



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office

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

March 6, 2001

VIA FEDERAL EXPRESS

Jean Smith Kirkland, President
Smith & Sons Seafood, Inc.
McIntosh Industrial Park
Building 1
Darien, GA 31305

Warning Letter

01-ATL-30

Dear Mrs. Kirkland:

On June 8 & 9, 2000, the Food and Drug Administration (FDA) conducted an inspection of your plant, located at Darien, Georgia. 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 IQF 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 were as follows:

1. You must implement the record keeping system listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not record monitoring observations at the receiving critical control point to control the sulfite hazard listed in your HACCP plan for IQF raw shrimp. Specifically, you failed to complete the "QC Incoming" logs for many incoming shipments of shrimp including, but not limited to, lot # PC 649 (5/4/00), lot # PC 652 (5/11/00), and lot # PC 654 (5/12/00).
2. You must have a HACCP plan that lists the critical control points, to comply with 21 CFR 123.6(c)(2). However, your firm's HACCP plan for IQF raw shrimp does not list the weigh/pack/label step as a critical control point for controlling the food safety hazard of presence of undeclared sulfiting agents. Our review of our records concerning our 10/14-15/99 inspection of your firm, shows that at that time your HACCP plan for IQF raw shrimp did list the weigh/pack/label step as a critical control point to control the sulfite hazard. The plan also identified the "Production log" as the monitoring record for this hazard. However, during our last inspection, the copy of the HACCP plan provided to our investigator did not list the

weigh/pack/label step as a critical control point. Notwithstanding this deficiency, it appears that your firm is still using the production log as a monitoring record to document when finished product labels bear a declaration for sulfites.

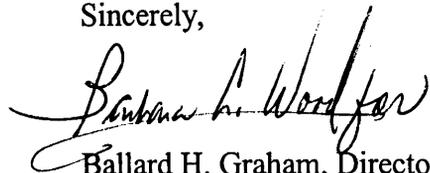
We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating. With regard to your letter to Mallory Lawrence, dated 4/27/00, in which you requested on behalf of your firm, to participate in the FDA-European Union (EU) Export Certificate Program, we have decided to withhold our decision until we receive your response to this letter, and after we have had an opportunity to reinspect your facility.

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, appearing to read "Ballard H. Graham".

Ballard H. Graham, Director
Atlanta District