



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

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HFI-35

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

WARNING LETTER

NWE-11-99W

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

February 24, 1999

Gary Sylvia, Owner
Clarks Cove Fish Co.
1497 Cove Road
New Bedford, MA 02742

Dear Mr. Sylvia:

On December 14 and 15, 1998, the Food and Drug Administration (FDA) conducted an inspection of your plant located at 1497 Cove Road, New Bedford, MA 02742. 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:

1. Your HACCP plan does not meet the requirements of 21 CFR 123.6 (c)(1) in that it does not include all food safety hazards that are reasonably likely to occur i.e. the potential for histamine in mackerel. In addition, a complete HACCP plan, as specified by 21 CFR 123.6(c) (2) through (7) includes appropriate controls, critical control points, monitoring procedures, critical limits, corrective actions, the establishment of verification procedures and record keeping for each food safety hazard.
2. Sanitation monitoring and corrective action documentation is inadequate, 21 CFR 123.11(c). For example, numerous sanitation deficiencies were observed and noted on the FDA 483.

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.

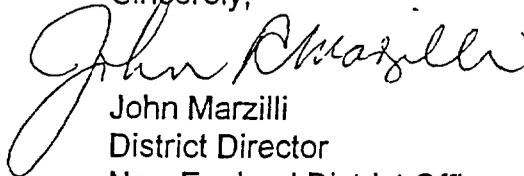
FDA will not issue any certificates for export of any of the seafood products processed at your facility until your firm is fully in compliance with the seafood HACCP regulations.

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 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 Marzilli
District Director
New England District Office