



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  
FAX: 425-483-4996

January 18, 2001

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

In reply refer to Warning Letter SEA 01-21

Carol A. Petraborg, Partner  
Alaska Bounty Seafoods & Smokery  
P.O. Box 6250  
407 Fairway Drive  
Sitka, Alaska 99835

WARNING LETTER

Dear Ms. Petraborg:

We inspected your firm located at 407 Fairway Drive, Sitka, Alaska, on August 8 and 9, 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). An FDA 483 form (copy enclosed) listing the deviations was presented to you at the conclusion of the inspection. The deviations, which were previously brought to your attention, cause your vacuum packaged hot smoked salmon 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 are as follows:

1. You must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(b). Your firm does not have a HACCP plan for vacuum packaged hot smoked salmon, stored frozen and distributed as a refrigerated product, to control the food safety hazard of *Clostridium botulinum*.

Your HACCP plan for vacuum packaged hot smoked salmon, stored frozen and distributed frozen, is not suitable for product that is distributed as a refrigerated product and labeled as "KEEP REFRIGERATED BELOW 38°F". You indicated during the August 8 and 9, 2000 inspection that you intended to revise your labels to indicate that product is distributed frozen, and intended for frozen storage at the consumer level. A telephone conversation with you on December 21, 2000 revealed that you have not revised your labels. If you intend to continue to distribute your product as a refrigerated product, you must have a HACCP plan that is specific to this product and addresses the hazards associated with it.

Carol A. Petraborg, Partner  
Alaska Bounty Seafoods & Smokery Sitka, Alaska  
Re: Warning Letter SEA 01-21  
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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 this deviation. You may wish to include in your response documentation or other useful information that would assist us in evaluating your correction. If you cannot complete your correction before you respond, we expect that you will explain the reason for your delay and state when you will correct the deviation.

Please send your reply to the Food and Drug Administration, Attention: Lisa M. Althar, Compliance Officer, 22201 23<sup>rd</sup> Drive SE, Bothell, Washington 98021-4421. If you have questions regarding any issue in this letter, please contact Ms. Althar at (425) 483-4940.

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: ADEC with disclosure statement