



DEPARTMENT OF HEALTH AND HUMAN SERVICE

939008

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

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

November 25, 2002

WARNING LETTER NO. 2003-NOL-04

**FEDERAL EXPRESS
OVERNIGHT DELIVERY**

Ms. Viengxay V. Femuchang, Owner
Heron Bay Seafood
8850 Satsuma Street
Codon, Alabama 36523

Dear Ms Femuchang

We inspected your crab processing facility, located at 4310 Heron Bay Loop Road, Codon, Alabama, on October 7, 8, and 15, 2002, and found that you have serious deviations from the Seafood Hazard Analysis Critical Control Point (HACCP) regulations, Title 21, *Code of Federal Regulations*, Part 123 (21 CFR 123), and the Current Good Manufacturing Practice (CGMP) regulations in manufacturing, packing, or holding food for human consumption, 21 CFR 110. Our investigators documented numerous insanitary conditions, which cause your crabmeat to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find the Act and the seafood HACCP regulations through links in FDA's home page at <http://www.fda.gov>

During the inspection, our investigators collected samples of your cooked, ready-to-eat claw crabmeat. The samples subsequently were analyzed for the presence of microorganisms. You should be aware that *Escherichia coli* (*E. coli*) was recovered from one sample, collected on October 8, 2002, of the cooked, ready-to-eat claw crabmeat. You already may have received a letter from our Southeast Regional Laboratory in Atlanta, Georgia, notifying you of the same. The presence of *E. coli* causes your crabmeat to be in violation of Section 402(a)(3) of the Act.

E. coli is part of the normal intestinal flora of humans or other primates. The presence of *E. coli* in your crabmeat is an indication of fecal contamination. Some strains of *E. coli* cause foodborne bacterial illness such as gastroenteritis that can be a serious illness for some people; especially the elderly, newborns, and those with weakened immune systems. Food processors and handlers should take all precautions necessary to reduce the risk of contamination and to keep food safe from *E. coli*. We strongly recommend you determine the cause(s) of this problem and take corrective action as soon as possible.

The following deviations were documented during the inspection:

- 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, packing, and cooler storage critical control points to control pathogen growth and toxin formation as listed in your HACCP plan for cooked crabmeat. In addition, you did not record the cooking time of the fourth batch of crabmeat on September 29, 2002. Similar deviations were noted in our correspondence to you dated February 21, 2002.
- You must document processing and other information on the monitoring records at the time of the observation to comply with 21 CFR 123.9(a)(4). However, your firm completed the cooking time monitoring records before the actual cooking time was completed.
- You must monitor sanitation conditions and practices adequately during processing to comply with 21 CFR 123.11(b). However, your firm did not monitor the exclusion of pests from the food plant as evidenced by numerous flying insects within the facility during processing. In addition, you did not monitor the safety of the water that comes in contact with food or food contact surfaces because there is no back flow prevention device on the faucet used to supply water for cooling cooked crabs and washing cooked crab contact surfaces.

In addition, our investigators 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 cross-contamination. For example, employees handled unclean objects and then handled cooked products without washing and sanitizing their hands. In addition, employees did not wear adequate hair restraints. Similar deviations were noted in our correspondence to you dated February 21, 2002.
- The inspection found that utensils and equipment are not sanitized in a manner that protects food and food contact surfaces from contamination. For example, your employees were observed using sanitizing solutions with less than 10 ppm chlorine, which is not adequate to sanitize food contact surfaces.
- Food processing equipment is not maintained in a sanitary condition to prevent food from becoming adulterated. For example, our investigators observed your employees using knives with handles encrusted with a black material. Your employees routinely used a plastic shovel, encrusted with black and brown material, on the cooked crabs. In addition, your employees submerged baskets of cooked crabs in an ice water vat with nicks and cracks encrusted with black, brown, and green residues. Similar deviations were noted in our correspondence to you dated February 21, 2002.
- You have not taken effective measures to exclude pests from the processing areas and to prevent contamination of filth in your crabmeat. For example, our investigator observed numerous flying insects on cooked crabmeat, on processing equipment throughout the facility,

and on finished crabmeat products. Similar deviations were noted in our correspondence to you dated February 21, 2002.

- In addition, our investigators documented conditions associated with the construction, design, and maintenance of your facility that facilitate unsanitary operations. For example, an opening approximately 2" X 4" was observed along the east wall of the equipment supply room that could provide an entrance for pests into the facility.

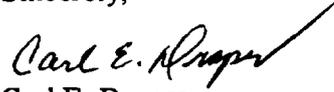
We may take action without further notice if you do not promptly correct these violations. For instance, we may seize your products and/or enjoin your firm from operating.

We are aware that during our inspection you made a verbal commitment to correct violations observed at your firm. However, you must respond in writing, within fifteen (15) working days from the date you receive this letter, outlining specific actions you have taken to correct the deviations and to assure that such violations will not recur. You may include in your response documentation such as copies of temperature monitoring records or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, explain the reason for the delay and provide a deadline by which 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 CGMP regulations. 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,


Carl E. Draper
District Director
New Orleans District

Enclosure: Form FDA 483