



DEPARTMENT OF HEALTH & HUMAN SERVICES

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

August 18, 2000

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

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 00-92

Charles W. Hosmer, General Manager  
Baranof Fisheries, Ltd, (Baranof F/V)  
3510 1<sup>st</sup> Avenue NW  
Seattle, Washington 98107

WARNING LETTER

Dear Mr. Hosmer:

We inspected your firm located at 3510 1<sup>st</sup> Avenue NW, Seattle, Washington, on May 30, 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 cooked crab product 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 cooked snow crab sections lists monitoring procedures at the cook critical control point that are adequate to control pathogen survival through cooking. The HACCP plan does not list how the monitoring is to be accomplished and who is responsible for the 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 cooked crab sections at the cooking critical control point to control the hazard of pathogen survival does not list how you will correct the cause of a deviation if it should occur.

Charles W. Hosmer, General Manager  
Baranof Fisheries, Ltd. (Baranof F/V) Seattle, Washington  
Re: Warning Letter SEA 00-92  
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This letter may not list all the deviations at your facility. You are responsible for ensuring 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. In addition, we may not provide certificates to your firm for export of your products to European Union (EU) countries if you do not correct these deviations.

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 23<sup>rd</sup> Drive SE, Bothell, Washington 9802-4421. If you have questions regarding any issue in this letter, please contact Lisa Elrand, Compliance Officer 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: ADEC with disclosure statement