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DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

Food & Drug Administration
158-15 Liberty Avenue
Jamaica, NY 11433

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

July 15, 2003

Carl Piscitello
President
Carl's Seafood, Inc.
103 South Street
New York, NY 10038

Ref: NYK-2003-29

Dear Mr. Piscitello:

We inspected your firm, located at 103 South Street, New York, New York on June 25, 26 and 27, 2003 and 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 vacuum packed smoked salmon is adulterated in that it 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 the Act and the Seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The deviations were as follows:

1. 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 vacuum packed smoked salmon to control the food safety hazard of Clostridium botulinum toxin formation.

Strict temperature control is necessary to prevent toxin formation by Clostridium botulinum. During the inspection our investigator observed vacuum packed salmon, which is labeled to keep refrigerated at 38°F, on street display not covered with ice. A HACCP plan must be implemented listing the critical control points (e.g., receiving, display, storage); the appropriate critical limit (e.g., 38°F or covered with ice); monitoring procedures; corrective actions; record keeping; and verification procedures.

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This deviation from the regulations was previously brought to your attention in our letter of August 10, 2001. We never received a response to that letter.

2. You must maintain sanitation control records that, at a minimum, document monitoring and corrections to comply with 21 CFR 123.11(c). However, your firm did not have records of monitoring the eight areas of sanitation listed in 21 CFR 123.11(b) required for your handling of ready-to-eat vacuum packaged smoked salmon.

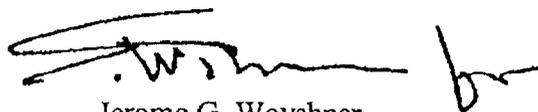
We may take further action if you do not promptly correct these deviations. For instance, we may initiate regulatory action without further informal notice. Such actions may include the initiation of a seizure action against your products and/or an action to enjoin your firm from operating.

Please respond in writing within 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 HACCP plan and copies of temperature and ice 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 deviations.

This letter and the inspectional observations (Form FDA 483) issued to and discussed with you, at the conclusion of the inspection, may not list all the deviations at your facility. You are responsible for ensuring that your seafood processing facility 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 Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Laurence D. Daurio, Compliance Officer, 158-15 Liberty Avenue, Jamaica, NY 11433. If you have questions regarding any issues in this letter, please contact Mr. Daurio at (718) 662-5585.

Sincerely,



Jerome G. Woyshner
District Director
New York District

Enclosure: Form FDA 483 dated June 27, 2003