



DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

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

23709d

WARNING LETTER

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

November 20, 2002

Mr. Neil Henry Smith  
President & CEO  
Caleb Haley Co., Inc.  
14 Fulton Fish Market  
New York, NY 10038

Ref: NYK-2003-06

Dear Mr. Smith:

We inspected your firm, located at 14 Fulton Fish Market, New York, New York on September 13 & 19, 2002, and found that you have serious deviations from the Seafood 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). Accordingly, your scombrototoxin (histamine) forming fish, your cooked ready to eat crabmeat, and your vacuum packaged salmon are adulterated. You can find this Act and the Seafood HACCP regulations through the links in FDA's home page at [www.fda.gov](http://www.fda.gov).

The deviations included, but are not limited to, the following:

1. You must have, at a minimum, a HACCP plan that lists the monitoring procedures for each critical control point to comply with 21 CFR 123.6(c)(4). However, we observed the following monitoring deviations:

Your firm's HACCP plans for histamine producing fish, vacuum packaged salmon, and crabmeat list monitoring procedures at the receiving critical control points that are not adequate to control histamine formation in the histamine producing fish and pathogen growth in ready-to-eat vacuum packaged smoked salmon and crabmeat. Your HACCP plans state that you will monitor temperatures. Monitoring internal temperatures is considered an appropriate procedure when transport time is less than 4 hours. For longer transportation periods, such as those incurred by your tuna from [REDACTED] and [REDACTED] FDA has determined that this method does not provide adequate assurance of continuous

chilling for an entire lot throughout shipment. The following procedures, or procedures that can be demonstrated to be equivalent, are acceptable to FDA for the control of histamine and pathogen growth during shipment:

- Monitoring the adequacy of ice or cooling media surrounding products during shipment or storage; or,
- Monitoring temperatures by temperature data recorders; or,
- Using time/temperature integrators during shipment.

Your monitoring frequency at the storage critical control point for histamine forming fish, "daily at beginning and end of shifts," is not adequate to control the hazard of histamine formation in your histamine forming fish. The same frequency is listed in the HACCP plan for vacuum packaged smoked salmon and is inadequate for the control of pathogen growth in ready to eat products. The following procedures, or procedures that can be demonstrated to be equivalent, are acceptable to FDA for the control of histamine and pathogen growth during storage:

- Monitoring the adequacy of ice or cooling media surrounding products during storage; or
- Monitoring temperatures by temperature data recorders.

Your monitoring procedures at the "cutting" critical control point for histamine forming fish (which is included with the "display" critical control point) did not specify how the temperature would be maintained at or below your critical limit of 40°F. If the cutting process is expected to expose the product to significant time and temperature abuse (i.e., temperatures of 70°F for more than 4 hours cumulatively), you should include a separate critical control point for this cutting process.

You list a monitoring frequency for "temp" at the display critical control point for histamine forming fish of "once a day on the fish cut into loins closest to 5 AM" which is not adequate to control histamine formation. Since in your HACCP plan you have chosen to monitor temperature to control histamine, it should be monitored continuously. However, our investigator observed that you actually use ice to control temperature during display. Your HACCP plan should reflect your actual practices. Further, if ice is used to control temperature, the *Fish & Fisheries Products Hazards & Controls Guidance: Third Edition* recommends that ice be controlled with visual checks at least twice a day for histamine control. During the summer months, more frequent observation may be necessary. You should also designate someone to monitor the ice. Our investigator noted that no one was responsible for monitoring temperature or ice.

2. You must take an appropriate corrective action when a deviation from a critical limit occurs, to comply with 21 CFR 123.7(a). However, your firm did not take a corrective action to control histamine formation when our investigator observed an opened box of fresh Spanish mackerel held for sale without adequate ice. The investigator measured the core temperature of the mackerel and found it to be 50°F. Cut tuna loins were also observed in an open display case on a bed of ice. The core temperature near the top of a loin was found to be 51°F. Instead of following the corrective action in your HACCP plan that required you to “destroy product that exceeds 40°F,” a worker at your firm added ice.

3. Our inspection also revealed that your firm imports fresh fish or fishery products from countries that lack an active memorandum of understanding or similar agreement with FDA. Therefore, to comply with 21 CFR 123.12(a)(2), your firm must have and implement written verification procedures to ensure that these products imported into the United States are processed in accordance with HACCP requirements. However, the inspection revealed that your firm does not have written verification procedures for such products.

To comply with 21 CFR 123.12(a)(2)(i), your written verification procedures must include, at a minimum, product specifications that are designed to ensure that the fish and fishery products you import are not adulterated under § 402 of the Act because they may be injurious to health or have been processed under insanitary conditions. However, your firm did not have product specifications for histamine forming fish imported from [REDACTED] and [REDACTED].

You must maintain records, in English, that document the performance and results of the affirmative step(s) you have taken as part of your verification procedures, to comply with 21 CFR 123.12(c). However, your firm did not have records for histamine forming fish imported from [REDACTED] and [REDACTED].

We may take further action if you do not promptly correct these deviations. For instance, we may take action without further notice to seize your products and/or enjoin your firm from operating in violation of the Act.

Please respond in writing within 15 days 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 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

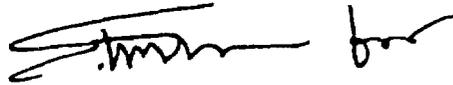
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Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Lillian C. Aveta, Compliance Officer, 158-15 Liberty Avenue, Jamaica, NY 11433. If you have questions regarding any issues in this letter, please contact Ms. Aveta at (718) 662-5576.

Sincerely,

A handwritten signature in black ink, appearing to read "Jerome G. Woysner".

Jerome G. Woysner  
District Director  
New York District

Enclosure: Form FDA 483 dated September 19, 2002