



DEPARTMENT OF HEALTH & HUMAN SERVICES

COPY

M27381

Food and Drug Administration  
Seattle District  
Pacific Region  
22201 23rd Drive S.E.  
Bothell, WA 98021-4421

June 30, 1999

Telephone: 425-486-8788  
FAX: 425-483-4996

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 99-26

Michael Mondello, President  
SeaBear, Incorporated  
Fisherman's Terminal  
1711 W Nickerson, Suite A  
Seattle, Washington 98119

**WARNING LETTER**

Dear Mr. Mondello:

On April 5 and 6, 1999, the Food and Drug Administration (FDA) conducted an inspection of your firm located at 605 - 30<sup>th</sup> Street, Anacortes, Washington. At the conclusion of the inspection, Cathy A. Hayward-Hughes, Vice President of Operations, was presented with a Form FDA 483 listing serious deviations from Title 21 of the Code of Federal Regulations (21 CFR) Part 123 - Fish and Fishery Products (HACCP Regulation). A copy of that Form FDA 483 is enclosed for your review. By virtue of these deficiencies, the vacuum-packaged "Beer Garden" hot smoked salmon processed by your firm is adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act) and 21 CFR Part 123.

1. Failure to implement the proper critical control limit to control the hazard as required by 21 CFR Part 123.6(b). Specifically, your HACCP plan lists a critical limit for fish thickness at a maximum of 1.5 inches. Your Smoking and Brining Log has a space for "Average Fish Thickness" to be documented, not the maximum thickness. Fish thickness is a critical factor that directly affects pathogen survival. If the fish thickness of chum salmon (which is the only fish you use as stated during the inspection) never exceeds 1.5 inches, then your critical limit should be as it is stated in your HACCP plan.
2. Failure of the monitoring records to contain the actual values and observations obtained during monitoring as required by 21 CFR Part 123.6(c)(7). Specifically, the Smoking and Brining Logs for "Beer Garden" Smoked Salmon does not reflect monitoring of critical limits. The critical limits of time and temperature established for the hot smoke step were not documented on six records, including lots #8090 dated 7/25/98; #8131 dated 9/30/98; #8186 and #8187 dated 1/4/99; #8199 dated 2/4/99, and #8204 dated 3/2/99. The critical limits of time and temperature established for the brine step were not documented on two

Michael Mondello, President  
SeaBear, Incorporated  
Fisherman's Terminal, Seattle, WA  
Re: Warning Letter SEA 99-26  
Page 2

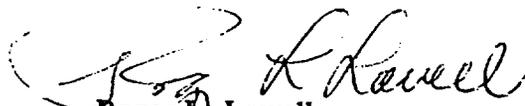
records, including lots #8063 dated 6/26/98 and #8090 dated 7/25/98. The lack of monitoring your critical control points was brought to your attention as a result of the June 17-18, 1998, inspection, and in a letter sent to your firm on August 17, 1998. In a letter to the FDA, dated September 1, 1998, Cathy Hayward-Hughes, Vice President of Operations, promised correction of this deficiency.

3. Your firm failed to monitor control of employees with adverse health conditions and proper labeling, storage, and use of toxic compounds as required under 21 CFR Part 123.11(b).

The above HACCP violations are not meant to be an all-inclusive list of deficiencies in your plant. Other violations can subject the food to legal action. It is your responsibility to assure that all of your products are in compliance with applicable statutes enforced by the FDA. You should take prompt action to correct all of the violations noted in this letter. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

You should notify this office in writing, within 15 working days of the receipt of this letter, of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within 15 working days, state the reason for the delay, and the time within which the corrections will be completed. Pertinent sections of the Act and the Regulations are enclosed for your review. Your reply relating to these concerns should be addressed to the Food and Drug Administration, Attention: Janelle K. Main, Compliance Officer, 22201 23<sup>rd</sup> Drive SE, Bothell, Washington 98021-4421.

Sincerely,

  
Roger D. Lowell  
District Director

3 Enclosures:  
Form FDA 483  
21 CFR Part 123  
Section 402 of the Federal Food, Drug, and Cosmetic Act

cc: With Disclosure Statement  
WSDA