



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-01-49

April 10, 2001

Manuel J. Prieguez, President
Miami River Lobster and Stone Crab
135 S.W. South River Drive
Miami, FL 33130

Dear Mr. Prieguez:

We inspected your firm at the above address on January 29-30, 2001 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 cooked lobster 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 FDA's home page at www.fda.gov.

We acknowledge receipt of a response from Manuel Prieguez, vice president, on February 7, 2001. This response has been reviewed and the corrective actions noted. While some of the objectionable conditions noted during the inspection have been corrected, the deviations listed below have not been corrected.

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 cooked lobster lists critical limits at the cooking critical control point that are not adequate to control the pathogen survival hazard, as there is no established minimum cooking temperature or reference to boiling.

You must have a HACCP plan that lists monitoring procedures for each critical control point, to comply with 21 CFR 123.6(c)(4). However, your firm's HACCP plan for cooked lobster lists monitoring procedures at the following cooking control point that are not adequate to control the pathogen survival, as they do not state the cook time and temperature or boiling must be monitored, how the cook time will be monitored, when the cook time monitoring will begin or require the recording of beginning and ending cook times for each batch.

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 cooked lobster at the cooking critical control point is not appropriate to control the pathogen survival hazard, as it does not address corrective action or disposition of lobsters subjected to an inadequate cook.

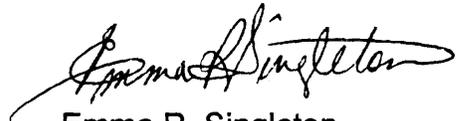
We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating. In addition, we may not provide certificates to your firm for export of your products to European Union (EU) countries if you do not correct these deviations.

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 and revised monitoring 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,

A handwritten signature in black ink, appearing to read "Emma R. Singleton", with a stylized flourish at the end.

Emma R. Singleton,
Director, Florida District