



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

December 21, 2000

VIA FEDERAL EXPRESS

James A. Johnson, Jr., President
Washington Crab Company, Inc.
321 Pierce Street
Washington, NC 27889

Warning Letter
01-ATL-18

Dear Mr. Johnson:

On June 20 - 21, 2000, the Food and Drug Administration (FDA) conducted an inspection of your plant, located at Washington, 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 deviation of concern is as follows:

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 fresh hand-picked crabmeat does not list the critical control points of picking, packing and finished product storage, for controlling the food safety hazard of pathogen growth & toxin formation as a result of time/temperature abuse. This deviation was previously brought to your attention in our letters of September 16, 1998, and August 16, 1999.

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 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