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VIA FEDERAL EXPRESS

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, FL 32751

WARNING LETTER

FLA-02-31

February 14, 2002

Oscar L. Reksten, Owner
Central Seafood Company, Inc.
1625 West Smith Street
Orlando, Florida 32804

Dear Mr. Reksten:

We inspected your firm at the above address on April 5 and 6, 2001, and found that you have serious deviations from the Seafood HACCP regulations (21 CFR Part 123). We apologize for not writing to you sooner regarding these deviations. The deviations cause your histamine producing fish and chilled stone crab claws to be in violation of the 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.

The deviations are as follows:

1. You must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6 (b). Your firm does not have a HACCP plan for cooked, ready-to-eat Stone Crab Claws to control the food safety hazard of pathogen growth and toxin formation during receipt and in storage. The current HACCP plan that you have on file for fresh ready-to-eat fish and shellfish does appear to be an adequate plan for this product. However, cooked Stone Crab Claws are not included on your product/species list for this particular HACCP plan. We suggest you merely add this product to that list as a solution to this deviation.
2. You must have a HACCP plan that lists the critical limits that must be met, to comply with 21 CFR 123.6 (c) (3). Your firm's HACCP plan for Scombrototoxin (histamine) producing fish lists a critical limit at the "Receive fresh" critical control point that is not adequate to control Scombrototoxin (histamine) formation. As a secondary processor receiving histamine producing fish delivered refrigerated and unfrozen you are required to set a critical limit depending upon the circumstance that includes:
 - a. For fish delivered refrigerated, all lots received are accompanied by transportation records that show that the fish were held at or below 40°F throughout transit, or
 - b. For fish held under ice or chemical cooling media, that there is adequate ice or cooling media at time of delivery to completely surround the product.

3. You must retain records at the processing facility for at least two years after the date they were prepared in the case of frozen products, to comply with 21 CFR 123.9(b)(1). Your firm's monitoring records, including receiving records and freezer temperature logs, were only being retained for one year.

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 U.S. Federal Food, Drug, and Cosmetic Act and all applicable regulations.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your aforementioned products 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 specifics you are doing to correct these deviations. You may wish to include in your response documentation such as amended HACCP plans, monitoring records, revised forms, 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

Please send your reply to the Food and Drug Administration, Attention: Diane J. Englund, Compliance Officer, 555 Winderly Place, Suite 200, Maitland, Florida, 32751. If you have any questions regarding any issue in this letter, please contact Ms. Englund at (407) 475-4741.

Sincerely,



Emma Singleton
District Director
Florida District Office