



DEPARTMENT OF HEALTH AND HUMAN SERVICES

M57224

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

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

January 26, 2001

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

In reply refer to Warning Letter SEA 01-22

Robert D. Bearden, Owner
Alder Springs Smoked Salmon, Inc.
61 River Road
Sequim, Washington 98382

WARNING LETTER

Dear Mr. Bearden:

We inspected your firm located at 61 River Road, Sequim, Washington, on September 5, 2000, 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 you at the conclusion of the inspection. These deviations, some of which were previously brought to your attention, cause your vacuum-packaged hot smoked products 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.

The deviations were as follows:

1. You must have a HACCP plan that lists the critical control points, to comply with 21 CFR 123.6(c)(2). Your firm's HACCP plan for vacuum-packaged hot smoked salmon does not list the critical control points of brining, smoking, cooking, and cold storage for controlling for the biological food safety hazard of pathogen growth, specifically *Clostridium botulinum*.
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 vacuum-packaged hot smoked salmon does not address how the cause of the deviation will be corrected. Correcting the cause of the deviation must be included at each critical control point along with what you will do with the affected product.
3. 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 vacuum packaged hot smoked salmon

Robert D. Bearden, Owner
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lists a critical limit, "the temp to exceed [REDACTED] F", at the smoking critical control point which is not adequate. The critical limit must specify also the time at which the temperature is to be at [REDACTED] F and that the temperature is an internal temperature of the fish.

4. You must have sanitation control records that document monitoring and corrections, to comply with 21 CFR 123.11(c). Your firm did not maintain sanitation control records to ensure the safety of the well water that comes into contact with food or food contact surfaces.

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: Lisa M. Elrand, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021. If you have questions regarding any issue in this letter, please contact Lisa Elrand at (425) 483-4913.

Sincerely,



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