



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

54351

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(781) 596-7700
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WARNING LETTER
NWE-26-03W

VIA FEDERAL EXPRESS

September 17, 2003

Jose A. Fernandes
Owner
Bayside Shellfish
169 Riverside Drive
Tiverton, RI 02878

Dear Mr. Fernandes:

We inspected your seafood processing facility, Bayside Shellfish, located at 169 Riverside Drive, Tiverton, RI on August 15 through 19, 2003. We found that you have a serious deviation from the Seafood Hazard Analysis and Critical Control Points (HACCP) Regulations, Title 21 Code of Federal Regulations, Part 123 (21 CFR 123). In accordance with 21 CFR 123.6 (g), failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part, renders the fishery products processed there adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 342(a)(4). Accordingly, your seafood product (bluefish) is adulterated, in that the product has been prepared, packed, or held under insanitary conditions whereby it may have been rendered injurious to health. You may find this Act and the seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The serious deviation observed was as follows:

You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and 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(a) and (b). However, your firm does not have a HACCP plan for bluefish; to control the food safety hazard of histamine.

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

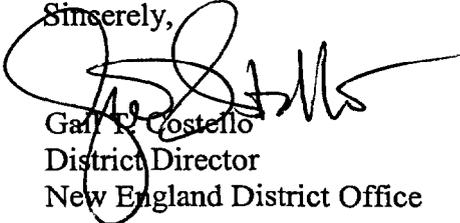
addition, we may not provide certificates to your firm for export of your products to European Union (EU) countries if you do not correct these deviations.

Please respond in writing within fifteen (15) working days from your receipt of this letter. Your response should outline the specific things you are doing to correct this deviation. You should include in your response any documentation, such as your HACCP plan, 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.

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) 596-7707.

Sincerely,



Gail P. Costello
District Director
New England District Office

Attachment: FDA 483