



DEPARTMENT OF HEALTH AND HUMAN SERVICES

04969d
Food and Drug Administration
Atlanta District Office

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

September 14, 2004

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Bertrand C. Jennette, President
Jennette Brothers, Inc.
P.O. Box 608
Elizabeth City, NC 27907

Warning Letter
04-ATL-21

Dear Mr. Jennette:

On July 21 and 22, 2004, FDA conducted an inspection of your multiple-food storage warehouse and seafood processing facility located at 506 N. Water St., Elizabeth City, North Carolina. During that inspection, our investigators documented serious deviations from the seafood Hazard Analysis and Critical Control Point (HACCP) regulations, Title 21, Code of Federal Regulations, Part 123 (21 CFR Part 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 to 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), 21 U.S.C. § 342(a)(4). Accordingly, your fresh, scombrototoxin-forming fish, and refrigerated pasteurized and/or fresh-picked crabmeat are adulterated, in that they 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 may 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 conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur, and you must have a written HACCP plan to control any food safety hazards that are likely to occur, to comply with 21 CFR 123.6(a) and (b). However, your firm does not have a HACCP plan for fresh refrigerated crabmeat to control the food safety hazard of pathogen growth as a result of time/temperature abuse.
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 pasteurized crabmeat lists critical limits at the "Receiving" and "Storage" critical control points that are not adequate to control the identified hazard. Specifically, a critical limit of "at or below 140°F" is too high to adequately control the growth of pathogens. Moreover, the hazard identified for these two critical control points, i.e. *Clostridium botulinum*, should be expanded to include "pathogen growth and toxin formation."

3. Because your HACCP plan includes corrective actions, the described corrective actions must be appropriate, to comply with 21 CFR 123.7(b). However, your corrective action plans for fresh, histamine-producing finfish at the "Receiving," "Storage," and "Staging Order for Loading" critical control points are not appropriate to control the histamine formation hazard. Specifically, re-icing the product when there is an inadequate amount of ice covering it is not adequate because it does not take into account the time/temperature the product has been subjected to. In other words, adding ice to fish that has been subjected to time/temperature conditions that can result in histamine formation may prove ineffective in controlling the histamine formation hazard. We are enclosing Chapter 7, *Scombrototoxin (Histamine) Formation*, from the third edition of the Fish & Fisheries Products Hazards & Controls Guidance for your use in developing an adequate HACCP plan for histamine-forming fish.
4. You must implement the record keeping system that you listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not record monitoring observations at the "Receiving," and "Staging Order for Loading" critical control points to control the histamine formation hazard listed in your HACCP plan for histamine-producing finfish. Specifically, your monitoring records (JB-888) for approximately ten days during the period of May to July 2004 were incomplete in that they were missing, among other things, a monitoring observation concerning the adequacy of ice at receipt and/or shipment of the product.

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.

We may take further action 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.

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,


MW Mary H. Woleske, Director
Atlanta District

Enclosure