at the end.

Ballard H. Graham, Director  
Atlanta District