



DEPARTMENT OF HEALTH AND HUMAN SERVICES

94743d
Food and Drug Administration
Atlanta District Office

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

October 18, 2002

VIA FEDERAL EXPRESS

Joel Knox, President
Inland Seafood
1222 Menlo Drive
Atlanta, GA 30318

Warning Letter
03-ATL-4

Dear Mr. Knox:

On September 16 - 18, 2002, investigators from the Food and Drug Administration (FDA), conducted an inspection of your seafood processing facility located at 3725 N. Davidson St., Charlotte, North Carolina. During that inspection, our investigators documented deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations cause your fresh, histamine-prone 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 HACCP deviations of concern are as follows:

1. You must have a written HACCP plan that lists the critical limits that must be met, to comply with 21 CFR 123.6(c)(3). However, your firm's HACCP plan for fresh, histamine-prone fish does not list a critical limit at the "receiving" critical control point to control the food safety hazard of histamine formation. The HACCP plan that Dustin M. Morgan, Plant Manager, provided to our investigators during the inspection had the critical limit at the receiving step crossed out.
2. Since your firm chose to include corrective actions in your HACCP plan, your described corrective actions must be appropriate, in order to comply with 21 CFR 123.7(b). However, your corrective action plans for fresh, histamine-prone fish at the "receiving" and "cooler" critical control points are not appropriate to control the histamine-formation hazard.
3. You must have monitoring records which document the actual values and observations obtained during monitoring, in order to comply with 21 CFR 123.6(c)(7). However, your monitoring record for the "cooler" critical control point (CCP) in your HACCP plan for

fresh, histamine-prone fish does not include observations about the adequacy of ice even though the latter is listed as part of the critical limit and the monitoring procedures for that CCP. In addition, your firm could not provide monitoring records for official review, i.e. receiving records for period covering September '01 through April '02.

4. You must implement the monitoring frequency listed in your HACCP plan, in order to comply with 21 CFR 123.6(b). However, your firm did not follow the monitoring frequency of visually checking the cooler temperature [REDACTED] as listed in your HACCP plan for histamine-prone fish.

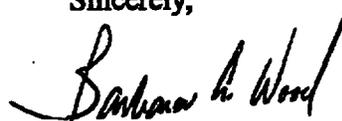
We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating. In addition, we may not provide certificates to your firm for export of your products to European Union (EU) countries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



Barbara A. Wood, Acting Director
Atlanta District