



April 23, 2002

**WARNING LETTER NO. 2002-NOL-27**

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

Mr. Henry J. Moore, President/Owner  
J & M Fisheries, Inc.  
d.b.a. Sandy Bay Seafood, Inc.  
14110 Shellbelt Road  
Bayou La Batre, Alabama 36509

Dear Mr. Moore:

We inspected your firm, located at 14110 Shellbelt Road, Bayou La Batre, Alabama, during January 23 - 25, 2002, and found that you have serious deviations from 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. These deviations, some of which were previously brought to your attention, cause your ready-to-eat crabmeat and frozen, raw shrimp 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 U.S. Food and Drug Administration's home page at <http://www.fda.gov>.

The deviations were as follows:

- You 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 raw shrimp to control the food safety hazard of undeclared sulfites.
- 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" and "Backed crab and claw cooling" critical control points to control pathogen growth and toxin formation listed in your HACCP plan for cooked crabmeat. Our investigator documented that the required temperature data were not recorded on the "DAILY BACKING AND COOLING LOG" on October 27, 2001, December 9, 2001, December 11, 2001, January 10, 2002, January 13, 2002, and January 22, 2002. It also was noted that on October 27, 2001, your firm failed to record the "Time Cook Ends" on the "Daily Cooking Log." In addition, your firm failed to monitor the finished product temperature due to a broken thermometer.

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

- You must adequately monitor sanitation conditions and practices during processing to comply with 21 CFR 123.11(b). However, your firm did not sufficiently monitor the following areas of sanitation:

Your firm failed to monitor the safety of water that contacts food and food contact surfaces, as evidenced by water hoses in both your cooking/backing and picking rooms that lacked backflow protection and were stored in direct contact with the floor. A picking room hose stored on the floor subsequently was used to rinse picking tables where ready-to-eat product was handled.

Your firm failed to monitor the condition and cleanliness of food contact surfaces. This was evidenced by the accumulation of residue, from previous production, on baskets used to hold backed, cooked crabs and claws, and by the residues observed on the underside of the picking table drain holes. It also was noted that the crab flume was constructed in a manner that makes it not readily cleanable. Metal seams with gaps were observed containing pieces of crabmeat. Your firm also failed to maintain hot water which is needed to properly clean the surfaces of process equipment.

Your firm failed to protect food and food packaging material from adulteration with pesticides as evidenced by the investigator who observed pesticide being sprayed into the air above boxes of product containers in the storage room.

Your firm failed to adequately exclude pests from the food plant as evidenced by live flies in the cooking/backing room and both live and dead flies in the picking room, where ready-to-eat product is processed. Also, our investigator observed that the door to the live crab receiving room was open during cooking and backing operations the morning of January 23, 2002, as well as a window with broken glass in the packing room, both possible routes of entry for pests.

Your firm failed to adequately prevent cross-contamination from insanitary objects to food as evidenced by the observation of an employee who wiped the back of his hand across his nose and resumed picking ready-to-eat crabmeat.

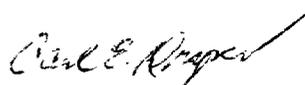
- You must have a HACCP plan that lists monitoring procedures for each critical control point to comply with 21 CFR 123.6(c)(4). However, your firm's HACCP plan for cooked crabmeat lists a monitoring frequency at the "Backed crab and claw cooler" critical control point that is not adequate to control the food safety hazard of pathogen growth and toxin formation. Continuous monitoring is required during storage to ensure proper time/temperature control.
- Since you chose to include corrective actions in your HACCP plan, your described corrective actions must be appropriate to comply with 21 CFR 123.7(b). However, your corrective action plan for fresh crabmeat at each critical control point to control pathogen growth and toxin formation is not appropriate. Your listed corrective actions do not include correcting the cause of the deviation.

We may take action without further notice 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. However, you must respond in writing, within three (3) weeks from your receipt of this letter, outlining specific actions you have taken to correct the deficiencies and to assure that such violations will not recur. You may wish to include in your response documentation such as copies of thermometer calibration records, and various logs cited above, 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 the delay and a deadline by which 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 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: 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,



Carl E. Draper  
District Director  
New Orleans District

Enclosure: Form FDA 483