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

Telephone: 407-475-4700  
FAX: 407-475-4769

**VIA FEDERAL EXPRESS**

**WARNING LETTER**

FLA-00-24

February 1, 2000

Mr. Charles Rosalis, owner  
Rosalis Crab Company  
7401 Jefferson Avenue  
Southport, FL 32409

Dear Mr. Rosalis:

We inspected your fresh crabmeat manufacturing plant located at 7401 Jefferson Avenue, Southport, FL on August 10-13, 1999 and found that you have serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations cause the crabmeat you produce to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act. You can find the Act and these regulations through links in FDA's home page at [www.fda.gov](http://www.fda.gov).

The deviations are as follows:

You must adequately monitor sanitation conditions and practices during processing in order to comply with 21 CFR 123.11(b). However, your firm did not monitor practices that could cause cross-contamination from insanitary objects to cooked crabs with sufficient frequency to ensure control. Some of the insanitary practices noted during the production of fresh crabmeat at your firm include:

Employees routinely handling wooden boxes of live crabs and unsanitized objects such as plastic milk baskets used as footstools, trash cans, brooms, shovels, a cooked crab rake, then handling cooked crabs without washing and sanitizing their hands/gloves;

Employees entering the processing area from outside the plant resumed handling or picking cooked crabs without washing and sanitizing their hands/gloves;

Employees routinely picked up cooked crabs off the floor and placed these crabs with other cooked crabs to be further processed;

Perforated baskets of cooked crabs were placed directly on the floor of the processing room where there is heavy foot traffic and one employee was observed dragging a basket filled with cooked crabs along the floor from the cooler to the backing table;

An employee routinely tested the temperature of cooked crabs by placing his arm on top of the crabs and placed cooked crabs into a perforated basket that was stored directly on the floor; and

Chlorine sanitizer for employees was found to have no detectable chlorine on three occasions during the inspection and your firm had no means to check the chlorine strength.

We also note that the critical limits at the cooking critical control point in your HACCP plan include minimum pressure, but no value is provided. Since pressure is not customarily considered a critical factor during retorting, we suggest that you remove the minimum pressure from your HACCP plan critical limits.

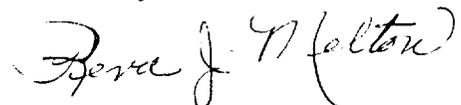
We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your crabmeat and/or enjoin your firm from operating.

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 employee and sanitation procedures 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 firm 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: Ken 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,



Reva J. Melton  
Acting Director, Florida District