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

Telephone: 504-253-4519
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May 14, 2001

WARNING LETTER NO. 2001-NOL-23

**FEDERAL EXPRESS
OVERNIGHT DELIVERY**

Mrs. Trina T. Nguyen, President
Dauphin Island Parkway Seafood, Inc.
4020 Dauphin Island Parkway
Mobile, Alabama 36605

Dear Mrs. Nguyen:

We inspected your firm, located at 4020 Dauphin Island Parkway, Mobile, Alabama, during April 18-20, 2001. During our inspection, we found that you have serious deviations from Seafood Hazard Analysis Critical Control Point (HACCP) regulations, Title 21, *Code of Federal Regulations* (21 CFR), Part 123, and the Current Good Manufacturing Practice (CGMP) in manufacturing, packing, or holding food for human consumption, 21 CFR 110. These deviations, some of which were previously brought to your attention, cause your cooked, ready-to-eat crawfish products to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (Act). You can find this Act and the Seafood HACCP regulations through links in FDA's homepage at <http://www.fda.gov>.

The deviations were as follows:

- You must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(b). However, your firm does not have a HACCP plan for cooked, ready-to-eat crawfish product to control the food safety hazard(s) of pathogen growth and toxin development during processing and subsequent storage. Additionally, our investigator observed that you did not monitor the cook temperature and time of all batches of cooked, ready-to-eat crawfish observed produced during April 17-18, 2001.
- You must adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR 123.11(b). However, your firm does not monitor the condition and cleanliness of food contact surfaces, the prevention of cross-contamination from insanitary objects, the maintenance of employee sanitation practices, the protection of food and food packaging material from adulteration, the proper labeling and storage of food product, or the exclusion of pests in your facility.

- You must maintain sanitation control records that at a minimum document the monitoring and correcting of conditions and practices during processing, to comply with 21 CFR 123.11(c). However, your firm does not maintain any sanitation records.
- You must maintain sanitary processing operations, including general pest control, to comply with 21 CFR 110.35(c). However, evidence of rodent activity, specifically rodent excreta, was observed in the crawfish processing room. Additionally, live cockroaches, flies, and ants were observed in the crawfish processing room.
- You must maintain the physical condition of your building facility, i.e. in good repair, particularly areas adjacent to your processing area, to comply with 21 CFR 110.20(b). However, several openings in the processing room facility walls, which led directly to the outdoors, were documented.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your products and/or enjoin your firm from operating.

We are aware that at the close of the inspection you made a verbal commitment to correct observed deficiencies, items #7-11, on the Form FDA 483.

Please respond to this office in writing within three (3) weeks from receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as: your HACCP plans for cooked crawfish, copies of your sanitation monitoring records, copies of corrective action data, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect you will explain, within three (3) weeks from receipt of this letter, the reason for your delay and state when you will correct any remaining deviations.

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 regulations, and the Current Good Manufacturing Practice regulations. 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 reply Ms. Rebecca A. Asente, Compliance Officer, at the above address. If you have questions regarding any issue in this letter, please contact Ms. Asente at (504) 253-4519.

Sincerely,



Carl E. Draper
District Director
New Orleans District

Enclosure: FDA Form 483