



DEPARTMENT OF HEALTH AND HUMAN SERVICES

1150247
Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
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January 4, 2001

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 01-14

Douglas J. Stuart, President
His Catch Value Added
1411 Lakeshore Drive
Homer, Alaska 99603

WARNING LETTER

Dear Mr. Stuart:

We inspected your firm located at 1411 Lakeshore Drive, Homer, Alaska, on August 1 and 2, 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 hot smoked vacuum packaged fish 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 deviation of concern was as follows:

1. 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 since beginning production on July 19, 2000. Our investigator noted that none of the eight areas of sanitation are being checked off on your sanitation report, unless they are deficient. This deficiency was noted during the last inspection and continues to be inconsistently recorded.

The above HACCP violations are not meant to be an all-inclusive list of deficiencies in your plant. It is your responsibility to assure that all of your products are in compliance with applicable statutes enforced by the FDA including the Seafood HACCP regulations and the Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food regulations in 21 CFR 110. We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product and/or enjoin your firm from operating. Pertinent sections of the Act and regulations are enclosed for your review.

Douglas J. Stuart, President
His Catch Value Added, Homer, Alaska
Re: Warning Letter SEA 01-14
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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.

For your information, upon review of your label for Smoked Alaskan Salmon, we are in agreement with the statement listed on your package "Keep frozen through distribution thaw under refrigeration". However, since your product is immediately frozen after processing and maintained frozen through distribution until use, you may want to consider more concise wording. We suggest that your label may be more clearly worded as "Important, keep frozen until used, thaw under refrigeration".

Please send your reply to the Food and Drug Administration, Attention: Diane J. Englund, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421. If you have any questions regarding any issue in this letter, please contact Diane J. Englund at (425) 483-4864.

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