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

Telephone: 504-253-4519
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July 25, 2003

WARNING LETTER NO. 2003-NOL-21

**FEDERAL EXPRESS
OVERNIGHT DELIVERY**

Leona T. Baudin, Owner
Baudin's Sausage Kitchen, Inc.
4636 Bridge Street Highway
St. Martinville, Louisiana 70582

Dear Ms. Baudin:

On March 17 - 19, 2003, we inspected your seafood processing facility, located at 4636 Bridge Street Highway, St. Martinville, Louisiana. We found that you have serious deviations from the Seafood Hazard Analysis and Critical Control Points (HACCP) Regulations, Title 21, *Code of Federal Regulations*, Part 123 (21 CFR 123) - Fish and Fishery Products. 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 products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C § 342(a)(4). Accordingly your vacuum-packaged crawfish boudin sausage and crawfish boudin balls are adulterated, in that they have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health. You may find the Act and the Seafood HACCP regulations through links in FDA's Internet home page at <http://www.fda.gov>.

The deviations were as follows:

- You must conduct, or have conducted for you, a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and to identify preventative measures that you can apply to control those hazards to comply with 21 CFR 123.6(a). In addition, you must verify that your HACCP plan is adequate to control the food safety hazards that are reasonably likely to occur and that the plan is being effectively implemented to comply with 21 CFR 123.8(a).

Your HACCP plan correctly identified *C. botulinum* as a hazard, but did not address the formation of *C. botulinum* toxin during the shelf-life of the product once it leaves your facility, e.g., during product distribution and storage by consumers, under normal and moderate abuse conditions. The lack of controls in the plan to prevent toxin formation after

finished product storage in your plant indicates that you did not properly perform the hazard analysis or verify the adequacy of your HACCP plan.

Clostridium botulinum toxin formation would not be reasonably likely to present a significant hazard during the expected shelf-life of refrigerated, vacuum-packaged products under conditions of normal and moderate temperature abuse, provided conditions such as the following are met:

- a. The product bears a validated time temperature integrator ("TTI"), including instructions as to its interpretation, as a monitoring device that is appropriate for control of *C. botulinum* toxin formation on each retail or consumer package. A TTI is a device that provides a clear indication to the retailer/consumer, by color change or other means, that the product may have been exposed to a time and temperature combination that could result in an unsafe product; or
 - b. The product is sealed in packaging material with a final thickness that, at 24°C and one atmosphere of pressure, has an oxygen transmission rate of more than 10,000 cubic centimeters per square meter per 24 hour period of time (10,000 cc/m²/24hr at 24°C and 1 atm); or
 - c. The product is frozen immediately after processing, maintained frozen throughout distribution, and labeled prominently to be held frozen and to be thawed under refrigeration immediately before use (e.g., "Important, Keep Frozen, Thaw Under Refrigeration Immediately Before Use").
- You must have a HACCP plan that, at a minimum, lists monitoring procedures for each critical control point to comply with 21 CFR 123.6(c)(4). However, your firm’s HACCP plans for vacuum-packaged crawfish boudin and crawfish boudin balls list a monitoring frequency at the storage critical control point of [REDACTED] that is not adequate to control pathogen growth and toxin formation. The cooler and freezer temperatures should be monitored on a continuous basis. More information can be found on page 158 of the *Fish and Fisheries Products Hazards & Controls Guidance: Third Edition*. Continuous temperature monitoring requires the installation of a temperature-recording device to provide monitoring records of the cooler temperatures during non-business hours, holidays, and weekends. This was brought to your attention in our letter dated October 1, 2002.
 - You must have a HACCP plan that, at a minimum, lists the critical limits that must be met to comply with 21 CFR 123.6(c)(3). A critical limit is defined in 21 CFR 123.3(c) as “the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard.” However, your firm’s HACCP plan for Crawfish Boudin does not list a critical limit at the Cooking/Mixing/Casing critical control point for time of exposure for cooking the casing. The time of exposure is the length of time to which the casing is exposed as it passes through the cooking unit at a temperature designed to cook the casing as specified in your firm’s processing (cooking) plan.

- You must take corrective action when a deviation from a critical limit occurs to comply with 21 CFR 123.7(a). Sections 123.7(b) and (c) require that a corrective action ensures: (1) no product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation and (2) the cause of the deviation is corrected. However, the corrective action listed in your crawfish boudin sausage and crawfish boudin balls HACCP plan, [REDACTED] does not describe the steps to be taken to ensure that the cause of the deviation is corrected.

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 [REDACTED], Manager, and [REDACTED], Assistant Manager, promised to purchase equipment to continuously monitor the temperature of the cooler and freezer during the discussion at the conclusion of the inspection. 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 copies of your revised labeling for vacuum-packaged crawfish boudin or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain 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 that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Current Good Manufacturing Practice regulations, 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 reply to the U.S. Food and Drug Administration, Attention: Mark W. Rivero, Compliance Officer, at the address above. If you have questions regarding any issue in this letter, please contact Mr. Rivero at (504) 253-4514.

Sincerely,


Carl E. Draper
District Director
New Orleans District