



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

HFI-35

11/7/00
WJ

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

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

VIA CERTIFIED MAIL

WARNING LETTER

FLA-01-05

October 24, 2000

Orlando Rioseco, President and Owner
Sea Lobster Company Inc.
P.O. Box 2099
Stock Island, Florida 33045

Dear Mr. Rioseco:

We inspected your firm, located at 5th Avenue, Stock Island, Florida 33045 on August 23, 2000 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 stone crab claws and scombroid species, such as mackerel, yellow tail and mahi-mahi, 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 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 receiving critical control point to control histamine formation in scombroid species or at the cooler storage critical control point to control the food safety hazards of histamine formation in scombroid species and pathogens in cooked stone crab claws.

You must maintain sanitation control records that document monitoring and corrections, to comply with 21CFR 123.11(c). However, your firm did not record sanitation monitoring observations for any of the sanitation conditions and practices listed in the regulations, including, safety of the water or ice that comes in contact with food, cleanliness of food contact surfaces, prevention of cross-contamination, maintenance of hand washing, hand sanitizing, and toilet facilities, protection of food from contaminants, proper labeling, storage, and use of toxic compounds, control of employee health conditions and exclusion of pests.

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 sanitation and process 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 "David J. Gallant". The signature is written in a cursive, flowing style.

David J. Gallant
Acting Director, Florida District