



DEPARTMENT OF HEALTH AND HUMAN SERVICES

9.13460  
Food and Drug Administration  
Seattle District  
Pacific Region  
22201 23rd Drive SE  
Bothell, WA 98021-4421

Telephone: 425-486-8788  
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June 6, 2001

**VIA CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

In reply refer to Warning Letter SEA 01-58

Gretchen A. Mathers, Operating Partner  
Gretchen of Schwartz  
2415 Airport Way South  
Seattle, Washington 98134

**WARNING LETTER**

Dear Ms. Mathers:

We inspected your firm located at 2415 Airport Way South, Seattle, Washington, on April 26, 2001, and found that you have serious deviations from Title 21 of the Code of Federal Regulations (21 CFR) Part 123 - Fish and Fishery Products (Seafood HACCP regulations). A FDA 483 form (copy-enclosed) listing the deviations was presented to Henry Carruth, Plant Manager, at the conclusion of the inspection. These deviations, some of which were previously brought to your attention, cause your ready to eat tuna sandwich to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the Seafood HACCP regulations through links in FDA's homepage at [www.fda.gov](http://www.fda.gov).

The deviations were as follows:

- 1). You must have a HACCP plan that lists monitoring procedures for each critical control point, to comply with 21 CFR 123.6 (c)(4). Your firm's HACCP plan for tuna products lists a monitoring procedure and frequency at the Draining Cans step that is not adequate to control bacterial growth in that the plan does not specify the method and frequency of monitoring.
- 2). 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). Your corrective action plan for canned tuna fish at the can draining critical control point to control the hazard of bacterial growth is not appropriate in that it does not address the cause of the deviation.
- 3). You must have a HACCP plan that lists the food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6 (c) (1). Your firm's HACCP plan for tuna fish products does not list the food safety hazard of pathogen growth at the refrigerated raw material or finished product storage steps.

Gretchen A. Mathers, Operating Partner  
Gretchen of Schwartz, Seattle, Washington  
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4). You must adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR 123.11 (b). Your firm did not monitor the safety of process water, the control of employees with adverse health conditions, or the proper labeling, storage and use of toxic compounds as evidenced by the fact that your sanitation monitoring record is missing these required elements. This observation was also pointed out in FDA's January 18, 2001, letter in item number two.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as your revised HACCP plan and copies of your monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

Please send your reply to the Food and Drug Administration, Attention: Bruce Williamson, Compliance Officer, 22201 23<sup>rd</sup> Drive SE, Bothell, Washington 98021. If you have questions regarding any issue in this letter, please contact Mr. Williamson at (425) 483-4976.

Sincerely,



Charles M. Breen  
District Director

Enclosures:  
Form FDA 483

cc: with disclosure statement