



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

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November 21, 2000

**WARNING LETTER NO. 2001-NOL-04**

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

Mr. Hixon D. Thomas, Owner  
Thomas Crab Company  
429 Lake Breeze Road  
Hackberry, Louisiana 70645

Dear Mr. Thomas:

On July 11-13, 2000, a U.S. Food and Drug Administration (FDA) investigator conducted an inspection of your crabmeat processing plant, located at 429 Lake Breeze Road, Hackberry, Louisiana. The inspection was conducted to determine compliance with FDA's seafood processing regulations, Title 21, *Code of Federal Regulations* (21 CFR), Part 123 and the Current Good Manufacturing Practice (CGMP) regulations for foods 21 CFR, Part 110. Our investigator documented numerous deviations from these regulations. This causes your finished, ready-to-eat products, fresh crabmeat, to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act.

The seafood processing regulations, which became effective on December 18, 1997, require that you implement a preventive system of food safety controls known as Hazard Analysis Critical Control Point (HACCP). HACCP essentially involves: (1) identifying food safety hazards that, in the absence of controls, are reasonably likely to occur in your products; and (2) having controls at "critical control points" in the processing operation to eliminate or minimize the likelihood that the identified hazards will occur. These are the kinds of measures that prudent processors already take. HACCP provides a systematic way of taking those measures that demonstrates to us, to your customers, and to consumers, that you are routinely practicing food safety by design. Seafood processors that have fully operating HACCP systems advise us that they benefit from it in several ways, including having a more safety oriented workforce, having less product waste, and having fewer problems generally.

During the July 2000 inspection, the FDA investigator observed shortcomings in your crabmeat processing facility, some of these were similar to those pointed out in the July 1999 inspection and stated in the warning letter sent to your firm dated December 9, 1999. Some of these shortcomings were identified in the December 29 and 30, 1998 inspection and stated in the untitled letter sent to your firm dated March 10, 1999. The FDA investigator also provided your firm with a copy of the Domestic Seafood HACCP Report (Form FDA 3501) and the Form FDA 483, which presents his evaluation of

your firm's performance regarding various aspects of the HACCP and CGMP requirements. The Form FDA 483 is enclosed for your review. The observations of concern to us are as follows:

- You must have a HACCP plan that lists the critical control points, to comply with 21 CFR, Part 123.6(c)(2). Your firm's HACCP plan for cooked, ready-to-eat crabmeat does not list the critical control points (CCPs) of time and temperature abuse for controlling pathogen growth;
- You must have a HACCP plan that lists the critical limits that must be met, to comply with 21 CFR, Part 123.6(c)(3). However, your firm's HACCP plan for cooked, ready-to-eat crabmeat does not list the critical limit for time and temperature CCPs to control pathogen growth;
- You must have a HACCP plan that lists the monitoring procedures for each CCP to comply with 21 CFR, Part 123.6(c)(4). However, your firm's HACCP plan for cooked, ready-to-eat crabmeat does not list the monitoring procedures or the frequency at the cooking, cooling, backing, picking, and packing CCPs to control pathogen growth; and,
- You must establish and implement a record keeping system in your HACCP plan, to comply with 21 CFR, Part 123.6(b). Your firm must record monitoring observations at each CCP and critical limit to control the pathogen hazards listed in your HACCP plan for cooked crabmeat.

Objectionable equipment and insanitary conditions as listed on Form FDA 483 and Form FDA 3501 are an indication that sanitation monitoring [21 CFR, Part 123.11(b)] at the firm is inadequate. An effective HACCP system is built upon implementing sanitation standard operating procedures. The noted objectionable insanitary conditions include the following:

- On July 11, 2000, cook room employees handled live crabs then handled cooked crabs, without washing and sanitizing their hands. There were no sanitizing solutions in the cook room;
- At various times on July 12, 2000, there was no traceable amount of iodine in the hand dip solutions located in the picking and packing rooms;
- Plastic crates used to hold and transport cooked crabs were slimy and encrusted with residues from previous operations;
- Approximately 15 live flies were observed in the cooking, picking and packing rooms from July 10 through July 13, 2000;
- Stagnant, standing water was observed approximately seven feet from the cook room door; and,
- Debris was stored within two feet of the processing facility, near the picking and packing room, which provided an attractant to live flies.

As the principal corporate officer, it is your responsibility to assure that your processing plant is operating in compliance with the applicable laws and regulations. It is also your responsibility to assure not only that the current objectionable conditions are corrected, but that adequate policies and procedures are implemented to prevent a recurrence of the problems. Many of these observations are repeat observations from the July 1999 and December 1998 inspections.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the applicable regulations. You should take prompt action to correct these deviations. Failure to promptly correct the deviations may result in regulatory action without further notice. These include seizure and/or injunction.

We are aware that at the close of the inspection you made a verbal commitment to correct the observed deficiencies. Our investigator documented this commitment by annotation of the FDA Form 483. You should notify this office in writing, within 30 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 30 working days, state the reason for the delay and the time within which corrections will be completed.

Your reply, relating to these concerns, should be addressed to the U.S. Food and Drug Administration, Attention: Patricia K. Schafer, Director, Compliance Branch, 6600 Plaza Drive, Suite 400, New Orleans, Louisiana 70127. If you have any questions regarding the implementation of the HACCP regulations, you may contact Ms. Schafer at (504) 253-4519.

Sincerely,



Carl E. Draper  
District Director  
New Orleans District

Enclosure: Form FDA 483