



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

One Montvale Avenue
Stoneham, Massachusetts 02180
Tel 781.596.7700
Fax 781.596.7899

April 10, 2003

WARNING LETTER

NWE-14-03W

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

John R. Sember
Milford Seafood Corporation
315 New Haven Avenue
Milford, CT 06460

Dear Mr. Sember:

On March 13 and 17, 2003, the United States Food and Drug Administration (FDA) inspected your seafood processing facility, located at 315 New Haven Avenue, Milford, Connecticut and found that you have serious deviations from the seafood Hazard Analysis and Critical Control Point (HACCP) plan regulations, 21 CFR § 123.6. 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 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 ready-to-eat pasteurized crabmeat and scombroid species fish products are adulterated, in that these products have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health. You may find the Act and the seafood HACCP regulation through links in FDA's home page at www.fda.gov.

The deviations found were as follows:

- ▶ You are required to 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 those food safety hazards, to comply with 21 CFR 123.6(a) and (b). But your firm has no HACCP plan for refrigerated, canned pasteurized crabmeat to control the food safety hazards of pathogen growth and toxin formation.
- ▶ You are required to implement the monitoring and recordkeeping procedures that you have listed in your HACCP plan for Histamine Species, to comply with 21 CFR 123.6(b). But the monitoring and recordkeeping procedures that you have listed for the Receiving and Dry Cooler Storage CCP's are not followed.
- ▶ You are required to conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and have a HACCP plan that, at a minimum, lists those food safety hazards, to comply with 21 CFR 123.6 (a) and (c)(1). A food safety hazard is defined in 21 CFR Part 123.3 (f) as "any biological, chemical, or physical property that may cause a food to be unsafe for human consumption." However, your firm's HACCP plan for Histamine Species does not list the food safety hazard of *Clostridium botulinum*. *Clostridium botulinum* toxin formation is a known hazard associated with refrigerated, vacuum packaged products. You must ensure control of this food safety hazard during thawing of frozen, vacuum packaged product, and during storage of iced, refrigerated product before and after thawing if the vacuum remains intact.
- ▶ Because you chose to include corrective actions in your HACCP plan, your described corrective actions must be appropriate, to comply with 21 CFR 123.7 (b). However, your corrective action plan for Histamine Species at the Dry Cooler Storage CCP to control histamines is not appropriate. Your corrective action lists "(a)dd ice to product." This is insufficient. The corrective action should also include a procedure to hold and evaluate the affected product based on cumulative time and temperature exposure when a deviation from the critical limit occurs.

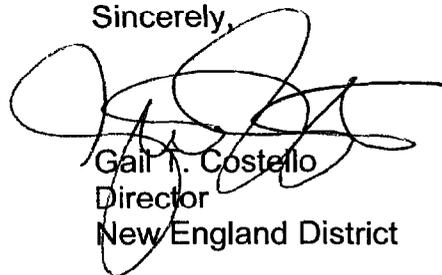
We may take further action if you do not promptly correct these violations. For instance, we may take action to seize your products and/or enjoin your firm from operating.

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 these deviations. You should include in your response documentation such as a complete HACCP plan for canned, pasteurized crabmeat, modifications to the existing HACCP plan for Histamine Species, and copies of associated monitoring records, or any 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 "Fish and Fishery Products" regulations set forth at 21 CFR 123, and the regulations relating to "Current Good Manufacturing Practice in Manufacturing, Packing or Holding Human Food" set forth at 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.

Please send your reply to the Food and Drug Administration, Attention: Mark Lookabaugh, Compliance Officer, 1 Montvale Avenue, Stoneham, MA 02180. If you have questions regarding any issue in this letter, please contact Mr. Lookabaugh at **781.596.7751**.

Sincerely,

A handwritten signature in black ink, appearing to read "Gail J. Costello", is written over the typed name and title. The signature is stylized and somewhat illegible due to overlapping loops and lines.

Gail J. Costello
Director
New England District