



DEPARTMENT OF HEALTH AND HUMAN SERVICE

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

Telephone: 504-253-4519  
Facsimile: 504-253-4520

August 4, 2004

**WARNING LETTER NO. 2004-NOL-32**

**FEDERAL EXPRESS  
OVERNIGHT DELIVERY**

Mrs. Trina T. Nguyen, Owner  
DIP Seafood Mudbugs  
1870 Dauphin Island Parkway  
Mobile, Alabama 36605

Dear Mrs. Nguyen:

U.S. Food and Drug Administration (FDA) investigators inspected your firm, located at 1870 Dauphin Island Parkway, Mobile, Alabama, on March 23, 24, 26 and April 1, 2004. We found you have serious deviations from the Fish and Fishery Products Hazard Analysis and Critical Control Point regulation (Seafood HACCP regulation), Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part, renders the fishery product adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. Section 342(a)(4). Accordingly, your cooked, ready-to-eat crawfish is adulterated, as the crawfish has been prepared, packed, or held under insanitary conditions whereby it may have been rendered injurious to health. You may find the Act and the Seafood HACCP regulation through links in FDA's home page at [www.fda.gov](http://www.fda.gov). In addition to the HACCP deviations, our investigators documented labeling deviations that cause your packaged, cooked, ready-to-eat crawfish to be misbranded within the meaning of 21 U.S.C. Section 343.

The deviations are as follows:

- You must implement the record keeping system you listed in your HACCP plan to comply with 21 CFR 123.6(b). However, your firm did not record monitoring observations at the "cooling" and "refrigerated storage" critical control points (CCP) to control pathogen growth as listed in your HACCP plan for cooked, ready-to-eat crawfish from January 2004 through March 2004. You did not document the temperature of your cooked crawfish after [redacted] and [redacted] hours for [redacted] batches of cooked crawfish as required by your HACCP plan at the "cooling" CCP. For the month of January 2004, you failed to record a daily, visual temperature of the cooler used to store cooked crawfish at the "refrigerated storage" CCP as required by your HACCP plan.



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- You must take corrective action when a deviation from a critical limit occurs to comply with 21 CFR 123.7. Your corrective action must ensure no product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation and the cause of the deviation is corrected. However, your firm did not take any corrective action to control pathogen growth when your process for cooked, ready-to-eat crawfish deviated from your critical limit at the “cooling” and “refrigerated storage” CCPs.
  - (1) Your firm repeatedly failed to take corrective action at the “refrigerated storage” CCP when your firm’s temperature recording device for the storage cooler reported a temperature that exceeded your critical limit of “**72°F** or less.” From January 6 to March 26, 2004, your firm’s temperature recording device for the storage cooler documented at least seventy-seven instances during which the temperature of the cooler exceeded the critical limit of “**72°F** or less.”
  - (2) Your firm failed to take corrective action when the temperature observed at the “cooling” CCP exceeded the critical limit of “**72°F** or below within **2** hours.” Specifically, no corrective action was documented when you recorded 72°F, 74°F, and 78°F for three consecutive batches of cooked, ready-to-eat crawfish on February 18, 2004.
- You must monitor sanitation conditions and practices adequately during processing to comply with 21 CFR 123.11(b). However, your firm did not monitor adequately the prevention of cross-contamination from insanitary objects to food and exclusion of pests from the facility as evidenced by the following:
  - (1) On March 23, 24, and 26, 2004, your firm failed to properly clean and sanitize the cooked crawfish cooling table after four live and two dead insects were observed on the table. Cooked crawfish were placed directly onto the cooling table after the insects contacted the table.
  - (2) Your food processing equipment was not maintained in a sanitary condition to prevent food from becoming adulterated. For example, a rusted chain routinely came into direct contact with cooked crawfish and the cooling table during crawfish processing operations.
  - (3) Your equipment and utensils used in the processing of cooked crawfish are not constructed in a way to allow for cleaning and sanitizing prior to use. The seam juncture between the lower and upper levels of the cooked crawfish cooling table was roughly welded and contained rust. Cooked crawfish were observed to come into direct contact routinely with this rusty, roughly welded seam during crawfish processing operations. Two metal paddles used to stir crawfish during the cooking and cooling operations also were roughly welded at the seam of the shaft/handle and the paddle.

During the inspection, our investigator observed unlabeled cartons and plastic bags used to package ready-to-eat crawfish. Based on the investigators’ photographs and

observations, we have concluded your product is misbranded under Section 403 of the Act as follows:

- The product is misbranded within the meaning of Section 403(e)(1) of the Act because the cartons fail to bear the name and place of business of the manufacturer, packer, or distributor;
- The product is misbranded within the meaning of Section 403(e)(2) of the Act because the cartons fail to bear a net quantity of contents statement;
- The product is misbranded within the meaning of Section 403(i)(1) of the Act because the cartons fail to bear a statement that identifies the commodity; and,
- The product is misbranded within the meaning of Section 403(i)(2) of the Act because the cartons fail to bear a list of ingredients. The product is further misbranded under Section 403(k) of the Act because the ready-to-eat crawfish is formulated with "[REDACTED]" labeled as containing the certified colors "YELLOW 6" and "YELLOW 6 LAKE," and/or "[REDACTED]" labeled as containing the certified color "YELLOW 6." Under 21 CFR 101.22(k)(1), certified color additives must be declared individually in the ingredient statement by their common or usual names (e.g., FD&C Yellow No. 6, FD&C Yellow 6 Lake). The common or usual name may be abbreviated to omit the "FD&C" prefix and the term "No." (e.g., Yellow 6, Yellow 6 Lake).

We may take further action if you do not correct these violations promptly. For instance, we may take further action to seize your product and/or enjoin your firm from operating. Please respond in writing within 15 working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You should include in your response documentation, such as HACCP and sanitation monitoring records or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect you to explain the reason for your delay and state when you will correct any remaining deviations.

We recognize at the close of the inspection you made a verbal commitment to correct the observed deficiencies; however, we have found deviations from the Seafood HACCP regulation in previous inspections of your facility. This letter may not list all the deviations at your facility. You are responsible for ensuring your processing plant operates in compliance with the Act, the Seafood HACCP regulation, and the Current Good Manufacturing Practice regulation (21 CFR 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your response to the attention of Cynthia R. Crocker, Compliance Officer, 100 W. Capitol Street, Suite 340, Jackson, Mississippi 39269. If you have questions, you may contact

Ms. Crocker at (601) 965-4581, extension 106, for answers, direction to guidance, and/or sources of training for achieving compliance.

Sincerely,

A handwritten signature in black ink, appearing to read "H. Tyler Thornburg", with a long, sweeping flourish extending to the right.

H. Tyler Thornburg  
District Director  
New Orleans District

Enclosure: Form FDA 483