



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Atlanta District Office

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

July 30, 2004

Certified Mail
Return Receipt Requested

Jeffrey Aiken, President
Jeffrey's Seafood
P.O. Box 473
Hatteras, NC 27943

Warning Letter
04-ATL-17

Dear Mr. Aiken:

On June 17 and 18, 2004, FDA conducted an inspection of your seafood processing facility located at 58195 Marc Basnight Highway, Hatteras, North Carolina. During that inspection, our investigator documented serious deviations from the seafood Hazard Analysis Critical Control Point (HACCP) regulations, contained in Title 21, Code of Federal Regulations, Part 123 (21 CFR Part 123). These deviations cause your histamine-producing fish to be in violation of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), because the fish has been prepared, packed, or held under insanitary conditions whereby it may become contaminated with filth, or may have been rendered injurious to health. You can find the Act and the seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The deviations of concern are as follows:

1. You must implement the record keeping system that you have listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not record monitoring observations at the "Receiving" critical control point to control the histamine formation hazard listed in your HACCP plan for histamine-prone fish. Specifically, there were no monitoring records to document that histamine-prone fish was being visually checked for signs of decomposition at the time of receipt. Moreover, our investigator documented numerous shipments of histamine-prone fish received by your firm from fishermen during the period of April 2004 and May 2004, for which the records for monitoring observations at the receiving step were missing. Additionally, our investigator documented that your firm did not have signed letters of

guarantee on file for numerous fishermen, and that several fishermen failed to initial the monitoring records as required in the HACCP plan.

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 histamine-susceptible fish lists a critical limit at the "Cooler" (storage) critical control point that is not adequate to control the food safety hazard of histamine formation. Specifically, your firm's HACCP plan lists a critical limit which requires the fish to be kept at 50°F or less, and surrounded with ice. A cooler temperature of 50°F may not be adequate to prevent histamine formation. Also your firm did not have any monitoring records to document visual checks of the adequacy of ice on the fish. If your firm is going to rely solely on cooler temperature as the critical limit, then the temperature must be modified to 40°F or below. Alternatively, since all of your histamine-forming fish products are stored completely surrounded with ice, you could change your HACCP plan, as suggested by our investigator, to only require a visual check for adequacy of ice at least twice a day, or immediately prior to shipment for product shipped the same day. A copy of Chapter 7 of the *Fish & Fisheries Products Hazards & Control Guidance (Third Edition)*, titled "Scombrototoxin (Histamine) Formation" is enclosed for your information. It contains guidance on how to improve your HACCP plan for histamine-susceptible fish.

We may take further action, without additional notice, if you do not promptly correct these violations. For instance, we may recommend that the United States bring a legal action to seize your product(s) and/or 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 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 Karen Y. Dodson, 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 Mrs. Dodson at (404) 253-1299.

Sincerely,

A handwritten signature in black ink that reads "Mary Woleske". The signature is written in a cursive style with a large initial "M".

Mary H. Woleske, Director
Atlanta District

Enclosure