



DEPARTMENT OF HEALTH AND HUMAN SERVICES

FEI: 1117573

94970d



Food and Drug Administration  
Baltimore District Office  
6000 Metro Drive  
Suite 101  
Baltimore, MD 21215-3215  
Telephone: (410) 779-5454

04-BLT-29

September 14, 2004

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Mr. Stuart P. O'Bier, President  
O'Bier Seafood Inc.  
447 Gardy's Mill Road  
Callao, Virginia 22435

Dear Mr. O'Bier:

The Food and Drug Administration (FDA) inspected your firm, located at 447 Gardy's Mill Road, Callao, Virginia on May 18-19, 2004, and found that you have serious deviations from FDA's seafood Hazard Analysis and Critical Control Point (HACCP) Regulations, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123) some of which were previously brought to your attention. 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 of 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(4). Accordingly, your frozen shrimp, frozen yellow fin tuna, frozen lobsters, imported pasteurized crabmeat, fresh-picked crabmeat, fresh oysters, fish, clams, and live crabs have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health. You can find the Act and seafood HACCP regulations through links on FDA's home page at [www.fda.gov](http://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 have a HACCP plan that, at a minimum, lists the 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 HACCP plans for fresh crabmeat and pasteurized crabmeat to control the food safety hazard of pathogen growth. Strict temperature controls are necessary to prevent the growth of *Clostridium botulinum* and possible toxin formation in pasteurized crabmeat.
2. You must have a HACCP plan that, at a minimum, lists the critical limits that must be met to comply with 21 CFR 123.6(c) (3). A critical limit is defined in 21 CFR 123.3(c) as "the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard." However, your firm's HACCP plan for Fresh

Scombroid Fish does not list critical limits at the receiving critical control point to control histamine formation in fish received directly from the fishing vessels or harvesters;

As a primary (first) processor of fresh scombroid fish, the critical limits for your receipt of fish from harvest vessels should ensure that the fish have been handled in a safe manner prior to their receipt by your firm. FDA suggests either histamine testing or monitoring of harvest vessel records from your suppliers in addition to taking temperatures and conducting sensory examinations. Chapter 7 of the Fish and Fisheries Products Hazards and Controls Guidance can provide guidance in determining which method is best suited to your process and the critical limits and monitoring procedures FDA considers adequate to control the hazard of histamine. This guidance can be accessed on-line at [www.fda.gov](http://www.fda.gov);

3. 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 maintain sanitation monitoring records required for the processing of seafood from 3/11/04 to 3/31/04 and 4/2/04 through 5/13/04;
4. You must adequately monitor sanitation conditions and practices during processing to comply with 21 CFR 123.11(b). However, your firm did not monitor the following key areas of sanitation with sufficient frequency to ensure control as evidenced by:
  - (1) Safety of water (ice): The presence of filth in ice.
  - (2) Condition & cleanliness of food contact surfaces: Containers used to store ice insufficiently cleaned; filth on surface of ice shovel; filth on interiors of baskets and trays used to hold fish; processing equipment, such as knives and scalers, inadequately cleaned; packaging equipment and film wrapping equipment inadequately cleaned.
  - (3) Prevention of cross contamination: Condensate dripping onto product in cooler; condensate dripping from refrigeration units onto work surfaces in processing area; filth and rust on interior surfaces of ice making and storage areas; employees not washing and sanitizing hands prior to returning to work.
  - (4) Maintenance of handwashing facilities: The lack of soap and hand sanitizer at hand wash station.
  - (5) Exclusion of pests: The presence of nesting materials, dead birds, and bird droppings in ice making area; the presence of flying insects in the receiving area; the presence of rodent droppings in crab/shellstock cooler; the presence of live and dead flies in the processing area.
  - (6) Proper storage and use of toxic compounds: The use of [REDACTED] a toxic cleaning compound that is not intended for use on food contact surfaces, to clean and sanitize food contact surfaces in the fish cutting room.

This is not an all-inclusive list of the deviations at your facility. You are responsible for ensuring that your firm operates in compliance with the Act, the seafood HACCP regulations (21CFR 123), and the Good Manufacturing Practice (GMP) regulations (21 CFR 110). You also have a responsibility to use procedures to prevent further violations of the Act and all other applicable regulations. We may take further action if you do not promptly correct these violations. For instance, we may take action to seize your product(s) and/or enjoin your firm from operating.

Mr. Stuart O'Bier  
September 14, 2004  
Page #3

Please respond in writing within fifteen (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 such as copies of your HACCP plans, 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.

Your response should be submitted to: Food and Drug Administration, 6000 Metro Drive, Suite 101, Baltimore, Maryland 21215, to the attention of Elizabeth A. Laudig, Compliance Officer at (410) 779-5441.

Sincerely,

A handwritten signature in black ink, appearing to read 'L B', with a long horizontal stroke extending to the right.

Lee Bowers  
Director, Baltimore District