



DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

g1606d

One Montvale Avenue
Stoneham, Massachusetts 02180
Tel 781.279.1675
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August 6, 2001

WARNING LETTER

NWE-36-01W

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Christopher Killenberg, President
Great Southern Shrimp Company
1154 Main Road
Westport, MA 02790

Dear Mr. Killenberg:

We inspected your firm, located at 1154 Main Road in Westport, MA on July 18, 2001, and found that you have serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations cause the cooked, ready-to-eat lobster and repacked frozen shrimp being processed by your firm 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.

The deviations were as follows:

- ▶ You must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, in order to comply with 21 CFR § 123.6(b). However, your firm does not have a HACCP plan for cooked, ready-to-eat lobster to control the food safety hazard of Pathogen Growth and Toxin Formation as a Result of Time/Temperature Abuse.
- ▶ You must also implement the record keeping system listed in your HACCP plan, in order to comply with 21 CFR § 123.6(b). However, your firm has not recorded the results of testing for sulfites on incoming shipments of shrimp, as is required by your HACCP plan for repacked shrimp.

- ▶ You must adequately monitor sanitation conditions and practices during processing to comply with 21 CFR 123.11(b). However, your firm has failed to maintain sanitation monitoring records documenting the monitoring (as appropriate to the plant and food being processed) of the conditions set forth at 21 CFR § 123.11(b). Sanitation controls are particularly important for ensuring the safety of ready-to-eat product (i.e., items that are intended to be consumed without further cooking).

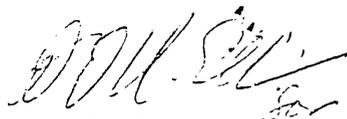
We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your products and/or enjoin your firm from operating. In addition, we may not provide certificates to your firm for export of your products to the European Union (EU), if you 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 completed HACCP plan and sanitation 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 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 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: Mark Lookabaugh, Compliance Officer, 1 Montvale Avenue, Stoneham, Massachusetts 02180. If you have questions regarding any issue in this letter, please contact Mr. Lookabaugh at **781.279.1675 x1718**

Sincerely,



Gail T. Costello
Director
New England District