



HFI-35
pungel PK
9/27/99
m2990m

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

Telephone: 504-240-4500
FAX: 504-240-4566

September 23, 1999

WARNING LETTER NO. 99-NOL-43

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Mr. Nolton A. Bailey, Jr., Co-Owner
Bailey's Basin Seafood, Inc.
1683 Front Street & Levee Road
Morgan City, Louisiana 70381

Dear Mr. Bailey:

On March 1-2, 1999, the U.S. Food and Drug Administration (FDA) conducted an inspection of your plant located at 1683 Front Street & Levee Road, Morgan City, Louisiana. The inspection was conducted to determine compliance with FDA's seafood processing regulations. Based on the deviations observed during this investigation, we have concluded that your seafood products are adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act), in that they are prepared, packed and held under conditions whereby they may be rendered injurious to health in that your firm is not in compliance with the regulations of Title 21, *Code of Federal Regulations* (CFR), Part 123. In addition, our inspectors were asked to review any corrective actions implemented in response to FDA's prior inspection of August 18-19, 1998.

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 of your crabmeat and fish processing facility, the FDA investigators observed continued deficiencies in your seafood processing plant that were similar to those pointed out in the August 18-19, 1998, inspection and stated in the Untitled Letter sent

to your firm on September 11, 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 that represent 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 observations of concern to us are as follows:

- You must describe appropriate corrective actions in any corrective action plan that you choose to list in your HACCP plan, in order to comply with 21 CFR 123.7(b). Your corrective action plans for crabmeat at each of the critical control points do not include how you will correct the cause of the deviation from your critical limits. In addition, your corrective action plans for the crabmeat backing, picking and packing, and cooling critical control points do not describe how you will ensure that crabmeat does not enter commerce if it is unsafe or otherwise adulterated, as a result of a deviation from your critical limits; and,
- You must have a HACCP plan that lists the critical limits that must be met, in order to comply with 21 CFR 123.6(b) and 123.6(c). However, your HACCP plan for crabmeat lists a critical limit for the cooling critical control point that does not provide a minimum or maximum value that is adequate to control pathogen growth and toxin formation during storage of the final packed crabmeat.

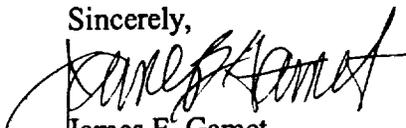
As the principal corporate officer, it is your responsibility to assure that your processing plant is operating in compliance with the applicable laws and regulations. It is also your responsibility to assure not only that the current objectionable conditions are corrected, but that adequate policies 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.

Your reply, relating to these concerns, should be addressed to the U.S. Food and Drug Administration, Attention: Patricia K. Schafer, Compliance Officer, 6600 Plaza Drive, New Orleans, Louisiana 70127. If you have any questions regarding the implementation of the HACCP regulations, you may contact Ms. Schafer at (504) 240-4519.

Sincerely,



James E. Gamet
District Director
New Orleans District

Enclosure: Form FDA 483