



June 20, 2001

**WARNING LETTER NO. 2001-NOL-29**

***FEDERAL EXPRESS***  
**OVERNIGHT DELIVERY**

Mr. John M. Bui, Owner  
Bui Family Seafood Company  
332 Penny Avenue  
Biloxi, Mississippi 39530

Dear Mr. Bui:

We inspected your firm, located at 332 Penny Avenue, Biloxi, Mississippi on May 21 through 23, 2001, and found that you have serious deviations from the Seafood HACCP regulations, Title 21, *Code of Federal Regulations*, Part 123 (21 CFR 123). These deviations, some of which were previously brought to your attention, cause your fresh cooked 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 HACCP plan that lists the critical control points, to comply with 21 CFR 123.6(c)(2). However, your firm's HACCP plan for cooked crab meat does not list the critical control point of cooking for controlling the food safety hazard of pathogen growth. This deviation was previously brought to your attention in our letter of November 20, 2000.
- You must implement the record keeping system listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not record monitoring observations at the backing, picking, and storage critical control points to control pathogen growth listed in your HACCP plan for cooked crab meat. This deviation was previously brought to your attention in our letter of November 20, 2000.
- You must adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR 123.11(b). However, your firm did not monitor condition and cleanliness of food contact surfaces as evidenced by the backing table used for processing cooked crabs contained

rust along with encrusted residue from previous operations. This deviation was previously brought to your attention in our letter of November 20, 2000.

In addition, the investigators documented numerous insanitary conditions that cause the crab meat you manufacture to be adulterated within the meaning of Section 402(a)(4) of the Act. They are adulterated because they have been prepared, packed or held under conditions whereby they may become contaminated with filth.

- Employees working in direct contact with food and food-contact surfaces did not take necessary precautions to protect against contamination of those items with microorganisms or foreign substances. For example:
  - (1) They contacted insanitary equipment and then handled cooked crabs without washing or sanitizing their hands;
  - (2) Unsanitized clothing came in direct contact with the cooked crabs;
  - (3) They placed a fly swatter with remnants of crushed insects on the cooked crabs without washing or sanitizing that implement;
  - (4) They routinely placed perforated baskets and crates filled with cooked crabs in water on the floor; and,
  - (5) They did not wear adequate hair restraints during 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.

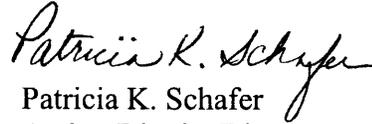
Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as your revised HACCP plan, monitoring records, sanitation standard operating procedures 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, Part 110). You also have a responsibility

to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Your response should be directed to Mark W. Rivero, Compliance Officer, at the above address.

Sincerely,



Patricia K. Schafer  
Acting District Director  
New Orleans District

Enclosure: Form FDA 483