



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 70127

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11/29/99  
HFI-35  
P. Prudhomme

September 13, 1999

**WARNING LETTER NO. 99-NOL-41**

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

Jimmy D. Prudhomme, Owner/President  
Crawfish Enterprises, Inc.  
146 Highway 758  
Eunice, Louisiana 70535

Dear Mr. Prudhomme:

On May 11, 1999, a U.S. Food and Drug Administration (FDA) investigator conducted an inspection of your crawfish processing facility, located at 146 Highway 758, Eunice, 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. During this inspection, our investigator documented numerous deviations from the HACCP regulations, CFR, Part 123.6. This causes your finished ready-to-eat product, vacuum packaged crawfish, 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 May 1999 inspection, the FDA investigator observed shortcomings in your system that were similar to those pointed out in the March 16-18, 1998, inspection and stated in the untitled letter sent to your firm on June 29, 1998. 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 her 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:

- ◆ Failure to control the hazard of Clostridium botulinum growth/toxin formation in vacuum packaged, fresh refrigerated crawfish tailmeat, as required by Title 21, CFR, Part 123.6(b);
- ◆ Failure to follow monitoring procedures provided in your written HACCP plan, as required by Title 21, CFR, Part 123.6(b) and (c)(4). Specifically, you failed to measure and record the cook time and temperature for every batch of crawfish cooked to control the hazard of pathogen growth;
- ◆ Failure to maintain HACCP records and sanitation records for each day of processing, as required by Title 21, CFR, Part 123.6(c)(7) and 21 CFR, Part 123.11(b);
- ◆ Failure to have adequate HACCP cooking logs and sanitation logs in that the logs did not record the actual time of the activities, and the cooking logs had no documentation of review, as required by Title 21, CFR, Part 123.9(a)(2); and,
- ◆ Failure to adequately monitor sanitation conditions and practices during processing, as required by Title 21, CFR, Part 123.11(b), specifically:
  - (1) Improper maintenance, cleaning and sanitizing of food contact surfaces, i.e., encrusted residues on equipment, sanitizer concentration too low, etc;
  - (2) Cross contamination, i.e., employees touched insanitary items, trash cans, etc., and peeled crawfish without washing and sanitizing their hands; peelers wore aprons outside and during lunch without changing before returning to the peeling room, etc.; and,
  - (3) Maintenance of hand sanitizing facilities, i.e., diluted or ineffective sanitizing solutions provided.

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.

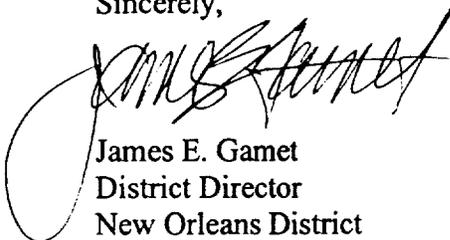
The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the applicable regulations. You should take prompt action to correct these deviations. Failure to promptly correct 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 Form FDA 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, 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) 240-4519.

Sincerely,



James E. Gamet  
District Director  
New Orleans District

Enclosure: Form FDA 483