

HFI-35



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration  
Atlanta District Office

M40117

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

July 27, 2000

**VIA FEDERAL EXPRESS**

Wayne Guthrie, President  
Outerbanks Seafood Co., Inc.  
1672 Highway 70 E.  
Stacy, NC 28581

**Warning Letter**

00-ATL-53

Dear Mr. Guthrie:

On April 26 & 27, 2000, the Food and Drug Administration (FDA) conducted an inspection of your plant, located at Stacy, North Carolina. During that inspection, our investigator documented serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations, some of which were previously brought to your attention, cause your fresh shrimp and scombrotoxic 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](http://www.fda.gov).

The deviations were as follows:

1. You must have a HACCP plan that lists: (a) critical control point(s); (b) critical limit(s); and (c) monitoring procedure(s) to comply with 21 CFR §§ 123.6(c)(2), (c)(3), and (c)(4), respectively. However, your firm's HACCP plan for histamine forming fish does not list the critical control point(s), critical limit(s), and monitoring procedures (what, how, frequency, and who) for the histamine hazard.
2. 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 raw shrimp does not list the food safety hazard of presence of sulfiting agents.

The above deviations were previously brought to your attention in our letter dated September 14, 1999.

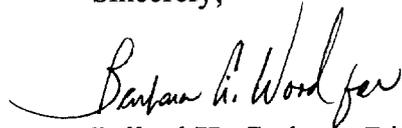
We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

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,

A handwritten signature in cursive script that reads "Ballard H. Graham". The signature is written in dark ink and is positioned above the printed name.

Ballard H. Graham, Director  
Atlanta District