



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
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October 16, 2003

WARNING LETTER NO. 2004-NOL-02

**FEDERAL EXPRESS
OVERNIGHT DELIVERY**

Mr. John M. Bui, Owner
Bui Family Crab Company
364 Bayview Avenue
Biloxi, Mississippi 39530

Dear Mr. Bui:

On August 25 – 28, 2003, we inspected your seafood processing facility, located at 364 Bayview Avenue, Biloxi, Mississippi. We found you have serious deviations from the seafood Hazard Analysis and Critical Control Points (HACCP) regulations, Title 21, *Code of Federal Regulations*, Part 123 (21 C.F.R. 123). In accordance with 21 C.F.R. 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 crabmeat is adulterated, in that the crabmeat 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 Internet home page at <http://www.fda.gov>.

The deviations were as follows:

- A. You must implement the record keeping system that you listed in your HACCP plan to comply with 21 C.F.R. 123.6(b). However, your firm did not record monitoring observations at the cooling and product storage critical control points to control pathogen growth and toxin formation as listed in your HACCP plan for processed crabs.
- B. You failed to maintain sanitation control records that, at a minimum, document the monitoring and corrections of problems involving safety of water that comes into contact with food or food contact surfaces; condition and cleanliness of food contact surfaces; prevention of cross-contamination; maintenance of hand washing, hand sanitizing, and toilet facilities; protection of food, food packaging material, and food contact surfaces from adulteration with contaminants; proper labeling, storage, and use of toxic compounds; control of employee health conditions that could result in microbiological contamination; and,

exclusion of pests from the facility as required by 21 C.F.R. 123.11(c). Specifically, your firm did not complete daily sanitation monitoring records for all operations.

- C. You must monitor sanitation conditions and practices adequately during processing to comply with 21 C.F.R. 123.11(b). However:
- 1) Your firm did not monitor adequately the prevention of cross-contamination from insanitary objects to food as required by 21 C.F.R. 123.11(b)(3). This omission also violates the requirements of 21 C.F.R. 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. This includes:
 - a. Employees handled uncooked crabs and then cooked crabs without washing or sanitizing their hands;
 - b. Employees touched unsanitized objects and then cooked crabs without washing or sanitizing their hands; and,
 - c. Storing containers of crabmeat and bottled water on ice that came in direct contact with cooked crabs.
 - 2) Your firm did not monitor adequately the conditions and cleanliness of food contact surfaces as required by 21 C.F.R. 123.11(b)(2). This omission also violates the requirements of 21 C.F.R. 110.35(d). Your firm's food processing equipment is not maintained in a sanitary condition to prevent food from becoming adulterated. For example:
 - a. Employees backing cooked crabs used knives that were encrusted with brown residues;
 - b. Storing cooked crabs in perforated plastic baskets and lugs that are stained with brown residues from previous operations;
 - c. Employees used an aluminum rake to move cooked crabs on the backing table that was not washed or sanitized; and,
 - d. Employees used a plastic shovel that contained black residue to transfer ice onto the cooked crabs.
 - 3) You did not monitor the exclusion of pests from the food plant as required by 21 C.F.R. 123.11(b)(8). This omission also violates the requirements of 21 C.F.R. 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, on August 25 and 26, 2003, live flies were observed on cooked crabs, crab processing equipment, and a garbage dumpster outside of the facility approximately eight feet from the cook room door. In addition, the cook room contained an unscreened window fan leading directly to the exterior of your facility.

- 4) You did not monitor the maintenance of hand washing, hand sanitizing, and toilet facilities as required by 21 C.F.R. 123.11(b)(4). This omission also violates the requirements of 21 C.F.R. 110.37. Specifically, your restroom facilities do not have hot running water, soap, or adequate hand drying equipment. On August 26, 2003, your firm did not have running hot water for approximately five hours during processing operations. In addition, the floor in your toilet facilities is soiled and the toilet seat is covered with brown residues.
- 5) You failed to remove litter and waste that may constitute an attractant, breeding place, or harborage area for pests, within the immediate vicinity of the plant buildings or structures as required by 21 C.F.R. 110.37(f). For example, roofing and other discarded building materials are located behind your facility.

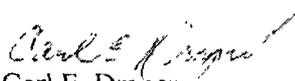
We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product and/or enjoin your firm from operating.

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. You should include in your response documentation, such as copies of your 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 your processing plant operates in compliance with the Act, the seafood HACCP regulations and the Current Good Manufacturing Practice regulations, 21 C.F.R. 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,


Carl E. Draper
District Director
New Orleans District

Enclosure: Form FDA 483