



CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Food and Drug Administration
Detroit District
1560 East Jefferson Avenue
Detroit, MI 48207-3179
Telephone: 313-226-6260

WARNING LETTER
2000-DT-28

July 20, 2000

Philip M. Sack, Vice President
Sea Fare Foods, Inc.
14440 Wildemere
Detroit, MI 48238

Dear Mr. Sack:

On September 28 and 29, 1999, the Food and Drug Administration (FDA) conducted an inspection of your facility located at 14440 Wildemere in Detroit, MI. The inspection was conducted to determine compliance with the FDA's Seafood Hazard Analysis Critical Control Point (HACCP) Regulation (21 CFR 123) for fish and fishery products and the current Good Manufacturing Practice requirements for foods (21 CFR 110).

During the inspection, the FDA investigator observed shortcomings in your system that are deviations from the principles of HACCP and the significant requirements of the program. The FDA investigator presented your firm with a form FD-483 which presents the investigator's evaluation of your firm's performance regarding various aspects of the HACCP requirements.

Your firm is in violation of 21 CFR 123, causing your pickled ocean herring in glass jars to be deemed adulterated under the provisions of 21 USC 342(a)(4) because of the following:

1. Since you chose to include corrective actions in your HACCP plan, your described corrective actions must be appropriate, to comply with 21 CFR 123.7(b). However, your corrective action plan for "Pickled Ocean Herring in Glass Jars" at the brining/pickling critical control point to control pathogen growth is not appropriate. The corrective action plan does not determine if the product is free of pathogens before adjusting the vinegar concentration. Pathogens can grow during the 5-day pickling procedure if a low pH and/or temperature is not maintained.
2. You must implement daily 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 brining/pickling critical control point to control pathogen growth listed in your HACCP plan for "Pickled Ocean Herring in Glass Jars." Specifically, monitoring records for the pickle concentration were not prepared for at least [REDACTED] consecutive days.

3. You must have product specifications that are designed to ensure that the fish and fishery products you import are not injurious to health, to comply with 21 CFR 123.12(a)(2)(i). However, your firm has a product specification for herring imported from Canada that does not adequately address the food safety hazards of histamine and pathogen growth, including *Clostridium botulinum* toxin, that are reasonably likely to be presented by the product.
4. You must have sanitation control records that document monitoring and corrections of the eight required items, in order to comply with 21 CFR 123.11(c). However, you do not have sanitation control records that document monitoring and corrections for any of the eight required items as follows: a) the safety of water that contacts the food or food contact surfaces; b) the condition and cleanliness of food contact surfaces; c) the prevention of cross contamination; d) the maintenance of hand washing, hand sanitizing and toilet facilities; e) the proper handling of toxic compounds; f) the protection of the food from contaminants and adulterants; g) the control of employee health conditions; and, h) the exclusion of pests from the food plant.

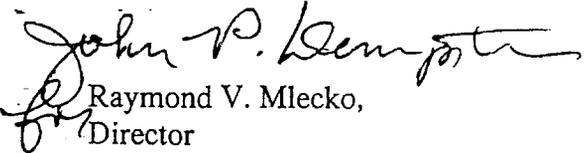
The above-identified deviations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that your establishment is in compliance with all requirements of the federal regulations.

You should take prompt measures to correct these deviations. Failure to promptly correct the deviations noted may result in regulatory action without further notice. Such action includes seizure or injunction.

Please notify this office in writing, within thirty (30) working days of receipt of this letter, of the specific steps you have taken to correct these violations, including an explanation of each step taken to prevent their reoccurrence. If corrections cannot be completed within thirty (30) working days, state the reason for the delay and the time frame within which the corrections will be completed. Also, please include copies of any available documentation demonstrating that corrections have been made.

Your written reply should be directed to Mr. Dennis P. Degan, Compliance Officer, U.S. Food and Drug Administration, 1560 E. Jefferson Avenue, Detroit, MI 48207, telephone 313-226-6260 x 135. If you need further assistance, all technical questions should be directed to Nicholas L. Majerus, Shellfish Specialist at extension 107.

Sincerely,


Raymond V. Mlecko,
Director
Detroit District