



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

94550d

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WARNING LETTER

NWE-16-03W

VIA FEDERAL EXPRESS

April 22, 2003

Jeffrey D. Holden
President
Portland Shellfish Company, Inc.
110 Dartmouth Street
South Portland, ME 04112

Dear Mr. Holden:

We inspected your seafood processing facility, located at 110 Dartmouth Street, South Portland, ME, from March 18 through 26, 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 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 pasteurized lobstermeat product is adulterated, in that the product has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or 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 deviation was as follows:

- 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 pasteurized lobstermeat in 15 ounce containers, to control the food safety hazard of *Clostridium botulinum*.

Portland Shellfish Co., Inc.
So. Portland, ME 04112
Page 2

We understand that you recently completed a validation study for this product in March, 2003. However, our inspection revealed that you have been manufacturing this product since at least January 2003 without a HACCP plan. You must have a HACCP plan which includes the critical limits that were established in your recent study for the pasteurization of lobstermeat in 15 ounce containers.

Also, keep in mind, that once you implement this HACCP plan for pasteurized lobstermeat, you will need to implement a record keeping system, to comply with 21 CFR 123.6(b). During the inspection, we noted that there were failures in your recordkeeping process, such as missing temperature charts and discrepant processing times.

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.

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 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 T. Costello
District Director
New England District Office