



DEPARTMENT OF HEALTH AND HUMAN SERVICE

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

Telephone: 504-253-4519
FAX: 504-253-4520

September 8, 2003

WARNING LETTER NO. 2003-NOL-24

**FEDERAL EXPRESS
OVERNIGHT DELIVERY**

Mr. Robert J. DeJean, President
B & G Seafood, Inc.
17358 Highway 631
Des Allemands, Louisiana 70030

Dear Mr. DeJean:

We inspected your firm, located at 17358 Highway 631, Des Allemands, Louisiana, on July 28 – 31 and August 6, 2003. We found that you have serious deviations from the Seafood Hazard Analysis and Critical Control Point (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 processed at that firm 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 crabmeat is adulterated, in that the products 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 <http://www.fda.gov>.

Sample Results

Our investigators collected samples of your cooked crabmeat (FDA sample #'s 235950 and 235951) on July 29, 2003, during the inspection of your facility. The samples were found contaminated with *Escherichia coli* (*E. coli*). We notified you of this finding in our letters dated August 13 and 14, 2003, from FDA's Southeast Regional Laboratory in Atlanta, Georgia. *E. coli* in your ready-to-eat, cooked crabmeat causes your crabmeat to be in violation of Section 402(a)(3) of the Act, in that it contains filth, as evidenced by FDA's isolation of *E. coli* in the cooked and peeled crabmeat packed by your firm. Further, your product and your firm are in violation of Section 402(a)(4) of the Act in that the cooked, ready-to-eat crabmeat have been prepared, packed, or held under insanitary conditions whereby they may have been contaminated with filth or whereby they may have been rendered injurious to health.

E. coli is a bacterium commonly associated with fecal contamination of warm-blooded animals. In the production of commercially processed crabmeat, the cooking process destroys non-spore

forming bacteria, including *E. coli*. Therefore, the presence of *E. coli* in finished product indicates either the cooking process was inadequate or the product was re-contaminated after the cooking step. Recontamination after the cooking step could be a result of insanitary practices by the employees in the plant. Strict in-plant sanitation measures must be instituted to prevent the presence of bacteria in the finished product.

Inspectional Findings

During our inspection, the investigators provided you with the Form FDA 483, which presents their evaluation of your firm's performance regarding various aspects of the HACCP and CGMP requirements. Upon further review, we found the following serious deviations from the principles of HACCP and the significant requirements of the program:

1. You must implement the record keeping system you list in your HACCP plan to comply with 21 CFR 123.6(b). However, on July 19, 2003, you did not record the internal temperature of the backed crabs during cooling as listed in your HACCP plan for crabmeat;
2. You must monitor sanitation conditions and practices adequately during processing to comply with 21 CFR 123.11(b). However, your firm did not monitor adequately the conditions and cleanliness of food contact surfaces, including utensils, gloves, and outer garments as required by 21 CFR 123.11(b)(2).
 - a) Your firm's food processing equipment is not maintained in a sanitary condition to prevent food from becoming adulterated. For example:
 - i. The perforated plastic baskets used to hold cooked crabs contained residues from previous operations;
 - ii. The picking table had rough seam welds encrusted with black residues.
 - b) You failed to use sanitizing agents to protect food from adulteration. For example, you used a sanitizing solution that contained greater than 200 ppm of chlorine on equipment and employee's hands.
 - c) Your firm did not monitor for the protection of food, food packaging material, and food contact surfaces from adulteration with physical contaminants as required by 21 CFR 123.11(b)(5). Specifically, you failed to provide safety-type light bulbs and lighting fixtures suspended over exposed food. For example, the cover of the florescent light bulb located above cooked crabs in the cook room was broken.
 - d) You did not monitor for the exclusion of pests from the food plant as required by 21 CFR 123.11(b)(8). For example, the door leading to the cook room from outside the facility was open, and live flies were observed in the cook room.

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

We are aware that you made a verbal commitment to correct the deviations during the inspection. 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. We request that you describe your actions regarding the crabmeat contaminated with *E. coli* that has been distributed in commercial channels. You should include in your response any documentation, such as copies of your firm's sanitation monitoring records, crab cooling 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 Current 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,


Patricia K. Schafer
Acting District Director
New Orleans District

Enclosure: Form FDA 483