



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office

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MSB/SB
HFI-35

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

January 5, 2001

VIA FEDERAL EXPRESS

Walter A. Dough, President/Owner
Wanchese Charter Boat, Inc.
dba Jaws Seafood
4417 Mill Landing Road
Wanchese, NC 27981

Warning Letter
01-ATL-19

Dear Mr. Dough:

On August 21 - 22, 2000, the Food and Drug Administration (FDA) conducted an inspection of your plant, located at Wanchese, North Carolina. During that inspection, our investigators 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 histamine-forming fish and fresh raw shrimp 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 of concern are as follows:

1. You must implement your firm's HACCP plans in order to meet 21 CFR 123.6(b). However, you failed to implement your HACCP plan for histamine fish after receiving shipments of dolphin (8/7/00), Spanish mackerel (8/7&8/00), mahi-mahi (8/14/00), and bluefish (8/15/00) in that you did not perform monitoring and recording procedures as specified in your HACCP plan.
2. Your HACCP plan for histamine fish is deficient and fails to meet 21 CFR 123 as follows:
 - a. Your plan does not comply with 21 CFR 123.6(b), i.e., it does not identify all the histamine-forming fish species handled by your firm, specifically, mahi-mahi.
 - b. Your plan does not list a critical limit at the receiving critical control point (CCP) that is adequate to control histamine formation, to comply with 21 CFR 123.6(c)(3).

Specifically, you are relying on annual guarantees from fishermen that the fish was handled in a way that would prevent histamine formation. Annual guarantees do not provide adequate control of this hazard.

- c. The monitoring procedure at the receiving CCP, i.e., "Visual inspection by Fish house manager," does not comply with 21 CFR 123.6(c)(4) in that it fails to identify *what* will be inspected and how often (*frequency*). Although your receiving record for histamine susceptible fish provides for the recording of parameters such as internal temperature, ice and decomposition, none of these are reflected in your HACCP plan in the form of monitoring procedures and/or critical limits.
 - d. Your plan fails to address the histamine formation hazard at the storage cooler critical control point, to comply with 21 CFR 123.6(c)(2). In addition, the storage cooler CCP should be included in the HACCP plan for histamine fish, instead of being represented as a separate HACCP plan.
3. You must have a HACCP plan that lists monitoring procedures for each critical control point, to comply with 21 CFR 123.6(c)(4). However, your firm's HACCP plan for fresh raw shrimp lists a monitor procedure and frequency that is not adequate to control the sulfite hazard. Specifically, the monitoring procedure at the receiving CCP does not identify *what* will be visually inspected by the Fish house manager, or how often (*frequency*). In addition, the only monitoring record available with regard to this product/hazard combination, i.e., a seasonal supplier's certification that no sulfiting agents were used, is inadequate in that it does not provide a lot-by-lot guarantee.

The above deviations are similar to those previously brought to your attention in our letter of July 30, 1998, which was hand delivered by our investigator during our 8/3 & 4/99 inspection of your firm.

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 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 and the FDA 483 issued to you 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 prominent initial "B".

Ballard H. Graham, Director
Atlanta District