



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

New England District

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

December 13, 2001

**WARNING LETTER**

**NWE-08-02W**

**FEDERAL EXPRESS**

William Wyman, President  
Kittery Lobster Co., Inc.  
21 Ranger Drive  
Kittery, Maine 03904

Dear Mr. Wyman:

We inspected your firm, located at 21 Ranger Drive in Kittery, Maine, on November 14 through 19, 2001, and found that you have a serious deviation from the Seafood HACCP regulations (21 CFR 123). This deviation causes the cooked lobster meat processed by your firm 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 though links in FDA's home page at [www.fda.gov](http://www.fda.gov).

The deviation is as follows:

- You must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR §123.6(b). However your firm does not have a HACCP plan for cooked lobster to control the hazard of pathogens.

The above violation was documented during the previous May ~~24-29~~, 2001; inspection of your firm and was included in a July 2, 2001, letter to your firm. The July 2, 2001, letter requested that you correct the violation as soon as possible. Your firm shows a history of non-compliance with the Seafood HACCP regulations. Further you told the FDA that an employee would attend a July 2001, and then a November 2001 HACCP course. This was not done. You have been given ample time to correct the above deviation.

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.

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 a completed HACCP plan, or other useful information that would assist 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 §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 the Food and Drug Administration, Attention: Bruce R. Ota, Compliance Officer, One Montvale Avenue, Stoneham, Massachusetts 02180. If you have questions regarding any issues in this letter, please contact Mr. Ota at (781) 596-7762.

Sincerely,

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Gail T. Costello  
District Director  
New England District