



January 10, 2003

**WARNING LETTER NO. 2003-NOL-06**

**FEDERAL EXPRESS  
OVERNIGHT DELIVERY**

Mary Lisa Porche, President/Owner  
Big River Seafood, Inc.  
11579 Cedar Park Avenue  
Baton Rouge, Louisiana 70809

Dear Ms. Porche:

During November 19-21 and 25, 2002, we inspected your firm, located in 11579 Cedar Park Avenue, Baton Rouge, Louisiana. 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 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 pasteurized crabmeat, sushi fish, and vacuum-packaged fish are 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>.

The deviations are as follows:

- You must implement the monitoring procedures you have listed in your HACCP plans to comply with 21 CFR 123.6(b). However, your firm did not follow the monitoring procedures of temperature control and checking for the presence of ice in the receiving and storage of pasteurized crabmeat. Also, your firm did not follow the monitoring procedures of time and temperature control during the freezing of sushi fish (grouper, cobia, salmon, and flounder).
- 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 receiving, storage, and shipment critical control points to control pathogen growth and toxin formation listed in your HACCP plan for pasteurized crabmeat. In addition, your firm did not record monitoring observations at the freezing critical control point to control parasites as listed in your HACCP plan for sushi fish (grouper, cobia, salmon, and flounder).

Additionally, in accordance with 21 CFR 123.9, all records required by your HACCP plans shall include: the date and time of the activity the record reflects; the signature or initials of the person performing the operation; and, where appropriate, the identity of the product and the production code, if any. All processing or other information must be entered concurrent with the activity or when the observation was made. All records in your HACCP plan, to comply with 21 CFR 123.8 and 123.10, must be verified by someone who has been trained in the application of HACCP principles.

Even though it was not documented on the Form FDA 483, as discussed on November 25, 2002, you also 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 vacuum-packaged fish to control for the hazard of *Clostridium botulinum* toxin formation. Additionally, FDA recommends that frozen, vacuum-packaged products be labeled, "Important, keep frozen until used, thaw under refrigeration immediately before use."

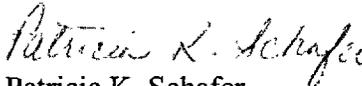
We may take further regulatory action if you do not promptly correct these violations. For instance, we may seize your product(s) and/or enjoin your firm from operating.

We are aware that during our inspection you made a verbal commitment to correct violations observed at your firm. Please respond in writing, within fifteen (15) working days from your receipt of this letter. Your response should outline specific actions you are taking to correct the deficiencies. You should include in your response documentation such as copies of HACCP plans, various monitoring logs, and 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 your delay and state when 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 Current Good Manufacturing Practice Regulations in manufacturing, packing, or holding food for human consumption (21 CFR 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.

Please send your reply to the U.S. Food and Drug Administration, Attention: Rebecca A. Asente, Compliance Officer, at the address above. If you have questions regarding any issue in this letter, please contact Ms. Asente at (504) 253-4519.

Sincerely,

  
Patricia K. Schafer  
Acting District Director  
New Orleans District

Enclosure: Form FDA 483