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

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

WARNING LETTER

NWE-08-99W

**VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

February 16, 1999

David Garborcauskas, President
Garbo Lobster Co., Inc.
72 Water Street
Stonington, CT 06378

Dear Mr. Garborcauskas:

On November 16-18, 20, 1998, the Food and Drug Administration (FDA) conducted an inspection of your plant located at 72 Water Street, Stonington, CT 06378. The Investigator documented serious violations of the seafood processing regulations in Title 21, Code of Federal Regulations (21 CFR) Part 123 "Safe and Sanitary Processing and Importing of Fish and Fishery Products" (Seafood HACCP Regulation) and Part 110 "Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food" (GMPs) causing the seafood products being processed by your firm to be adulterated within the meaning of Section 402 (a)(4) of the Federal Food, Drug, and Cosmetic Act, as follows:

1. Monitoring procedure at the cooling step in the Plan is inadequate, 21 CFR 123.6(c)(4). For example, your HACCP Plan for cooked ready-to-eat lobstermeat states that the actual time that the cooling process ended will be recorded on the Cooked Lobster Report. The Plan does not require monitoring of the product temperature at the end of cooling to insure product is [REDACTED]. The temperature should be taken and recorded to determine the time available for processing.
2. Appropriate critical limit is not listed in the Plan, 21 CFR 123.6(c)(3). For example, your HACCP Plan for cooked ready-to-eat lobstermeat states that during the pick/weigh/pack step the time the product is allowed to remain [REDACTED] is [REDACTED]. Unless you have documentation that [REDACTED] ambient temperature [REDACTED] will not result in the internal temperature of the product exceeding the critical limit

of [REDACTED] at [REDACTED] or above, this critical limit should be based on internal temperatures as per the Fish & Fisheries Products Hazards & Controls Guide (Hazards Guide). The critical limit for the pick/weigh/pack step states two temperature options and uses the word "and" to connect them. This should be "or". the way it is worded now, the ambient temperature could be [REDACTED] hours and [REDACTED] for an additional [REDACTED]. This is not appropriate. Since the critical limit is based on a cumulative time (starting after the cooking step), this time/temperature parameter may permit microorganism growth.

3. Monitoring of finished product storage is inadequate, 21 CFR 123.6(c)(4). Your Plan indicates the hazard of C.botulinum will be addressed at this step by assuring that the cooler temperature will be monitored and recorded twice a day, before the cooked lobstermeat is placed in the cooler and again when the product is removed. The cooler temperature is recorded only once during holding. In addition, the adequacy of the cooling media is not monitored and recorded on the Daily Inspection Log as stated in your Plan.
4. Controls are not applied where critical control point should be located, 21 CFR 123.6(b). Proper controls need to be in place to assure the safety of the product from production to consumption. Processors of vacuum-packaged fish should expect that at some point during storage, distribution display, or consumer handling, proper refrigeration (i.e 38°F or less), required to inhibit the growth of C.botulinum type E will not be maintained. Even if the product is distributed "refrigerated," the temperature during such shipment may fluctuate and there is nothing in your Plan which would control the formation of toxin by C.botulinum during distribution.

However, if the product is immediately frozen after processing, maintained frozen throughout distribution, and labeled to be held frozen and to be thawed under refrigeration immediately before use ("Important, keep frozen until used, thaw under refrigeration"), then formation of C.botulinum toxin may not be a significant hazard during storage and distribution.

5. Sanitation monitoring is inadequate, 21 CFR 123.11(b). The records do not reflect the monitoring of the following:
 - protection of food, food packing materials, and food contact surfaces from adulterants;
 - maintenance of hand sanitizing (strength of sanitizer is not documented);
 - proper labeling, storage, and use of toxic compounds;
 - prevention of cross-contamination; and
 - control of employee health conditions.
6. Corrective action is not fully documented in your records, 21 CFR 123.7(d). For example, 10 of 22 records reviewed have a storage ambient temperature greater than [REDACTED] and on 6/24/98, the critical limit for cooling was not met [REDACTED].

David Garborcauskas, President
Garbo Lobster Co., Inc.
February 16, 1999

Vacuum breakers in the cook room were replaced. There is no documentation of corrective actions.

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.

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.

We acknowledge receipt of your letter dated December 23, 1998 which addressed the concerns noted on the FDA 483 that was issued to your firm at the conclusion of our inspection on November 20, 1998. We look forward to reviewing a further response which addresses the specific items above.

We also recommend you include calibration of thermometers as part of your verification procedures in your Plan. Presently, there are no verification procedures or record of periodic calibration of the thermometers used.

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 Karen N. Archdeacon, Compliance Officer, at the address noted above. If you have any questions concerning this matter, please contact Ms. Archdeacon at (781) 279-1675, Extension 113.

Sincerely,



John R. Marzilli
District Director
New England District Office