



DEPARTMENT OF HEALTH AND HUMAN SERVICE

Public Health Service

Food and Drug Administration
New Orleans District
Southeast Region
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New Orleans, LA 70122

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December 9, 1999

WARNING LETTER NO. 2000-NOL-05

**FEDERAL EXPRESS
OVERNIGHT DELIVERY**

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

Dear Mr. Thomas:

On July 7,8,9 and 12, 1999, 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* (CFR), Part 123 and the Current Good Manufacturing Practice (CGMP) regulations for foods 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 1999 inspection, the FDA investigator observed shortcomings in your system that were similar to those pointed out in the December 29 and 30, 1998, inspection, and stated in the untitled letter sent to your firm on 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 observation of concern to us is as follows:

- You must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, in order to comply with Title 21, CFR, Part 123.6(b). Your firm does not have a HACCP plan for ready-to-eat crabmeat to control the food safety hazard of pathogens.

Objectionable equipment and insanitary conditions as listed on Form FDA 483 and Form FDA 3501 are an indication that sanitation monitoring [Title 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 includes the following:

- On July 7 and 8, 1999, backing employees repeatedly handled insanitary trashcans and doorknobs, and then handled cooked crabs without sanitizing their hands;
- On July 8, 1999, the pack/weigh employee twice handled crabmeat without sanitizing his hands;
- On July 8, 1999, a backing employee removed two crabs off the picking room floor, backed them and placed the de-backed crabs into the backed crab crate;
- On July 8, 1999, both of the cooking employees repeatedly handled live crabs, wooden crates, doorknobs and hoist control, then handled cooked crabs without first washing or sanitizing their hands;
- On July 8, 1999, three out of four hand dip stations on the picking table had non-detectable amounts of iodine;
- Three out of four picking employees' knives had decorative etching including one wrapped with electrical tape with blackish residues from previous operations;
- On July 7 and 8, 1999, approximately 100 live flies were observed in stagnant water, stacked wooden crates and tall grass that were located six feet from the cook room door and frame, and approximately 20 live flies were observed in the backing/picking/packing rooms;
- On July 8, 1999, live crabs were stored four inches from cooked crabs in the cook room. Approximately 50 live flies were observed on live crabs and cooked crabs;
- On July 8, 1999, plastic crates used to hold backed crabs were not sanitized between use, and residues from previous operations were observed on plastic crates;
- On July 8, 1999, cooked crabs in the cooked crab cooler rested on a brownish-residue encrusted metal cart;

- A chain used to hoist crabs in and out of the cooler repeatedly touched live crabs and cooked crabs without being re-sanitized;
- On July 7 and 8, 1999, two out of four picker did not wear hair restraints;
- An entry/exit door leading from the pick room to the parking lot had an approximate one-inch crack between the door and frame; and,
- An entry/exit door leading from picking room to the dock and trash storage area had an approximate three-fourths inch gap between the door and the floor.

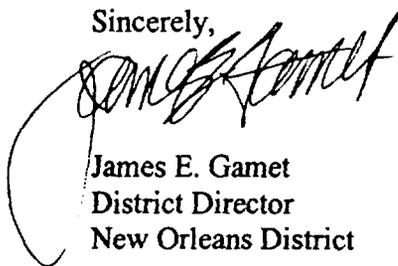
As the principal corporate officer, it is your responsibility to assure that your processing plant is operating in compliance with the applicable laws and regulations. It is also your responsibility to assure not only that the current objectionable conditions are corrected, but that adequate policies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

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 15 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 15 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, Compliance Officer, 6600 Plaza Drive, New Orleans, Louisiana 70127. If you have any questions regarding the implementation of the HACCP regulations, you may contact Ms. Schafer at (504) 253-4500.

Sincerely,



James E. Gamet
District Director
New Orleans District

Enclosure: Form FDA-483