



March 10, 2003

WARNING LETTER NO. 2003-NOL-11

**FEDERAL EXPRESS
OVERNIGHT DELIVERY**

Mr. Lloyd B. Bearden, Owner and President
Bearden Sandwich Co., Inc.
d.b.a. Southern Belle Sandwich Co.
1969 North Lobdell Boulevard
Baton Rouge, Louisiana 70806

Dear Mr. Bearden:

On January 27 – 29, January 31, and February 3, 2003, we inspected your firm, located at 1969 North Lobdell Boulevard, Baton Rouge, Louisiana. We found that you have serious deviations from the Seafood Hazard Analysis and Critical Control Points (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), 21 U.S.C. § 342(a)(4). Accordingly, your tuna salad sandwich is adulterated, in that the sandwich has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it 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 <http://www.fda.gov>.

The deviations are as follows:

- You must have a HACCP plan that lists the critical control points to comply with 21 CFR 123.6(c)(2). However, your HACCP plan for tuna salad sandwiches does not list the critical control points of assembling the sandwiches for controlling the food safety hazards of pathogen growth and toxin formation from time and temperature abuse. This deviation was previously brought to your attention in our letter of February 1, 2002.
- 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 tuna salad sandwiches lists a temperature, [REDACTED], at the tuna salad storage critical control point that is not adequate to control pathogen growth and toxin formation.
- 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 procedure of recording the

time and temperature of the tuna salad component during its preparation at the processing and preparation critical control point.

- You must have a HACCP plan that lists monitoring procedures for each critical control point to comply with 21 CFR 123.6(c)(4). However, your firm's HACCP plan for tuna salad sandwiches lists a monitoring procedure frequency at the tuna salad component storage critical control point that is not adequate to control pathogen growth and toxin formation. If you choose to list cooler temperature, you must keep adequate records of the monitoring activity and take appropriate corrective actions if monitoring reveals that a critical limit has been compromised. The cooler temperature should be monitored on a continuous basis. Continuous temperature monitoring requires the installation of a temperature-recording device to provide monitoring records of the cooler temperatures during non-business hours, holidays and weekends. In addition, the temperature of the cooler must be monitored visually twice daily.
- You must retain records at the processing facility for at least one year after the date they were prepared to comply with 21 CFR 123.9(b)(1). However, your temperature logs for the cooler holding tuna salad sandwiches were not retained for the months of March through November 2002. This deviation previously was brought to your attention in our letter of February 1, 2002.

In addition, the investigator documented numerous insanitary conditions that cause the tuna salad sandwiches you manufacture to be adulterated within the meaning of Section 402(a)(4) of the Act.

The deviations are as follows:

- Employees working in direct contact with food and food contact surfaces did not take necessary precautions to protect against contamination of the food with microorganisms or foreign substances. For example:
 - a. Employees handled unsanitized objects and then prepared sandwiches without washing or sanitizing their hands; and,
 - b. Employees preparing sandwiches were observed wearing jewelry.

This deviation previously was brought to your attention in our letter of February 1, 2002.

- Food processing equipment is not maintained in a sanitary condition to prevent food from becoming adulterated within the meaning of the Act. For example, [REDACTED] contained food particles and foreign substances from previous operations.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

We are aware that during our inspection you made a verbal commitment to correct violations observed at your firm. We are in receipt of your revised HACCP plan for Tuna Fish Sandwiches and Sanitation Check List, received in this office on February 21, 2003. We have noted that you have included tuna salad storage and finished product storage as critical control points. We agree

with your assessment of the hazards associated with the product at those points. Although you have begun to address FDA's concerns, we have noted the following:

- You have not included data on the time needed to assemble the tuna fish sandwiches to ensure that the product does not remain above 50°F for more than six hours. The tuna sandwich assembly therefore should be considered a critical control point to monitor the time and temperature of the salad to ensure that the product does not exceed 50°F for more than six hours; and,
- You have listed the critical temperature limit for the storage of tuna salad and finished tuna fish sandwiches as 48°F. Please note that the product must not exceed 40°F to control pathogen growth and the toxin formation of *Salmonella* or *Listeria* species.

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 your revised HACCP plan and temperature 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 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 U.S. Food and Drug Administration, Attention: Mark W. Rivero, Compliance Officer, at the address above. If you have questions regarding any issue in this letter, please contact Mr. Rivero at (504) 253-4519.

Sincerely,



F. Dwight Herd
Acting District Director
New Orleans District

Enclosure: Form FDA 483