



March 29, 2000

WARNING LETTER NO. 2000-NOL-18

OVERNIGHT DELIVERY
FEDERAL EXPRESS

Jason G. Guidry, President
Victory Seafood Processors, Inc.
208 West Elina Street
Abbeville, Louisiana 70510-8239

Dear Mr. Guidry:

On November 1, 2 and 4, 1999, a U.S. Food and Drug Administration (FDA) investigator conducted an inspection of your crabmeat processing facility, located at 208 West Elina Street, Abbeville, 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 crabmeat 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.

Your firm's letter, dated November 9, 1998, stated that all cited observations listed in FDA's untitled letter dated November 3, 1998, had been corrected. However, during the November 1999 inspection, the FDA investigator observed continued deficiencies in your seafood processing plant, some of which were similar to those pointed out in the September 1998, inspection. The FDA investigator also provided you with a copy of the Domestic Seafood HACCP Report (Form FDA 3501) and the Form FDA 483, which present 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 observations of concern to us are as follows:

- You must have a HACCP plan that lists the critical limits that must be met to comply with 21 CFR, Part 123.6(c)(3). However, your firm's HACCP plan for crabmeat does not list the critical limit related to control of belt speed (i.e. revolutions per minute or time necessary for test unit or belt marking to pass through the equipment) during the continuous cooking cycle at the cooking critical control point to control pathogen survival. In addition, you may need to consider product volume on the conveyer belt and/or individual crab size when determining your critical limits at the cooking critical control point.

Your firm's HACCP plan lists a critical limit at the picking critical control point that is not adequate to control pathogen growth and toxin formation resulting from excessive exposure to unrefrigerated conditions. The critical limit does not define the total maximum safe time that the product can be exposed to unrefrigerated conditions during the picking and packing operations.

- You must take appropriate corrective action when a deviation from a critical limit occurs to comply with 21 CFR, Part 123.7(a). However, your firm did not take a corrective action to control pathogen survival when on August 28, 1999, you deviated from the critical limit at the cooking critical control point [REDACTED]
- You must implement the record keeping system listed in your HACCP plan to comply with 21 CFR, Part 123.6(b). However, your firm did not record monitoring observation at the backing crab and backed crab super cooler critical control points to control pathogen growth and toxin formation as listed in your HACCP plan for crabmeat. For example, there is no documentation to show that these critical control points are being monitored at the frequency listed in your HACCP plan.

You must adequately monitor sanitation conditions and practices during processing to comply with 21 CFR, Part 123.11(b). However, your firm did not monitor prevention of cross contamination from insanitary objects to cooked product with sufficient frequency to ensure control as evidenced by:

- The employee who delivered backed cooked crabs to the picking tables would routinely handle unsanitized items, such as the cooler door and the outside of baskets, then handle cooked crabs without first washing or sanitizing hands.
- On November 1, 1999, the employee who delivered cooked crabs to the picking tables was chewing gum.
- Most cooked crab picking employees were not wearing proper hair restraints.

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. However, 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: Mr. Jose R. Hernandez, 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 Mr. Hernandez at (504) 253-4500.

Sincerely,



Lawrence A. D'Hoostelaere, Ph.D.
Acting District Director
New Orleans District

Enclosure: Form FDA 483