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One Montvale Avenue  
Stoneham, Massachusetts 02180  
(781) 279-1675  
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May 25, 2001

**WARNING LETTER**

**NWE-23-01W**

**VIA FEDERAL EXPRESS**

Richard Stavis, President  
Stavis Seafood Inc.  
7 Channel Street  
Boston, Massachusetts 02210

Dear Mr. Stavis:

We inspected your firm, located at 7 Channel Street, Boston, Massachusetts, on April 25 and 26, 2001 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 vacuum packed fresh fish 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](http://www.fda.gov).

The deviations were as follows:

1. You must have a 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 vacuum packed/ fresh fish to control the food safety hazard of Clostridium botulinum.

Processors of vacuum-packed seafood need to consider that all through storage, distribution, display, and consumer handling proper refrigeration, i.e., <38° F, is required to inhibit the growth of Clostridium botulinum type E. It is unlikely that the vacuum-packaged product will remain a <38° F though all these stages of handling. Freezing of the vacuum-packaged product is an acceptable control measure.

Beyond freezing, we are not aware of any adequate controls for this type of product once it leaves the processor. Therefore, in your response to this letter, please explain how the temperature of the product will be maintained until it reaches the final consumer.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating. In addition, we may not provide certificates to your firm for export of your products to European Unions (EU) countries if you do not correct these deviations.

For your information you must have written importer verification procedures for ensuring that the vacuum packed/MAP fresh fish that you import into the United States are processed in accordance with the Seafood HACCP requirements. The procedures shall list at a minimum:

- a) product specifications that are designed to ensure the product is not adulterated under Section 402 of the Act (21 CFR 123.12(a)(2)(i)), and
- b) affirmative steps that may include any of the ones listed in 21 CFR 123.12(a)(2)(ii).

Firms that cannot provide importer verification procedures may be placed on Import Alert 16-119. The imported article is then subject to refusal of admission pursuant to Section 801(a)(3) of the Act in that it appears to have been prepared, packed, or held under insanitary conditions, or it may be injurious to health, due to the failure of the importer to provide verification of compliance pursuant to 21 CFR 123.12(d).

Please respond in writing within fifteen (15) working days from your receipt of this letter. Your response should outline the specific things your are doing to correct these deviations. You may wish to include in your response documentation 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 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, U.S. Food and Drug Administration, One Montvale Avenue,

Stavis Seafood, Inc.  
Boston, Massachusetts 02210  
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Stoneham, Massachusetts 02180. If you have questions regarding any issue in this letter, please contact Mr. Ota at (781) 279-1675.

Sincerely,

A handwritten signature in black ink, appearing to read 'Gail F. Costello', with a long horizontal stroke extending to the right.

Gail F. Costello  
District Director  
New England District Office