

FOI message
HFI-35
1/1/99Food and Drug Administration
New Orleans District
Southeast Region
6600 Plaza Drive, Suite 400
New Orleans, LA 70127Telephone: 504-240-4500
FAX: 504-240-4568

September 29, 1999

WARNING LETTER NO. 99-NOL-48**FEDERAL EXPRESS
OVERNIGHT DELIVERY**

Robert J. Collins, Owner
Bobby Collins Seafood
Cheremie Lane
Grand Isle, Louisiana 70318

Dear Mr. Collins:

On May 20 and 24, 1999, a U.S. Food and Drug Administration (FDA) investigator conducted an inspection of your shrimp dock, located on Central Avenue, Grand Isle, 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 CFR, Part 110. Our investigator documented numerous deviations from these regulations. This causes your fresh, raw shrimp packed in ice, 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" 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 May 1999 inspection, the FDA investigator observed shortcomings in your system that were similar to those pointed out in the August 31, 1998, inspection performed by the Louisiana Department of Health and Hospitals, Seafood Sanitation Unit, and stated in the untitled letter sent to your firm on September 11, 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 observation of concern to us is as follows:

- You do not have monitoring records to document sulfite labeling for the boxing and/or tagging critical control point, sulfite identification, in your shrimp in order to comply with Title 21, CFR, Part 123.6(c)(7).

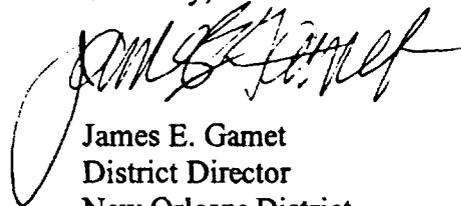
As the principal corporate officer, it is your responsibility to assure that your processing plant is operating in compliance with the applicable laws and regulations. It is also your responsibility to assure not only that the current objectionable conditions are corrected, but that adequate policies 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 FDA Form 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 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: Nicole F. Hardin, Compliance Officer, 6600 Plaza Drive, Suite 400, New Orleans, Louisiana 70127. If you have any questions regarding the implementation of the HACCP regulations, you may contact Ms. Hardin at (504) 240-4500.

Sincerely,



James E. Gamet
District Director
New Orleans District

Enclosure: Form FDA 483