



DEPARTMENT OF HEALTH AND HUMAN SERVICES, FOOD AND DRUG ADMINISTRATION

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June 17, 1998

**WARNING LETTER NO. 98-NOL-24**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Mr. E. James Bernard, Jr. President  
J. Bernard Seafood Processing, Inc.  
Post Office Box 623  
Cottonport, Louisiana 71327

Dear Mr. Bernard:

During an inspection of your crawfish processing facility, located at 204 Bryan Street, Cottonport, Louisiana, on April 20-22, 1998, our investigator documented numerous objectionable insanitary conditions. This causes your product, crawfish tail meat, to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act).

Our inspection disclosed numerous insanitary conditions and practices, including:

- 1) Residues from previous operations encrusted on numerous equipment, including the cart for cooked crawfish, vacuum packing machine, colanders, picking table drain holes, rake for cooked crawfish, and trays used to hold cooked crawfish tail meat;
- 2) No soap present in the packing room for colanders which were returned to the pickers while still containing residual material;
- 3) No available chlorine at 9:00 AM on April 20, 1998, in the solution used to sanitize the rake and shovel used on cooked crawfish;
- 4) Cook employee routinely handling live crawfish, trash cans, water hoses and then handling cooked crawfish without washing and sanitizing his hands, and, on one occasion, entering the peeling room from outside and handled cooked crawfish without washing and sanitizing his hands;
- 5) 13 of 16 peelers returned to the peeling room after lunch on April 21, 1998, and failed to wash their hands, 10 of these peelers also failed to sanitize their hands;

- 6) Peelers sneezing into the back of their hands or rubbing their noses/face and continued peeling crawfish;
- 7) Numerous other objectionable employee practices including employees handling stools, wearing jewelry, wearing loose clothing and one peeler with no apron;
- 8) Five live flies in the cook room during cooking operations, one fly in direct contact with the cooked crawfish chute;
- 9) Several structural defects creating openings from the plant to the outside; and,
- 10) Eight apparent roach excreta pellets on top of the crawfish chute.

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 Good Manufacturing Practice Regulations.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. This may include seizure and/or injunction.

You should notify this office in writing, within 15 working days of receipt of this letter, of the steps taken to correct the noted violations, including an explanation of each step taken to prevent the recurrence of similar violations. If corrective action can not be completed within 15 working days, state the reason for this delay and the time within which the corrections will be completed.

Your response should be directed to Richard D. Debo, Compliance Officer, U.S. Food and Drug Administration, 4298 Elysian Fields Avenue, New Orleans, Louisiana, 70122-3896, telephone number (504) 589-7166. Should you have any questions concerning the contents of this letter, or if you desire a meeting with the agency staff, do not hesitate to contact Mr. Debo.

In addition, this inspection of April 20-22, 1998, was conducted to determine compliance with FDA's seafood processing regulations (21 CFR 123) and the Good Manufacturing Practices requirements for foods (21 CFR 110).

The seafood processing regulations, which became effective on December 18, 1997, require you to 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 operations to eliminate or minimize the likelihood the identified hazards will occur. These are the kinds of measures 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 inspection, the FDA investigator observed shortcomings in your system that, upon preliminary review, appear to be deviations from the principles of HACCP and the significant requirements of the program. The FDA investigator also provided you with a copy of the Domestic Seafood HACCP Report (form FDA 3501) and the FDA 483 which presents his/her evaluation of your firm's performance regarding various aspects of the HACCP and GMP requirements. The observations of concern to us are as follows:

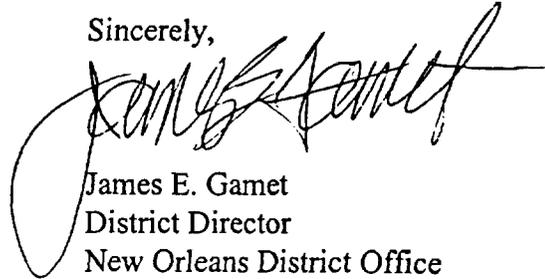
- 1) There was no written HACCP Plan available for review;
- 2) No documentation that the cooking process was adequate to control the hazard of pathogen survival;
- 3) Actual cook times of less than the firm's stated cook times and inaccurate entries on the Boiling Log;
- 4) Lack of preventative measures to control the hazards pathogen growth and C. botulinum growth/toxin formation;
- 5) The firms Slush Log (ice slush) failed to document that the product remained in the ice slush for the required 30 minutes;
- 6) No documentation of the monitoring of all required sanitation items; and,
- 7) Monitoring records do not have the signature or initials of the person performing the operations, and are not signed and dated by the reviewer.

We encourage you to make the necessary improvements as soon as possible. However, if you disagree with FDA's preliminary assessment of deviations from HACCP Regulations, you should explain how your system identifies hazards and implements controls in a manner the agency should regard as complying with the regulations. We understand that HACCP systems may be uniquely tailored to meet the circumstances of the individual processor and there may be more than one right way to control hazards.

In either case, it is essential that you respond to this office on this matter within 30 working days of the receipt of this letter. Upon receipt of a timely response, we will work with you to resolve any outstanding issues associated with your HACCP system. If we do not hear from you, or if your response is inadequate, we will assume our preliminary conclusions are correct and we will schedule a follow-up inspection for the immediate future.

Your reply, relating to these concerns, should be directed to the Food and Drug Administration, Attention: Richard D. Debo, 4298 Elysian Fields Avenue, New Orleans, Louisiana 70122-3896. If you have questions regarding the implementation of the HACCP regulation or the application of HACCP to your specific process, you may contact Mr. Debo at (504) 589-7166 for answers and/or direction towards guidance and sources of training in achieving compliance.

Sincerely,

A handwritten signature in black ink, appearing to read "James E. Gamet", written over a large, stylized flourish that loops back to the left.

James E. Gamet  
District Director  
New Orleans District Office

Enclosure: FDA-483

/tjt