



**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

*Purpad DSW*  
**Food and Drug Administration**  
**Atlanta District Office**  
*HFI-35 m3279n*

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

November 17, 1999

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

Frank D. Teeter, Owner  
Ocracoke Crab Company  
Highway Route 12, P.O. Box 480  
Ocracoke, NC 27960

**Warning Letter**  
**00-ATL-12**

Dear Mr. Teeter:

On May 26 & 27, 1999, the Food and Drug Administration (FDA) conducted an inspection of your firm located at Ocracoke, North Carolina. During that inspection, our investigator documented serious deviations from FDA's Seafood HACCP regulations (21 CFR Part 123). These deviations, some of which were previously brought to your attention, cause your fresh histamine-forming fish, including blue fish and Spanish mackerel, 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 deviations were as follows:

1. You must implement the monitoring procedures and frequencies listed in your HACCP plan, in order to comply with 21 CFR 123.6(b). However, your firm did not follow the monitoring procedures and frequencies (e.g. Internal temperature of fish/transit temperature checks of every lot received) at the "Receiving Histamine Fish" critical control point, to control the hazard of scombrototoxin formation listed in your HACCP plan for "Histamine Fish."

Even though you claimed not to have distributed any fresh blue fish and/or Spanish mackerel for human consumption since our previous inspection, we have evidence to the contrary. According to our investigators, you told them that your firm only distributed the above referenced fish for bait. However, based on our inspectional findings, it is clear to us that your statements were false. Consequently, it appears that you deliberately misrepresented your fin fish operation to our investigators, in an effort to hide your failure to implement the HACCP plan.

2. 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 "Histamine Fish" does not list the critical control point of "Refrigerated Storage" for controlling the hazard of scombrototoxin formation. Storage temperatures, and processing time and temperature must be monitored to control the length of time a product has been exposed to a temperature that will allow histamine-producing bacteria to grow.

These deviations were previously brought to your attention in our letter of September 3, 1998.

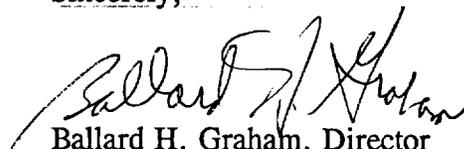
We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

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,



Ballard H. Graham, Director  
Atlanta District