



DEPARTMENT OF HEALTH & HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

94866d
PHILADELPHIA DISTRICT

900 U.S. Customhouse
2nd and Chestnut Streets
Philadelphia, PA 19106

Telephone: 215-597-4390

WARNING LETTER

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

04-PHI-04

July 8, 2004

T. Richard Sansone, President
Sansone's Seafood Market, Inc.
1830 W. Seventh Street
Wilmington, Delaware 19805

Dear Mr. Sansone:

On April 6-8, and 20, 2004, we inspected your seafood processing facility, located at the above address. We found that you have serious deviations 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 canned crabmeat has been prepared, packed, or held under insanitary conditions whereby it may have been rendered injurious to health. You may find the Act and the seafood HACCP regulations through links in the FDA's home page at www.fda.gov.

The following deviation was observed:

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 has not properly established and has not implemented a HACCP plan for your ready-to-eat fishery products, such as canned pasteurized crabmeat to control the food safety hazard of pathogen growth and toxin formation, specifically *Clostridium botulinum*.

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Sansone's Seafood Market, Inc.

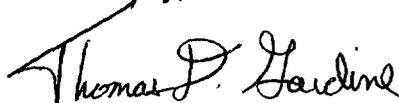
July 8, 2004

At the conclusion of the inspection, the observed deviation was listed on Form FDA 483 and discussed with you. A copy of this form is enclosed for your reference. This deviation is not meant to be an all-inclusive list of violations. 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 implement procedures to prevent further violations of the Act and all applicable regulations.

We may take further action if you do not promptly correct the violations. 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 the violations. You should include in your response documentation, such as a copy of your HACCP plan for pasteurized canned crabmeat, 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 violations.

Please send your reply to the Food and Drug Administration, Attention: Lynn S. Bonner, Compliance Officer at the address in the letterhead. If you have questions regarding any issue in this letter, please contact Ms. Bonner at 215-597-4390, Ext 4401.

Sincerely,



Thomas D. Gardine
District Director
Philadelphia District

Enclosure

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cc:

