



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region *93422d*

Telephone (973) 526-6008

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

WARNING LETTER

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

September 6, 2002

File # 02-NWJ-29

Mr. Keith Laudeman
Vice President
Cold Springs Fish & Supply Co.
906 Schellinger's Landing Road
Cape May, New Jersey 08204

Dear Mr. Laudeman:

We inspected your firm, located at 906 Schellinger's Landing Road, Cape May, New Jersey on July 10-12, 15 & 23, 2002 and found that you have serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations, some of which were previously brought to your attention, cause your Scombroid species fresh fish (tuna, mackerel, mahi-mahi and bluefish) and canned, pasteurized crabmeat to be adulterated within the meaning of Section 402(a)(4) of the Federal Food Drug & Cosmetic Act (the Act). You can find this Act and the Seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The deviations found were as follows:

- Your firm does not have a written HACCP plan for the secondary receipt and subsequent refrigerated storage of Scombroid species fish; i.e. fresh mackerel, tuna and mahi-mahi. In order to comply with 21 CFR 123.6(b), you must have a written HACCP plan to control the potential food safety hazard of histamine formation for these products. Documents reviewed by our investigators during the current inspection showed that you received mackerel from a primary processor on February 10, 2002 and March 3, 2002, and stored and distributed tuna or mahi-mahi on January 1 & 13, 2002, February 8, 2002, April 11, 2002, May 23, 2002, June 14, 2002 and July 1, 2002. Further, no temperature monitoring records were maintained regarding the receipt and storage of these lots.

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- You must fully implement the record keeping and monitoring system as listed in your HACCP plan for the primary receipt and processing of bluefish in order to comply with 21 CFR 123.6(b). Your firm's receiving records showed that bluefish were received and processed by your firm on January 6, 7, 9, 11, 13, 16, 17 18, & 19, 2002. However, the monitoring activities performed by your firm at the receiving critical control point (CCP) to control the hazard of histamine production are inadequate. For example:
 - 1) Harvest vessel record data obtained by your firm does not show the estimated time of death and adequacy of onboard cooling procedures.
 - 2) Adequacy of ice was not monitored or recorded.
 - 3) A representative number of bluefish per lot were not monitored for internal temperatures.
 - 4) Monitoring records do not indicate that your firm performed any examinations of incoming product for decomposition at this CCP.
- Your HACCP plans must identify all applicable critical control points necessary to control the food safety hazard(s) identified in the plans, in order to comply with 21 CFR 123.6(c)(2). However, your HACCP plan for the primary receipt and storage of bluefish does not list storage as a CCP. Further, your current monitoring procedure for refrigerated storage of bluefish at this CCP is inadequate, as ambient air temperatures in the cooler unit are monitored only once or twice daily, which is insufficient to control the food safety hazard of histamine formation.
- Your HACCP plan for the canned, pasteurized crabmeat must list all critical limits that need to be met, in order to comply with 21 CFR.123.6(c)(3).- However, your HACCP plan does not list adequate critical limits at the receiving CCP. The critical limit listed in your HACCP plan at this CCP does not provide for assurance that the product is held at adequate temperatures throughout the transportation process in order to adequately safeguard against the potential food safety hazard of Clostridium Botulinum toxin formation. Your firm's records showed that canned, pasteurized crabmeat was received by your firm on at least 13 distinct occasions in 2002.
- You must fully implement the record keeping and monitoring systems identified at the storage CCP in your HACCP plan for canned pasteurized crabmeat in order to comply with 21 CFR 123.6(b). However, the monitoring activities performed by your firm at this CCP are inadequate to control the food safety hazard of Clostridium Botulinum toxin formation. Your monitoring records indicate that

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ambient air temperatures in the cooler unit are monitored only once per day, while your HACCP plan identifies continuous monitoring as the control strategy.

- You must adequately monitor sanitation conditions and practices at your firm and take appropriate corrective actions when warranted, in order to comply with 21 CFR 123.11(b). However, sanitation monitoring at your firm was inadequate. For example, our investigators observed sanitation deficiencies at the following key sanitation control points: (a) safety of water (the roof on the ice storage silo had visible gaps and openings allowing access to the outside environment. Avian excrement was observed on the exterior of the roof. Additionally, ice utilized to store bagged scallops was observed as having black, greasy particulate matter adhering to it), (b) prevention of cross contamination (A tote of cooked shrimp was stored adjacent to a tote containing raw halibut; an absorbent tablecloth used as a covering was in direct contact with both products), and; (c) maintenance of hand washing and toilet facilities (A dockside toilet facility had an inoperable hand dryer and no paper towels were available). Your firm's lack of adequate sanitation monitoring was previously brought to your attention during our inspection of June 27, 2001.

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

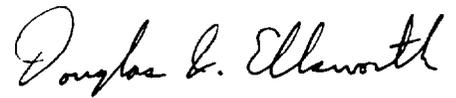
Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as a revised HACCP plan, revised monitoring procedures, copies of revised 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 the delay and state when the corrections will be completed.

This letter may not list all 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 Current Good Manufacturing Practice regulations (21 CFR 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.

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Your response to this letter should be directed to the U.S. Food and Drug Administration,
Attention: Richard D. Manney, Compliance Officer at the address and telephone number -
listed above.

Sincerely,



Douglas I. Ellsworth
District Director
New Jersey District