



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

WARNING LETTER

NWE-02-03W

VIA FEDERAL EXPRESS

November 25, 2002

Peter M. Vorvis
President
New Wave Seafood, Inc.
81 Camp Avenue
Stamford, CT 06907

Dear Mr. Vorvis:

We inspected your firm located at 81 Camp Avenue, Stamford, CT, on October 3, 8 and 9, 2002, and found that you have serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations cause your scromboid species of seafood to be in violation of section 402(a)(4) (21 USC § 342(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 serious seafood HACCP deviation was as follows:

1. You must implement the monitoring procedure listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not follow the monitoring procedure of icing product at your storage critical control point (CCP) to control the histamine hazard listed in your plan for scromboid species. For example, during the inspection on October 3, 2002, the investigator observed tuna loins being held in the cooler that were not covered with ice.

We may take further action if you do not promptly correct these above violations. For instance, we may 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 also wish to include 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.

We also acknowledge that during the inspection, you were planning to modify the storage critical limit (CL) of your HACCP plan for scromboid species from 45°F to 40°F. Please forward us a copy of your HACCP plan with this change. Please keep in mind that time/temperature controls are essential in controlling the histamine hazard.

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 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,

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

Gail J. Costello
District Director
New England District Office