



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

HFI-35 4/5/09 MBG

MBG

Food and Drug Administration
Florida District
555 Winderley Place
Suite 200
Maitland, Florida 32751

Telephone: 407-475-4700
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VIA FEDERAL EXPRESS

WARNING LETTER

FLA-00-40

March 21, 2000

Nguyet Nguyen, president and owner
Florida Crab Company
1121 Hub Drive
Panama City, FL 32402

Dear Ms. Nguyen:

We inspected your firm, located at 1121 Hub Drive, Panama City, Florida on August 4 and 5, 1999 and found that you have serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations, some of which were previously brought to your attention, cause your crabmeat to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act. You can find this Act and the seafood HACCP regulations through links in the FDA's home page at www.fda.gov.

The deviations were as follows:

You must have a HACCP plan that lists the critical limits that must be met, to comply with 21 CFR 123.6(c)(3). However, your firm's HACCP plan for crabmeat lists critical limits at the cooking, picking and packing, and storage critical control points that are not adequate to control pathogen growth and toxin formation. For example, the HACCP plan lists a maximum cook time, but no minimum cook time. The minimum cook time is the value or limit that is critical to delivery of a safe scheduled process. The picking and packing critical control point includes a maximum hold time, but no maximum product temperature. In addition, the finished product storage temperature of 30°F is inappropriate because the product is not stored frozen.

You must have a HACCP plan that lists the food safety hazards that are reasonably likely to occur, to comply with 21 CFR Part 123.6(c)(1). However, your firm's HACCP plan for crabmeat does not list pathogen growth at the picking and packing and finished storage critical control points. In addition to toxin formation by *Staphylococcus aureus*, pathogen growth is also a hazard.

You must have a HACCP plan that lists adequate monitoring procedures for each critical control point, to comply with 21 CFR Part 123.6(c)(4). However, your firm's HACCP plan for crabmeat lists a monitoring procedure at the picking and packing critical control point that does not ensure that the critical limit will be met. In addition, monitoring records that are required to be maintained are described simply as "records" without sufficient detail.

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 consistently record monitoring observations at the cooking, picking and packing, and finished storage critical control points as listed in your HACCP plan to control "pathogen growth" and toxin formation for your crabmeat.

Since you chose to include corrective actions in your HACCP plan, your described corrective actions must be appropriate, to comply with 21 CFR 123.7(b). However, your corrective action plan for crabmeat at the picking and packing and finished storage critical control points to control toxin formation and "pathogen growth" is not appropriate. For example, freezing and/or adding ice after the product has exceeded the time and/or temperature critical limits alone is not appropriate. This will address the cause of the deviation, but will not address the possibility of unsafe product being distributed into commerce.

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 1) prevention of cross contamination from insanitary objects to food, food contact surfaces and from raw product to cooked product; 2) conditions and cleanliness of food and food contact surfaces, including utensils, gloves, and outer garments and 3) exclusion of pests (i.e., insects) with sufficient frequency to ensure control as evidenced by the following:

Numerous live insects noted in the production area on cooked crabs, plastic tubs used to hold crabmeat, processing tables, baskets and carts used to hold or transport cooked crabs.

Cooked crabs that fell on the floor were routinely placed with other cooked crabs to be further processed into crabmeat.

Employees routinely handled live crabs and unsanitized objects such as trashcans, burlap sacks, handcarts, stools, clothing, a broom, a crab scoop and live crab crates then handled cooked crabs without washing and sanitizing their hands.

A backing employee repeatedly observed biting off crabmeat attached to cooked crab claws, then placing the claws with other cooked claws to be further processed.

Perforated baskets of cooked crabs were routinely stored directly on the floor and on unsanitized carts that were previously used to hold baskets of live crabs.

Water from baskets of live crabs routinely dripped onto baskets of cooked crabs as the live crabs were being hoisted into the retort.

You must have sanitation control records that document monitoring and corrections, to comply with 21 CFR Part 123.11(c). However, your firm did not maintain sanitation control records.

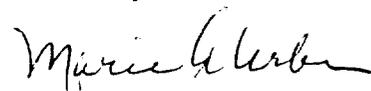
We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as a revised HACCP plan, monitoring records, sanitation control records, 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 the 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 Good Manufacturing Practice regulations (21 CFR Part 110). 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 the Food and Drug Administration, Attention: Kendall W. Hester, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, Florida 32751. If you have questions regarding any issue in this letter, please contact Mr. Hester at (407) 475-4730.

Sincerely,



Marie A. Urban
Acting Director, Florida District