



DEPARTMENT OF HEALTH AND HUMAN SERVICE

Public Health Service

Purged, PHS, 7/1/99 *HFI-35*

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Food and Drug Administration
New Orleans District
Southeast Region
4298 Elysian Fields Ave.
New Orleans, LA 70122

Telephone: 504-589-6341
FAX: 504-589-6360

June 29, 1999

WARNING LETTER NO. 99-NOL-35

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Mr. E. James Bernard, Jr., President
J. Bernard Seafood Processing, Inc.
204 Bryan Street
Cottonport, Louisiana 71327

Dear Mr. Bernard:

On April 20-21, 1999, a U.S. Food and Drug Administration (FDA) investigator conducted an inspection of your crawfish and wholesale seafood processing facility, located at 204 Bryan Street, Cottonport, 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 21 CFR, Part 110. Our investigator documented numerous deviations from these regulations. This causes your crawfish products 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" (CCP) 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 April 20-21, 1999 inspection, the FDA investigator observed shortcomings in your system that were similar to those pointed out in the April 20-22, 1998, inspection and stated in the letter sent to your firm on June 17, 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 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:

- ◆ Failure to have and implement a HACCP plan to address the hazard of *C. botulinum* growth and toxin formation due to time and temperature abuse for refrigerated, vacuum-packed bags of cooked crawfish tail meat during normal conditions of distribution and storage, as required by 21 CFR, Part 123.6(b);
- ◆ Failure to have and implement a HACCP plan to address the hazard of pathogen growth and toxin formation as a result of time and temperature abuse for the cooked crawfish tail meat between the cook step and the ice slush step, as required by 21 CFR, Part 123.6(b). In a related matter, significant time and temperature abuse was observed when batches of cooked crawfish product were held up to two and a half hours at temperatures ranging from 75 degrees to 77 degrees Fahrenheit;
- ◆ Failure to consistently implement appropriate record keeping procedures at the CCP of the ice bath as required by 21 CFR, Part 123.6(b) and 123.6(c)(7), e.g., the firm did not document that bags of crawfish tail meat remained in the ice slush for [REDACTED] per the firm's HACCP plan;
- ◆ Failure to consistently implement appropriate record keeping procedures at the CCP of finished product storage, as required by 21 CFR, Part 123.6(b) and 123.6(c)(7), e.g., the firm did not complete the daily Cooler Logs for monitoring storage conditions of crawfish tail meat in the cooler per the firm's HACCP plan;
- ◆ Failure to maintain sanitation control records since the June 1998 production, as required by 21 CFR, Part 123.9a(4) and 123.11(c);
- ◆ Failure to record observations on HACCP monitoring and sanitation records at the time the observations were made, as required by 21 CFR, Part 123.6(c)(7) and 123.11(c)(7), e.g., the ice log notations were made at the end of the day and the sanitation records were made as much as seven days later;
- ◆ Failure to adequately monitor sanitation in accordance with 21 CFR, Part 123.11(b) as evidenced by:
 - ◆ Numerous live flies inside the plant, on cooked product, on a box containing an open bag of seafood boil seasoning mix, product contact equipment, on the walls, wooden pallets, and floors;
 - ◆ A dead fly entangled in spider webs inside the cooked crawfish chute in the cook room;
 - ◆ Water dripped from the drainpipe under the refrigerator unit in the cooler onto cardboard boxes containing in-shell raw oysters;

- ◆ Peeler employee picked up two handfuls of cooked crawfish from the floor, placed them back on the table with other cooked crawfish, and then peeled the crawfish;
- ◆ Gritty brown and black residues from previous operations were encrusted on the cart used to hold and transport cooked crawfish in the peeling room;
- ◆ A rusty screw wrapped with soiled string and inserted through a hole in the flap at the end of the cooked crawfish chute, and the string contacted cooked crawfish;
- ◆ Pieces of crawfish shell and legs, grass, and black extraneous material from previous operations on all three peeling tables;
- ◆ Yellowish and orange residues from previous operations were encrusted on the peeling tables, in the plastic covering the weigh scales keypad, on and around strips on the edges of the vacuum-pack equipment, and on the metal runners of the window sill located between the peeling and packing rooms and used to hold colanders of crawfish tail meat;
- ◆ Prior to handling cooked product, seven of seven peelers returned to peeling room and washed, but did not sanitize their hands;
- ◆ One peeler partially covered her mouth and coughed for about three minutes over cooked crawfish. She continued peeling cooked crawfish and did not wash or sanitize her hands;
- ◆ Numerous other objectionable employee practices including employees handling stools, wearing loose clothing, rubbing their noses, touching their eyeglasses or hair net without washing or sanitizing their hands.

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.

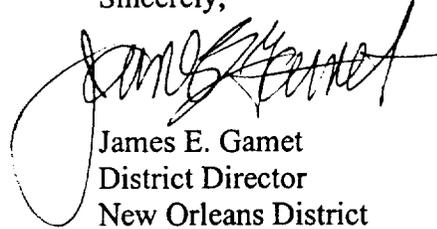
We are aware that at the close of the inspection you made a verbal commitment to correct the observed deficiencies. Our investigator documented this commitment by annotation of the Form FDA 483. You should notify this office in writing, within 15 working days of receipt of this letter, of the specific 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

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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, 4298 Elysian Fields Avenue, New Orleans, Louisiana 70122-3896. If you have any questions regarding the implementation of the HACCP regulations, you may contact Ms. Schafer at (504) 589-7166.

Sincerely,



James E. Gamet
District Director
New Orleans District

Enclosure: FDA 483