



DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

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

July 2, 2002

WARNING LETTER

NWE-23-02W

VIA FEDERAL EXPRESS

Mr. Tom P. Flanigan
Seaview Fisheries, Inc.
43 Government Street
Kittery, ME 03904

Dear Mr. Flanigan,

We inspected your firm, located at 43 Government Street, Kittery ME, on June 12, 2002 and found that you have serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations, some of which were previously brought to your attention, 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. You can find this Act and the seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The deviation was 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, cooling and storage critical control points 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 May 25, 2001.

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

A copy of the revised critical control monitoring record that you sent to our investigator on June 15, 2002 has been reviewed and appears to be adequate. However, we note that your firm's failure to implement the recordkeeping system has been observed during past inspections. We will need additional assurance that your firm has implemented a record keeping system.

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 this deviation. Please include in your response documentation such as photocopies of your current monitoring records completed since June 15, 2002 and any other useful information that would assist in evaluating your corrections.

This letter may not list all of 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 Federal Food, Drug and Cosmetic Act and all applicable regulations.

Please send your reply to Patricia Murphy, Compliance Officer, at One Montvale Avenue, Suite 4, Stoneham, MA 02180. If you have any questions concerning this matter, please contact Mrs. Murphy at (781) 596-7758.

Sincerely,



Gall T. Costello
District Director
New England District Office