



September 18, 2001

WARNING LETTER NO. 2001-NOL-58

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Mrs. Bridget C. Sprinkle, President
Donald Johnson Seafood, Inc.
14980 Bellingrath Road
Codon, Alabama 36523

Dear Ms. Sprinkle:

We inspected your firm, located at 14980 Bellingrath Road, Codon, Alabama, on August 13 - 15, 2001, and found that you have serious deviations from seafood Hazard Analysis Critical Control Point (HACCP) regulations, Title 21, *Code of Federal Regulations*, Part 123 (21 CFR 123). These deviations, some of which were previously brought to your attention, cause your picked crab meat products to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The deviations were as follows:

- You must implement the record keeping system listed in your HACCP plan to comply with 21 CFR 123.6(b). However, your firm did not record monitoring observations at the "Picking and Packing" critical control point to control pathogen growth and toxin formation listed in your HACCP plan for picked crab meat. For example, you did not check nor record the internal temperature of cooked crabs, cooked claws, or picked crab meat at the specified [REDACTED] intervals to assure the temperature was maintained at or below [REDACTED].
- You must implement the monitoring procedures listed in your HACCP plan to comply with 21 CFR 123.6(b). However, your firm did not follow the monitoring procedures of time and internal temperature at the "Backing" critical control point to control pathogen growth and toxin formation listed in your HACCP plan for picked crab meat. For example, you did not conduct the [REDACTED] check to monitor the crab internal temperature at the "Backing" critical control point.
- You must take an appropriate corrective action when a deviation from a critical limit occurs to comply with 21 CFR 123.7(a). However, your firm did not take a corrective action to control pathogen growth and toxin formation when your process for picked crab meat

deviated from your critical limit at the “Backing” critical control point. For example, no corrective action was taken when the internal temperature of cooked crabs and claws exceeded [REDACTED] at the 2:15 observation on July 14, 2001.

- You must record actual values and observations obtained during the monitoring procedures listed in your HACCP plan to comply with 21 CFR 123.6 (c)(7). However, your firm did not monitor the actual cooking time at the “Cooking” critical control point listed in your HACCP plan for picked crab meat. For example, on July 21, 2001, when the cooking began, the projected time the cook should end was entered on the log as the “Time Cook Ends”.
- You must verify that your HACCP plan is adequate to control food safety hazards that are reasonably likely to occur to comply with 21 CFR 123.8(a). However, your firm did not verify the adequacy of the calibration of process-monitoring equipment used at the “Backing” and “Backed Crab and Claw Cooling” critical control points for control of pathogen growth and toxin formation in picked crab meat. For example, the thermometer used to monitor temperatures at these critical control points was routinely incorrectly calibrated on 20 dates during the period of June 12 through August 11, 2001.
- You must verify that your HACCP plan is adequate to control food safety hazards that are reasonably likely to occur to comply with 21 CFR 123.8(d). However, your firm did not document the calibration of the process-monitoring instrument used at the “Picking and Packing” critical control point for control of pathogen growth and toxin formation in picked crab meat. For example, there are no calibration records for the thermometer used to monitor temperatures of cooked crab meat in the picking and packing room.
- You must adequately monitor sanitation conditions and practices during processing to comply with 21 CFR 123.11(b). However, your firm did not monitor prevention of cross contamination with sufficient frequency to ensure control as evidenced by: cooked crabs protruding from perforated baskets repeatedly came into direct contact with the unsanitized wall of the backing room; and, an employee repeatedly contacted the inside of a dirty container and subsequently contacted cooked crabs without first washing and sanitizing his hands.

We may take action without further notice if you do not promptly correct these violations. For instance, we may seize your product(s) and/or enjoin your firm from operating.

We are aware that during our inspection you made a verbal commitment to correct violations observed at your firm. However, please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific steps you have taken to correct the noted violations and prevent their recurrence. You may wish to include in your response documentation such as copies of the Daily Picking and Packing Log, Daily Backing and Cooling Log, the Thermometer Calibration log 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. 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 Ms. Nicole F. Hardin, Compliance Officer, at the above address. If you have questions regarding any issue in this letter, please contact Ms. Hardin at (504) 253-4519.

Sincerely,



Carl E. Draper
District Director
New Orleans District

Enclosure: Form FDA 483