



November 16, 2001

**WARNING LETTER NO. 2002-NOL-11****FEDERAL EXPRESS**  
**OVERNIGHT DELIVERY**

Mr. Bruce W. Maghan, President  
Bayou Blend, Inc.  
3411 Shortcut Road  
Pascagoula, Mississippi 39581

Dear Mr. Maghan:

We inspected your firm, located at 3411 Shortcut Road, Pascagoula, Mississippi, on October 23 – 24 and 26, 2001, and found that you have serious deviations from seafood Hazard Analysis Critical Control Point (HACCP) regulations, Title 21, *Code of Federal Regulations*, Part 123 (21 CFR 123). These deviations, some of which were previously brought to your attention in our letter dated December 20, 2000, cause your pasteurized crab meat 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 deviations were as follows:

- You must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur to comply with 21 CFR 123.6(b). However, your firm does not have a HACCP plan for pasteurized crab meat in plastic containers to control the food safety hazard of pathogen survival through pasteurization.
- 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 plan for "Pasteurized crabmeat and marinated crabmeat products" does not list the critical control point of water bath container cooling for controlling the food safety hazard of pathogen introduction. Also, this HACCP plan does not include a critical control point to address the growth and formation of heat-stable toxins where there is no time/temperature control of received cooked crab products.
- You must verify that your HACCP plan is adequate to control food safety hazards that are reasonably likely to occur to comply with 21 CFR 123.8(a). However, your firm did not verify the adequacy of the critical limit of "Cook at [REDACTED] deg F. for [REDACTED] minutes" for "Pasteurized crabmeat and marinated crabmeat products" at the "Thermal cook" critical control point to control the hazards of "Pasteurization failure." For example, there is no

documentation the critical limit will eliminate pathogens in the 12 ounce marinated claw or 12 ounce marinated lump crabmeat products. Also, no tests have been performed to determine that adequate temperatures are delivered throughout the cooker during processing.

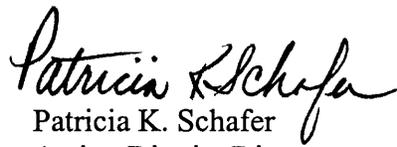
- You must retain records at the processing facility for at least 2 years after the date they were prepared to comply with 21 CFR 123.9(b)(2). However, your firm has no records documenting the accuracy of the temperature recorder used for processing operations from November 10, 2000 to October 16, 2001, or the calibration monitoring records for the digital thermometer.
- You must have a HACCP plan that lists verification procedures for each critical control point to comply with 21 CFR 123.6(c)(6). However, your firm's HACCP plan for "Pasteurized crabmeat and marinated crabmeat products" does not list the verification procedure at the "Thermal cook" critical control point to control "Pasteurization failure." For example, the HACCP plan does not provide for calibrations of the temperature recorder or the digital thermometer.
- You must fully document, in records, all corrective actions taken to comply with 21 CFR 123.7(d). However, you did not document that a corrective action was taken when you deviated from your critical limit of "Cook at [REDACTED] deg F. for [REDACTED] minutes" for "Pasteurized crabmeat and marinated crabmeat products" at the "Thermal cook" critical control point to control "Pasteurization failure."
- You must routinely review your HACCP plan records to verify they document values that are within the critical limits needed to control food safety hazards that are reasonably likely to occur to comply with 21 CFR 123.8(a)(3). However, your firm did not review HACCP records for, but not limited to, the production dates May 15, 2001, August 13 and 19, 2001, September 9, 17, and 22, 2001, and October 13, 2001.

We may take action without further notice if you do not promptly correct these violations. For instance, we may 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. However, you must respond in writing, within three (3) weeks from your receipt of this letter, outlining specific actions you have taken to correct the deficiencies and to assure that such violations will not recur. You may wish to include in your response documentation such as a revised HACCP plan, calibration 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 you will explain the reason for the delay and a deadline by which you will correct any remaining deficiencies.

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 CGMP regulations. You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Nicole F. Hardin, Compliance Officer, at the address above. If you have questions regarding any issue in this letter, please contact Ms. Hardin at (504) 283-4519.

Sincerely,

  
Patricia K. Schafer  
Acting District Director  
New Orleans District

Enclosure: Form FDA 483