



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

February 1, 2001

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

In reply refer to Warning Letter SEA 01-25

Theodore Otness, President
Alaska Fresh Seafoods, Inc.
4241 21st Avenue West, Suite 204
Seattle, Washington 98199

WARNING LETTER

Dear Mr. Otness:

We inspected your firm located at 105 Marine Way, Kodiak, Alaska, on August 7, 2000, and found 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 David M. Woodruff, Vice President, at the conclusion of the inspection. These deviations, some of which were previously brought to your attention, cause your cooked crab 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 limits that must be met, to comply with 21 CFR 123.6(c)(3). Your firm's HACCP plan for cooked crab does not list critical limits at the Cooking critical control point to control the hazard of pathogen survival. Although you maintain a Laboratory Memorandum from the National Food Processors Association that includes time and temperature critical limits for Dungeness Crab Sections, your HACCP plan must specifically list adequate critical limits that your firm has concluded will be implemented in your seafood processing plant for your cooked crab product. Designation of appropriate critical limits is required to control the food safety hazard of pathogen survival. Your failure to adequately address the food safety hazard of pathogen survival for your cooked crab product was previously brought to your attention in our letters dated October 30, 1998 and November 8, 1999.
2. You must have a HACCP plan that lists monitoring procedures for each critical control point, to comply with 21 CFR 123.6(c)(4). However, your firm's HACCP plan for cooked

crab lists a monitoring procedure at the Cooking critical control point that is not adequate to control pathogen survival through cooking. You must list "What" the critical process factors are that are needed to ensure that the critical limits are being met, and "How" they are being monitored. For example, you must indicate if you are monitoring the initial temperature of the crab, cook time and cook temperature using a temperature recording device and clock, or time/temperature data logger. Adequate monitoring procedures are required to control the food safety hazard of pathogen survival. As stated above, your failure to adequately address the food safety hazard of pathogen survival for your cooked crab product was previously brought to your attention in our letters dated October 30, 1998 and November 8, 1999.

3. 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 at the Cooking critical control point to control pathogen survival through cooking is not appropriate. Pre-determined corrective actions must address both product and process. Your corrective action of "recook if necessary" only addresses the product and does not include identifying and correcting the cause of the deviation.

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. 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 15 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 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.

Theodore Otness, President
Alaska Fresh Seafoods, Inc., Kodiak, Alaska
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Please send your reply to the Food and Drug Administration, Attention: Lisa M. Althar, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421. If you have questions regarding any issue in this letter, please contact Lisa M. 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: David M. Woodruff, Vice President
Alaska Fresh Seafoods, Inc.
105 Marine Way
P.O. Box 647
Kodiak, Alaska 99615

cc: ADEC with Disclosure Statement