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DEPARTMENT OF HEALTH AND HUMAN SERVICES

m41047
Food and Drug Administration
Atlanta District Office
purged RSW

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

August 10, 2000

VIA FEDERAL EXPRESS

Gerry T. Smith, Owner/President
T. B. Smith Seafood Co., Inc.
464 Old Causeway Road
Beaufort, NC 28516

Warning Letter
00-ATL-56

Dear Mr. Smith:

On May 1, 2 & 8, 2000, the Food and Drug Administration (FDA) conducted an inspection of your plant, located at Beaufort, North Carolina. During that inspection, our investigator documented 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 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 deviation of concern to us is as follows:

You must implement the monitoring procedures listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not follow the monitoring procedure and frequency of visually checking that every lot of fresh, ice-packed shrimp had been labeled with a sulfite declaration at the "Finished Product Labeling" critical control point listed in your HACCP plan.

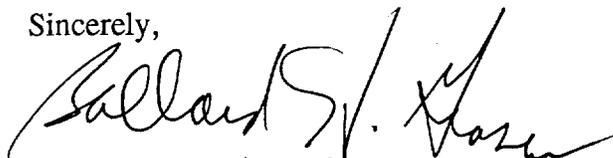
We may take further action if you do not promptly correct this violation. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

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 this deviation. 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 black ink, appearing to read "Ballard H. Graham". The signature is written in a cursive style with a large initial "B" and "H".

Ballard H. Graham, Director
Atlanta District