



54330d

Food and Drug Administration  
New Orleans District  
Southeast Region  
6600 Plaza Drive, Suite 400  
New Orleans, Louisiana 70127

Telephone: 504-253-4519  
Facsimile: 504-253-4520

October 3, 2003

**Warning Letter No. 2004-NOL-01**

**FEDERAL EXPRESS  
OVERNIGHT DELIVERY**

Mr. David M. Graham, President  
Gulf City Seafoods, Inc.  
4111 North Cedar Street  
Pascagoula, Mississippi 39567

Dear Mr. Graham:

We inspected your firm, located at 4111 North Cedar Street, Pascagoula, Mississippi, on August 20 – 21 and 26, 2003, 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), and the Current Good Manufacturing Practice (CGMP) regulations in manufacturing, packing, or holding food for human consumption, 21 CFR 110. These deviations cause your crabmeat products to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find the Act and the seafood HACCP regulations through links in FDA's home page at <http://www.fda.gov>.

The deviations were as follows:

- (a) 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 crabmeat stuffing in crab shells and crab cakes does not list the critical control point of the hydrated batter in the mixing machine for controlling the food safety hazards of *Staphylococcus aureus* growth and toxin formation.
- (b) You must implement the monitoring procedures listed in your HACCP plan to comply with 21 CFR 123.6(b). However, on August 20, 2003, your firm did not follow the monitoring procedure of determining the internal temperature of [redacted] batches of crabs at the cooking critical control point to control pathogen survival as listed in your HACCP plan for frozen crab clusters. In addition, you did not record the actual cooking times on the cooking log until approximately two hours after the cooking operations on the same day in violation of 21 CFR 123.6(c)(7).
- (c) 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 reasonably likely to occur to comply with 21 CFR 123.6(a) and (b). However, your firm does not have a separate HACCP plan for crabmeat stuffing in crab shells and crab cakes to control the food safety hazards of pathogen growth and toxin formation.

- (d) Your firm did not monitor adequately the prevention of cross-contamination from insanitary objects to food as required by HACCP regulations, 21 CFR 123.11(b)(3). This omission further violates CGMP regulations, 21 CFR 110.10(b)(9). Specifically, employees working in direct contact with food and food contact surfaces did not take necessary precautions to protect against contamination. For example, an employee was observed eating a cooked crab claw in the processing room and did not wash or sanitize his hands before contacting cooked crab claws on the picking table.
- (e) You did not monitor adequately the exclusion of pests from the food plant as required by HACCP regulations, 21 CFR 123.11(b)(8). This omission further violates CGMP regulations, 21 CFR 110.35(c). Specifically, you have not taken adequate measures to exclude pests from the processing areas and protect against the contamination of food on the premises by pests. For example, at least 120 live house-type flies were observed in the cooking/packing room during processing on August 20, 2003, and at least 50 live house-type flies were observed in the cooking/packing room during processing on August 21, 2003.
- (f) Your firm did not monitor adequately the protection of food, food packaging material, and food contact surfaces from adulteration with condensate and other biological or physical contaminants as required by HACCP regulations, 21 CFR 123.11(b)(5). This omission further violates CGMP regulations, 21 CFR 110.20(b). In particular, you failed to provide safety-type light bulbs and lighting fixtures suspended over exposed food. Four unprotected light bulbs were located in the crab backing area. In addition, the lighting in the backing room was inadequate to ensure proper cleaning of employee's hands.

We may take action without further notice if you do not promptly correct these violations. For instance, we may recommend that the United States bring action to seize your product 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 your revised HACCP plans, thermometer calibration 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 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,

*Patricia K. Schafer*  
Patricia K. Schafer  
Acting District Director  
New Orleans District

Enclosure: FDA Form 483