



DEPARTMENT OF HEALTH AND HUMAN SERVICE

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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March 3, 2003

WARNING LETTER NO. 2003-NOL-10

**FEDERAL EXPRESS
OVERNIGHT DELIVERY**

Mr. Noy Paul Phangnivong, President
Laomerica Seafood Inc.
14580 Saint Michael Street
Codon, Alabama 36523

Dear Mr. Phangnivong:

On December 9 – 11, 2002, we inspected your seafood processing facility, located at 14580 Saint Michael Street, Codon, Alabama. We found that you have serious deviations from the Seafood Hazard Analysis and Critical Control Points (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 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:

- You must fully implement the monitoring procedures listed in your HACCP plan to comply with 21 CFR 123.6(b). However, your firm did not follow the monitoring procedure of recording the temperature of the cooler during storage and the time the product is exposed during storage, picking, and packing critical control points (CCPs) on nine days during April 2002 and nine days during June 2002, as listed in your HACCP plan.
- You must have a HACCP plan that lists the critical limits that must be met to comply with 21 CFR 123.6(c)(3). However, your firm's HACCP plan, entitled Blue Crab Meat, lists a critical limit, accumulative time only, at the cooking, backing, picking, and packing CCPs that is not adequate to control pathogen growth. Your firm does not monitor the temperature of the cooked crabs during the cooking, backing, picking, and packing CCPs.
- You must adequately monitor sanitation conditions and practices during processing to comply with 21 CFR 123.11(b). However, your firm did not monitor the prevention of cross-contamination from insanitary objects to food, as evidenced by employees using etched-handled knives encrusted with black residues, during picking operations.

In addition, the investigator documented numerous insanitary conditions that cause the crabmeat you manufacture to be adulterated within the meaning of Section 402(a)(4) of the Act.

The deviations were as follows:

- 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, employees contacted insanitary equipment and then handled cooked crabs without washing or sanitizing their hands [21 CFR 110.10(b)(3)]. In addition, an employee picking crabs was observed touching his mouth while consuming ice and then touching an opened container of cooked crabmeat without washing or sanitizing his hands [21 CFR 110.10(b)(8)].
- Food processing equipment is not maintained in a sanitary condition to prevent food from becoming adulterated within the meaning of the Act. For example, employees used etched-handled knives encrusted with black residues during picking operations [21 CFR 110.40(a)].
- The inspection found that cleaning and sanitizing utensils and equipment are not conducted in a manner that protects food and food-contact surfaces from contamination. For example, the concentration of chlorine (less than 50 PPM) is not adequate for sanitizing employee hands, food-processing equipment, and utensils [21 CFR 110.35(d)(5)].

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your products 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 revised HACCP plan and 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 that your processing plant operates in compliance with the Act, the Seafood HACCP regulations, and the Good Manufacturing Practice regulations, 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: 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,



F. Dwight Herd
Acting District Director
New Orleans District

Enclosure: Form FDA 483