



DEPARTMENT OF HEALTH & HUMAN SERVICES

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June 11, 1999

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

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

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 99-24

Garry M. Loncon, CEO
Royal Aleutian Seafoods, Inc.
701 Dexter Avenue North, Suite 408
Seattle, Washington 98109

WARNING LETTER

Dear Mr. Loncon:

On January 26, 1999, the Food and Drug Administration (FDA) conducted an inspection of Royal Aleutian Seafoods, Inc., located on the Royal Aleutian Barge at 1014 Eastpoint Loop Road, Dutch Harbor, Alaska. At the conclusion of the inspection, Steven J. Stubbe, Plant Manager, was presented with a Form FDA 483 listing serious deviations from Title 21 of the Code of Federal Regulations (21 CFR) Part 123 - Fish and Fishery Products (HACCP Regulation). A copy of that Form FDA 483 is enclosed for your review. By virtue of these deficiencies, the cooked, frozen crab sections processed by your firm are adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act) and 21 CFR Part 123.

1. Your HACCP plan did not include adequate critical control point monitoring procedures and did not establish a record keeping system to document critical control point monitoring as required under 21 CFR Parts 123.6(c)(4) and 123.6(c)(7).
2. Your sanitation monitoring record did not cover prevention of cross contamination or corrective action. 21 CFR Part 123.11(c) requires you to maintain records of eight areas of sanitation monitoring, including prevention of cross contamination, as well as corrections made as a result of monitoring.
3. Your firm could not provide documentation that supported the establishment, by an appropriate or established scientific study of the critical limits, of a minimum -minute cook at degrees F as effective to control the food safety hazard of pathogen survival at

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the cook step. Therefore, the critical limit is inadequate and your HACCP plan does not meet the requirement of 21 CFR Part 123.6(c)(3).

The above HACCP violations are not meant to be an all-inclusive list of deficiencies in your plant. Other violations can subject the food to legal action. It is your responsibility to assure that all of your products are in compliance with applicable statutes enforced by the FDA. You should take prompt action to correct all of the violations noted in this letter. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

Other deficiencies with your HACCP program have also been noted. These deficiencies are not considered to be serious deviations from the HACCP Regulation; however, it is important that you consider our comments and make necessary corrections. An overall review of your *HACCP MANUAL* found it to be confusing and incomplete. Some of those issues have already been brought to your attention in this letter; however, a few issues remain a concern to the FDA.

On page five, under product description, it reads: "The product is intended to be heated before consumption by the general public". As stated in the May 6, 1998 letter to your firm, the FDA does not agree that cooking instructions on the label for cooked crab means that you are not manufacturing a cooked, ready-to-eat product. Labeling the product with cooking instructions does not dictate the intended use of this particular product. The FDA still considers this to be a ready-to-eat seafood product.

On page eight, under your rationale for deciding whether or not a hazard should be included or not, it reads: "decomposition is a hazard". Decomposition does not result in a food safety hazard in crab, as histamine is not associated with crab.

On page nine, under critical control points, it reads: "Two critical control points are identified for King/Snow/Dungeness crab, frozen sections; receiving live crab and labeling". On page 10, under the Receiving, Cooking and Labeling Steps, you have answered "YES" these steps are critical control points. Clearly, your critical control points are not consistent throughout this manual.

You should notify this office in writing, within 15 working days of the receipt of this letter, of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within 15 working days, state the reason for the delay, and the time within which the corrections will be completed. Pertinent sections of the Act and the Regulations are

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enclosed for your review. Your reply relating to these concerns should be addressed to the Food and Drug Administration, Attention: Janelle K. Main, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421.

Sincerely,



Roger L. Lowell
District Director

3 Enclosures:
Form FDA 483
21 CFR PART 123
Section 402 of the Federal Food, Drug, and Cosmetic Act

cc: With Disclosure Statement
ADEC