



DEPARTMENT OF HEALTH AND HUMAN SERVICE

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

Telephone: 504-253-4519
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October 17, 2001

WARNING LETTER NO. 2002-NOL-05

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Ms. Marie Z. Murray, Owner
H & M Seafood
14765-E Archie Zirlott Road
Codon, Alabama 36523

Dear Ms. Murray:

We inspected your firm, located at 14765-E Archie Zirlott Road, Codon, Alabama, on September 17-20, 2001, 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) requirements, 21 CFR 110. These deviations cause your ready-to-eat crabmeat 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.

The deviations were as follows:

- You must implement the monitoring procedures listed in your HACCP plan to comply with 21 CFR 123.6(b). However, your firm did not follow the time and temperature monitoring procedure at the "picking and packing" critical control point (CCP) to control the hazard of pathogen growth and toxin formation as listed in your HACCP plan for crabmeat. For example, you did not monitor time and temperature during picking and packing on the dates of September 6, 10, 12, and 17, 2001.
- 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 "picking and packing" CCP to control the hazard of pathogen growth and toxin formation as listed in your HACCP plan for crabmeat. For example, there are no records to document the monitoring of time and temperature during picking and packing on the dates of September 6, 10, 12, and 17, 2001.

- You must have a HACCP plan that lists monitoring procedures for each CCP to comply with 21 CFR 123.6(c)(4). However, your firm's HACCP plan for crabmeat lists a time and temperature monitoring procedure at the "backing hot cooked crabs" CCP that is not adequate to control the hazard of pathogen growth and toxin formation. For example, your firm does not document the cumulative time and temperature for each batch of backed product.
- 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 sufficient monitoring observations at the "backed crab and claw cooling" CCP to control the hazard of pathogen growth and toxin formation as listed in your HACCP plan for crabmeat. For example, your firm did not record a start time to measure the cumulative time from the initial handling.
- You must have a HACCP plan that lists monitoring procedures for each CCP to comply with 21 CFR 123.6(c)(4). However, your firm's HACCP plan for crabmeat lists a monitoring procedure at the "picking and packing" CCP that is not adequate to control the hazard of pathogen growth and toxin formation. For example, on September 18, 2001, FDA's temperature checks of your backfin lump crabmeat and jumbo lump crabmeat on the picking table showed them to be 58°F and 52°F, respectively. These measurements exceed your HACCP plan's Critical Limit which indicates the temperature of picked crabmeat will be at or below 50°F at all times.
- You must maintain records that document monitoring of sanitation conditions and practices during processing to comply with 21 CFR 123.11(c). However, your firm's daily sanitation monitoring record does not document water safety, protection from adulterants, and proper storage of toxic compounds.

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

The deviations were as follows:

- On September 17, 2001, our investigator observed conditions that facilitate cross-contamination from insanitary items to food. For example, a hose rested on the floor in standing water where totes of live crabs also set. The hose was used, without prior cleaning or sanitizing, to deliver water to cool cooked crabs before backing. Also, several backed, cooked crabs came into contact with an unsanitized waste barrel.
- On September 18, 2001, our investigator observed employees, who work in direct contact with food, not taking the necessary precautions to protect against the contamination of food with microorganisms. For example, several picking room employees entered the process area and began picking crabs without first washing their hands. Also, one employee was observed chewing gum while picking crabmeat.

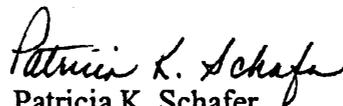
We may take action without further notice if you do not promptly correct these violations. For instance, we may seize your product(s) and/or enjoin your firm from operating. We are aware

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 modifications to your HACCP plan, and Cooking and Baking Cooked Crab Log, or 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: Nicole F. Hardin, Compliance Officer, at the address above. If you have questions regarding any issue in this letter, please contact Ms. Hardin at 504-253-4519.

Sincerely,


Patricia K. Schafer
Acting District Director
New Orleans District

Enclosure: FDA Form 483