

HFT-3
M25817Food and Drug Administration
New Orleans District
Southeast Region
4298 Elysian Fields Ave.
New Orleans, LA 70122Telephone: 504-589-6341
FAX: 504-589-6360

April 30, 1999

WARNING LETTER NO. 99-NOL-25**FEDERAL EXPRESS**
OVERNIGHT DELIVERY

Mrs. Paula A. McDaniel, Co-Owner
Belle River Seafood
1225 Highway 70
Belle River, Louisiana 70339

Dear Mrs. McDaniel:

On March 2-3, 1999, U.S. Food & Drug Administration (FDA) investigators conducted an inspection of your specialty seafood and catfish processing plant, located at 1225 Highway 70, Belle River, Louisiana. The investigators documented that your firm was not in compliance with FDA's seafood processing regulations and the Good Manufacturing Practices requirements for foods. This causes your finished products to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act), in that you failed to operate in accordance with the requirements of Title 21, *Code of Federal Regulations*, Part 123 (21 CFR Part 123) covering the Processing of Fish and Fishery products and the Current Good Manufacturing Practice (CGMP) regulations for foods (21 CFR Part 110).

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" 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 been 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 March 1999 inspection, the FDA investigators observed shortcomings in your system that were identical to those pointed out in the August 20-21, 1998, inspection and stated in the untitled letter sent to your firm on September 14, 1998. The FDA investigators also provided your firm with a copy of the Domestic Seafood HACCP Report (Form FDA-3501) and the Form

FDA-483, which presents their 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 observation of concern to us is as follows:

1. Failure to have and implement a written HACCP plan. Our inspection found at least one or more food safety hazards with your specialty seafood products: shrimp, crab, crawfish, patties, balls, etc. The regulations in 21 CFR Part 123.6(a) require that you perform a hazard analysis for each seafood product you manufacture. When you identify one or more food safety hazards associated with a product, 21 CFR Part 123.6(b) requires that you have and implement a HACCP plan. Information on what a HACCP plan should include is detailed in 21 CFR Part 123.6(c).

We are particularly concerned with your failure to implement a HACCP plan to control pathogen growth/toxin formation in all your specialty products, and to detect sulfites added to the shrimp used in your shrimp specialty products. Without systematic control measures for these hazards, toxin formation may occur in your products during processing, packaging, and storage, and sensitive consumers may be exposed to undeclared sulfites in shrimp products.

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.

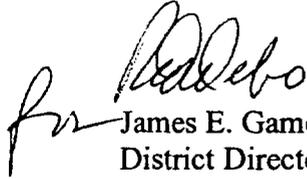
The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the applicable regulations. You should take prompt action to correct these deviations. Failure to promptly correct the deviations may result in regulatory action without further notice. These include seizure and/or injunction.

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 corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which corrections will be completed.

HACCP sanitation is covered under 21 CFR 123.11. FDA recommends that you have and implement a written sanitation operating procedure. You are required to monitor aspects of sanitation as they apply to your firm. Additionally, you are required to document the monitoring of sanitation and any corrections you take as a result of your monitoring.

Your reply, relating to these concerns, should be addressed to the U.S. Food and Drug Administration, Attention: Carolyn S. Olsen, 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. Olsen at (504) 589-7166.

Sincerely,

A handwritten signature in black ink, appearing to read "James E. Gamet", is written over the typed name.

James E. Gamet
District Director
New Orleans District

Enclosure: FDA-483