



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration  
Atlanta District Office

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60 8th Street, N.E.  
Atlanta, Georgia 30309

July 2, 2001

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

Roland C. Blackburn, President  
Blackburn Brothers, Inc.  
P.O. Box 1605  
Carolina Beach, NC 28428

**Warning Letter**  
01-ATL-59

Dear Mr. Blackburn:

On March 26 - 28, 2001, an investigator from the Food and Drug Administration (FDA) conducted an inspection of your plant located at 440 Lake Park Boulevard, Carolina Beach, North Carolina. During that inspection, our investigator documented deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations, some of which were previously brought to your attention, cause your fresh histamine-producing fish to be in violation of section 402(a)(4) of the Federal Food, Drug, and 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](http://www.fda.gov).

The HACCP deviations of concern are as follows:

1. You must have a HACCP plan that lists the critical control points, to comply with 21 CFR 123.6(c)(2). However, your firm's HACCP plans for histamine-producing fish do not list a critical control point (CCP) for temperature control during processing (referred to in your HACCP plan as butchering/packaging). Your HACCP plan must address the hazard of histamine formation as a result of temperature abuse during the heading, gutting, filleting, portioning, and packaging operations.
2. You must have a HACCP plan that lists the critical limits that must be met, to comply with 21 CFR 123.6(c)(3). However, your firm's HACCP plan for primary processor (referred to as "First Receiver" in your HACCP plan) lists critical limits that are inadequate to control the hazard of histamine formation at the "receiving" critical control point. You must have a critical limit that ensures the prevention of histamine before receipt. You have chosen a combination of critical limits that includes vessel harvest records, and sensory evaluation. However, the critical limits that your firm has chosen are inadequate because the vessel harvest record (catcher statement) you cite in the

critical limit is incomplete. At a minimum, the vessel harvest record must include the following information:

- a. Method of capture
- b. Date and time of landing
- c. Estimated time of death
- d. Method of cooling
- e. Date and time cooling began
- f. Sea and air temperature, if exposure temperature is greater than 83°F
- g. That the fish were placed on ice within 12 hours of death.

In this combination of critical limits, the vessel harvest records are augmented by internal temperature requirements at receiving (see the *Fish & Fishery Products Hazards & Controls Guide*, third edition, for recommended temperature critical limits), and sensory evaluation at receiving to insure that the histamine-producing fish were handled properly while in transit. In addition, the HACCP plan should state clearly that the critical limits cited in your "receiving" critical control point apply to each lot of histamine-producing species received.

3. You must implement the monitoring procedures listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not follow the monitoring procedures listed in the HACCP plans for histamine-producing fish as follows:
  - a. Even though the "storage" CCP listed in your firm's "First Receiver" HACCP plan for histamine-producing fish calls for three daily visual checks for the presence of ice on fish stored in the walk-in refrigerated cooler, this was not being done. Your firm didn't complete any records documenting adequacy of ice covering the histamine-producing fish stored in the cooler. The only monitoring records available were for the cooler temperature checks, which show that in many instances during the period between February 12 and March 19, 2001, the temperature of the cooler exceeded 40°F. This is very significant and serious since exposing histamine fish to temperatures above 40°F for extended periods can result in histamine formation.
  - b. Although both HACCP plans for histamine fish require a sensory determination for decomposition at the "receiving" CCP, this was not being done. In addition, it is not clear whether the frequency for this check is "Every lot received" or is missing from the HACCP plans.

- c. Your firm failed to follow the monitoring procedures listed at the "receiving" CCP in your "2<sup>nd</sup> Receiver" HACCP plan for histamine fish. Specifically, your firm failed to review and document that the transportation records accompanying incoming lots of histamine fish showed that the fish were maintained at 40°F or below; the adequacy of ice at the time of delivery; and/or the internal temperature of the fish at time of receipt.
4. 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 the hazard of histamine formation when your process for temperature control during storage deviated from the critical limit at the "storage" CCP. This is evidenced by the fact that your cooler temperature monitoring records show that your firm took no corrective actions when cooler temperatures exceeded the critical limit of 40°F for storage of histamine-producing species at the "refrigerated storage" CCP. Your own records show that on several occasions between February 12 and March 19, 2001, your cooler temperatures were consistently higher than 40°F, yet no corrective actions were taken to correct the deviations.
5. Since you chose to include corrective actions in your HACCP plan, your described corrective actions must be appropriate, to comply with 21 CFR 123.7(b). However, your corrective action plan for histamine-producing species at both the primary and secondary processor is not adequate to control the hazard of histamine formation. Your corrective action in both the primary and secondary processor critical control points requires that you "reject decomposed fish" when the level of decomposition is greater than 2.5%. The appropriate corrective action when the critical limit for level of decomposition has been exceeded is to reject the entire lot.

We may take further action if you do not promptly correct this violation. 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 copies of HACCP plans, and HACCP 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 may not list all the 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 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 Carlos A. Bonnin, Compliance Officer, U.S. Food and Drug Administration, 60 Eighth Street, N.E., Atlanta, Georgia 30309. If you have questions regarding any issue in this letter, please contact Mr. Bonnin at 404-253-1277.

Sincerely,

A handwritten signature in black ink, appearing to read "Ballard H. Graham". The signature is written in a cursive style with a large initial "B".

Ballard H. Graham, Director  
Atlanta District