



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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November 13, 2001

WARNING LETTER NO. 2002-NOL-09

**FEDERAL EXPRESS
OVERNIGHT DELIVERY**

Mr. Be V. Truong, Owner
Lynn's Seafood
217A Graveline Road
Gautier, Mississippi 39553-6317

Dear Mr. Truong:

We inspected your firm, located at 217A Graveline Road, Gautier, Mississippi, on October 9 – 12, 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) regulations in manufacturing, packing, or holding food for human consumption, 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.

During the inspection, the investigator collected samples of your cooked, ready-to-eat crabmeat. The samples were subsequently analyzed for the presence of microorganisms. You should be aware that *Escherichia coli* (*E. coli*) was recovered from one sample, collected on October 10, 2001, of the cooked, ready-to-eat crabmeat. You may already 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 indicator of either undercooked product or insanitary conditions, including poor employee practices, within your facility. 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 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 ready-to-eat crabmeat to control the food safety hazards of pathogen growth and toxin formation.
- 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 condition and cleanliness of food contact

surfaces as evidenced by the cooked crab backing table containing a black and brown encrusted residue from previous operations.

In addition, the investigator documented numerous insanitary conditions that cause the crabmeat products you manufacture to be adulterated. Employees working in direct contact with food and food contact surfaces did not take necessary precautions to protect against contamination of the food with microorganisms or foreign substances. For example:

- Employees routinely contacted unclean equipment, including door knobs with black and brown residues, and resumed handling cooked crabs without washing or sanitizing their hands;
- Employees were observed retrieving cooked crabs from an unsanitized waste container and placing them into a basket containing cooked crabs;
- An employee sprayed water on crabs with a hose that had previously rested in standing water on the floor; and,
- An employee repeatedly coughed over cooked crabs during backing operations.

Food processing equipment is not maintained in a sanitary condition to prevent food from becoming adulterated. For example:

- Etching on the handles of knives used to pick crabmeat contained black residues;
- Cooked crabs routinely came in contact with the backing table that contained a black and brown encrusted residue from previous operations; and,
- Cooked crabs routinely contacted the wall adjacent to the backing table that contained brown residues from previous operations.

You have failed to keep the grounds about your processing facility in a condition that will protect against contamination of your crabmeat product. For example:

- The grounds near the entrance to the cooking/backing room had litter and debris; and,
- Numerous live flies and maggots were observed within twenty feet of the entrance to the cooking room.

You have not taken effective measures to exclude pests from the processing areas and to protect against the contamination of food on the premises by pests. Failure to exclude ants and flying pests is a potential contributing factor to microbiological contamination in that:

- Numerous flies and ants were observed throughout the processing area directly on windows, walls, trashcans and other potential sources of contaminants;
- Ants were observed on processing equipment containing cooked product;
- Flies were observed freely moving within the plant between potential sources of pathogens and exposed cooked product; and,
- Numerous dead ants and flies were observed in the window of the backing room during operations.

The inspection found that the sanitizing of utensils and equipment is not conducted in a manner that protects food and food contact surfaces from contamination. For example, your firm did not sanitize cooked crab contact surfaces such as employees' hands, gloves, crabmeat containers, knives, picking tables, backing table, or packing table prior to processing cooked crabs.

We may take action without further notice if you do not promptly correct these violations. For instance, we may seize your product 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 your product HACCP plans, sanitation and process 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 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 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,



Patricia K. Schafer
Acting District Director
New Orleans District

Enclosure: FDA Form 483