



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

October 23, 2000

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Jeffrey A. Milliken, Owner
Shalotte River Crab Company
P.O. Box 6609
South Brunswick, NC 28470

Warning Letter
01-ATL-6

Dear Mr. Milliken:

On August 7 - 8, 2000, the Food and Drug Administration (FDA) conducted an inspection of your plant, located at 1579 Russtown Road, Shallotte, North Carolina. 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 fresh handpicked crabmeat 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 the record keeping system listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not maintain monitoring records at the cooking, picking/packing, and refrigerated storage critical control points for all days of operation to control the pathogen survival and pathogen growth hazards listed in your HACCP plan for fresh handpicked crabmeat. In addition, some of these monitoring records were incomplete, as in the case of the "Daily Picking & Packing Log" which was started on 8/7/00, while our investigator was at your firm, but was never completed.
2. You must maintain records that document the sanitation monitoring and corrections undertaken as a result of that monitoring, to comply with 21 CFR 123.11(c). However, you failed to maintain sanitation control records for several days of operation on which crabs were processed.

The above deviations were previously brought to your attention in my letter of October 20, 1998, which was hand delivered by our investigator during our 5/17/99 inspection of your firm.

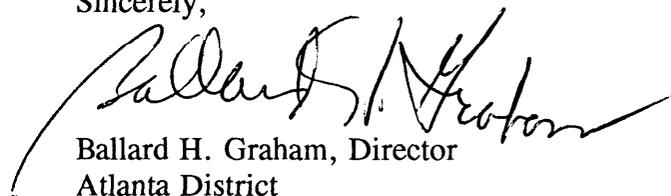
We may take further action if you do not promptly correct this violation. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

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 (copy enclosed) issued to, and discussed with, William J. Smith, Manager, 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,



Ballard H. Graham, Director
Atlanta District

Enclosure