



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

Telephone: 425-486-8788  
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September 14, 2001

**VIA CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

In reply refer to Warning Letter SEA 01-78  
Robin Bratton & Lee Olheiser, Co-Owners  
Gilmore Fish Smokehouse  
229 Highway 197  
Dallesport, Washington 98617

**WARNING LETTER**

Dear Ms. Bratton & Ms. Olheiser:

We inspected your firm located at 229 Highway 197, Dallesport, Washington, on April 20, 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 James A. Olheiser, Plant Manager, at the conclusion of the inspection. These deviations, some of which were previously brought to your attention, cause your vacuum packaged hot smoked salmon, which is distributed refrigerated, 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 of concern were as follows:

1. You must have a HACCP plan that lists the critical limits that must be met, to comply with 21 CFR 123.6(c)(3). Your firm's HACCP plan for hot smoked vacuum packaged salmon does not list all critical limits at the "Brining" critical control point to control the significant hazards of "pathogen growth and c bot" (e.g., *Clostridium botulinum* growth and toxin formation). Your firm's HACCP plan lists a critical limit of "minimum 10 hours Brining Time" but fails to specify other critical factors listed under the monitoring column titled "What" (e.g., formula and fish thickness). The critical limits need to list the maximum or minimum value of the attributes that are monitored (e.g., the formula ingredients and their weights, a final salometer value, and fish thickness value).

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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 hot smoked vacuum packaged salmon at the "Brining" critical control point to control *Clostridium botulinum* is not appropriate. Your corrective actions list only to "extend time". Corrective actions should also address the cause of the deviation and how to prevent it from reoccurring. In addition, an appropriate corrective action plan must also include steps to ensure that potentially unsafe product does not enter commerce (i.e., holding and evaluating the affected product).
3. You must verify that your HACCP plan is adequate to control the food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.8(a). Your HACCP plan for hot smoked vacuum packaged salmon correctly identified pathogens and *Clostridium botulinum* as food safety hazards and correctly listed brining, cooking, and final storage in the facility as critical control points. However, your HACCP plan does not include controls sufficient to prevent the formation of *Clostridium botulinum* toxin during the shelf life of the product (e.g., product distribution and consumer storage under normal and moderate abuse conditions). Your hazard analysis should consider each step in your process, including product storage, distribution, final preparation, and use by the consumer.

The results of analysis from a final product sample collected during our April 20, 2001 inspection revealed that 6 of 10 units in the sample were below 3.5% water phase salt, with a range of 1.91 to 4.23%. As evidenced by these laboratory results, your process does not consistently achieve the 3.5% water phase salt listed in your HACCP plan. The lack of controls in your HACCP plan to prevent toxin formation beyond finished product storage in your firm's facility, confirms that the adequacy of the HACCP plan has not been verified.

This letter may not list all the deficiencies 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 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 and/or enjoin your firm from operating.

Please respond in writing within fifteen (15) working days 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

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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: Diane J. Englund, Compliance Officer, 22201 23<sup>rd</sup> Drive SE, Bothell, Washington 98021. If you have any questions regarding any issue in this letter, please contact Diane J. Englund, Compliance Officer, at (425) 483-4864.

Sincerely,

A handwritten signature in black ink, appearing to read "Charles M. Breen", with a long horizontal flourish extending to the right.

Charles M. Breen  
District Director

Enclosures:

Form FDA 483

21 CFR Part 123

Section 402 of the Federal Food, Drug, and Cosmetic Act

cc: WSDA with Disclosure Statement