



DEPARTMENT OF HEALTH AND HUMAN SERVICES

HFI-35
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Food and Drug Administration
Atlanta District Office

Purged 2/20

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

December 6, 1999

VIA FEDERAL EXPRESS

Kenneth R. Pittman, Owner
Kenny Pittman Seafood Company
314 Royal Road
Beaufort, NC 28516

Warning Letter
00-ATL-14

Dear Mr. Pittman:

On August 19 & 20, 1999, the Food and Drug Administration (FDA) conducted an inspection of your plant located at Beaufort, 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 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 were as follows:

1. You must implement monitoring procedures listed in your HACCP plan in order to comply with 21 CFR 123.6(b). However, your firm did not follow the monitoring procedure of checking each lot of incoming shrimp at the receiving critical control point (CCP) for a supplier's guarantee that no sulfites were used on the shrimp. Your current HACCP plan for fresh shrimp is designed to prevent your firm from accepting any incoming shrimp that has or may have been treated with sulfites.
2. You must have a HACCP plan that lists all critical control points in the process, in order to comply with 21 CFR 123.6(c)(2). Your HACCP plan for fresh shrimp does not list finished product labeling as a CCP to control the potential hazard of added sulfites. According to our investigator, your firm will occasionally receive, process, and distribute sulfite treated shrimp purchased from other fishermen, as well as shrimp that you personally treated with sulfites on your fishing boats. Labeling the finished product container with a sulfite content declaration is a preventative measure for controlling a potential sulfite hazard in shrimp, with adequate monitoring of the labeling process.

3. You must have monitoring records that document the actual values or observations obtained during monitoring, in order to comply with 21 CFR 123.6(c)(7). However, you did not have any monitoring records to document the monitoring for sulfiting agents in raw shrimp at the receiving CCP to control the potential sulfite hazard. CCP monitoring records must be made available for FDA review in accordance with 21 CFR 123.9(c).

These deviations were previously brought to your attention in our letter of September 15, 1998.

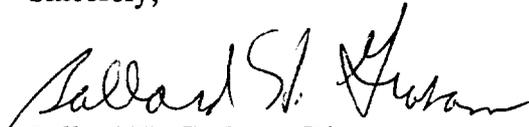
We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

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