



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
New England District

93184d

One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 596-7700
FAX: (781)596-7896

WARNING LETTER

NWE-15-02W

VIA FEDERAL EXPRESS

April 1, 2002

Ronald A. Fatulli
President
Aquidneck Lobster Company
31 Bowens Wharf
Newport, RI 02840

Dear Mr. Fatulli:

We inspected your firm, located at 31 Bowens Wharf, Newport, RI, on February 26 through 28, 2002 and found that you have serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations cause your cooked ready-to-eat lobster meat 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 recordkeeping system listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not record monitoring observations at the cooking critical control point to control the pathogen hazard listed in your HACCP plan for cooked ready-to-eat lobster meat. Monitoring records of this critical control point have not been kept since April 20, 2001.

2. You must adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR 123.11(b). However, your firm does not monitor the required eight areas of sanitation with sufficient frequency to ensure control. This deficiency was evidenced by the number of sanitation deficiencies observed during the inspection and listed on the FDA 483 that was provided to you after the inspection. For example, birds were observed in your plant and feathers and debris were observed in metals bins used to store ice.

We may take further action if you do not promptly correct these above 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 fifteen (15) days 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 your current 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 deficiencies.

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.

You may direct your reply to Karen N. Archdeacon, Compliance Officer, at the address noted above. If you have any questions concerning this matter, please contact Ms. Archdeacon at (781) 596-7707.

Sincerely,



Gail P. Costello
District Director
New England District Office