



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

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Food and Drug Administration
One Montvale Avenue
Stoneham, Massachusetts 02180
(781)279-1675 FAX: (781)279-1742

WARNING LETTER

NWE-05-99W

December 23, 1998

**VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

Kevin B. Bates, Managing Partner
Ocean State Lobster LLC
270 Great Island Road
Narragansett, RI 02882

Dear Mr. Bates:

On October 28-30, 1998, the Food and Drug Administration (FDA) conducted an inspection of your plant located at 270 Great Island Road, Narragansett, RI 02882. The Investigators documented violations of Section 402 (a)(4) of the Federal Food, Drug, and Cosmetic Act and Title 21, Code of Federal Regulations (21 CFR) Parts 110 "Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food" (GMPs) and 123 "Safe and Sanitary Processing and Importing of Fish and Fishery Products" (Seafood HACCP Regulation), as follows:

- Failure to develop and implement a HACCP Plan for the manufacture of vacuum packed, ready-to-eat lobstermeat in accordance with the requirements of 21 CFR 123.6(b).
- Sanitation Monitoring is inadequate, 21 CFR 123.11(c). For example, sanitation monitoring records do not document monitoring of the following areas of their vacuum packed, ready-to-eat, lobstermeat manufacture: cleaning and sanitation of food contact surfaces; prevention of cross-contamination from insanitary objects to food, and food contact surfaces; protection from adulterants; employee health; and exclusion of pests.

Kevin B. Bates, Managing Partner
Ocean State Lobster LLC
Narragansett, RI 02882
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The above identified deviations are not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to assure that your establishment is in compliance with all requirements of the federal regulations.

FDA will not issue any certificates of export for any of the seafood products processed at your facility until your firm is fully in compliance with the seafood HACCP regulations. You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure and/or injunction.

You should notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which corrections will be completed.

You may direct your reply to Maureen E. Donahue, Acting Compliance Officer, at the address noted above. If you have any questions concerning this matter, please contact Ms. Donahue at (781) 279-1675, Extension 125.

Sincerely,



John Marzilli
District Director
New England District Office