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**WARNING LETTER**

**NWE-15-00W**

VIA FEDERAL EXPRESS

December 20, 1999

Anthony Ciarametaro  
President  
Capt. Vince Inc.  
Db. Capt. Vince Seafoods  
3-5 Parker Street  
Gloucester, MA 01930

Dear Mr. Ciarametaro:

We inspected your firm, located at 3-5 Parker Street, Gloucester, MA, on November 30 and December 1, 1999 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 lobstermeat products 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](http://www.fda.gov).

The deviations were as follows:

- Failure to have monitoring record data of your critical control points for cooking lobster, [21 CFR 123.6 (c)(7)]. For example, your HACCP plan identifies the cooking, cooling and storage steps as critical control points and includes monitoring procedures for each step. During the inspection, there were no records to show that these steps are being monitored for each batch of cooked lobsters.
- There were no sanitation records available for November 29 and 30, 1999, [21 CFR 123.11(b)]. Numerous sanitation deficiencies were observed during the inspection and listed on the FDA 483 that was presented to you at the close of the inspection.

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 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 temperature monitoring records for your cooking, cooling and storage steps 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 Federal Food, Drug, and Cosmetic 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) 279-1675, Extension 113.

Sincerely,



John Marzilli  
District Director  
New England District Office