



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

May 5, 2000

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

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 00-40

Sandro Lane, President
Taku Smokeries/Fisheries
550 South Franklin Street
Juneau, Alaska 99801

WARNING LETTER

Dear Mr. Lane:

We inspected your firm located at 550 South Franklin Street, Juneau, Alaska on August 8-9, 1999, 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 Jeremy A. LaPierre, Administrative Smokehouse Manager, at the conclusion of the inspection. These deviations, some of which were previously brought to your attention, cause your hot and cold 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.

The deviations were as follows:

1. You must have a HACCP plan that lists the food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(c)(1). Your firm's HACCP plan for hot smoked salmon does not list the food safety hazard of *Clostridium botulinum*.
2. You must have a HACCP plan that lists the critical control points, to comply with 21 CFR 123.6(c)(2). Your firm's HACCP plans for both hot and cold smoked salmon, and halibut lox (cold smoked) do not list the critical control point of brining for controlling the food safety hazard of *Clostridium botulinum*.
3. 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 your hot smoked products does not list time and temperature at the cooking critical control point to control for the food safety hazard of *Clostridium botulinum*, but they are listed on the HACCP worksheet.

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4. Since you chose to include corrective actions in your HACCP plans for hot and cold smoked salmon, your described corrective actions must be appropriate, to comply with 21 CFR 123.7(b). Your corrective actions listed in your various hot and cold smoked seafood product HACCP plans address only the safety of the product and does not address how you are going to correct the cause of the deviation.
5. You must have sanitation control records that document monitoring and corrections, to comply with 21 CFR 123.11(c). Your firm did not have a sanitation control record that included proper labeling, use, and storage of toxic compounds.

In addition, your TAKU SPREAD is misbranded within the meaning of Section 403(i)(2) of the Act in that it is fabricated from two or more ingredients, two of which are standardized foods, namely mayonnaise and cream cheese. However, the label fails to bear the common or usual name of each ingredient in the standardized foods as set forth in 21 CFR 101.4(b)(2).

During the previous inspection, on August 15, 1998, you were notified of deficiencies similar to those described in this letter. During the inspection, the FDA explained that you would need to take steps to correct those deficiencies. In a letter from you dated May 30, 1999, you assured the FDA that you had addressed those deficiencies and/or that your current practices were adequate to address the hazard of *Clostridium botulinum* toxin formation. The FDA is concerned that in one year's time your firm has not adequately corrected these deficiencies or developed fully adequate HACCP plans.

For your information, our investigator also noted during the inspection that your HACCP plan did not list the critical control point of label review for controlling the food safety hazard of allergens (eggs) in your salmon spread product. Our Center for Food Safety and Applied Nutrition (CFSAN) and Office of Seafoods is currently in the process of clarifying their position on this issue and a formal policy has not been issued.

The importance of the brining and smoking/drying steps as critical control points is reflected in the failure of samples (collected by our investigator during the August, 1999 inspection) of your hot and cold smoked salmon product to attain acceptable water phase salt levels (WPS). For products without added nitrites, a minimum 3.5% WPS level is required to discourage the growth of pathogenic bacteria. The average of ten packages of your hot smoked salmon was only 2.80% WPS, and none of those ten packages individually had an acceptable WPS. Your cold smoked salmon had one out of ten packages with an inadequate WPS level (subsample #9, with 3.44% WPS). This shows us that your brining and/or smoking/drying steps are inadequate (and the critical limits need to be more carefully defined). The salinity, time in brine, and smoking/drying time and temperature parameters (as the critical limits) work together to determine the WPS level and can easily be monitored and controlled, whereas actual WPS levels need to be determined by

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laboratory analysis (which takes longer and is not cost effective). Your HACCP plans must be revised to address these issues.

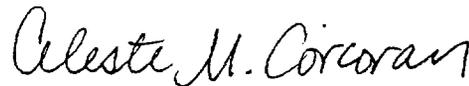
The above HACCP violations are not meant to be an all-inclusive list of deficiencies in your plant. Other violations can subject the food to legal action. It is your responsibility to assure that all of your products are in compliance with applicable statutes enforced by the FDA. We may take further 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.

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.

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 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations. Pertinent sections of the Act and regulations are enclosed for your review.

Please send your reply to the Food and Drug Administration, Attention: Lisa M. Elrand, Compliance Officer, 22201 23rd Drive SE, Bothell, WA 98021-4421. If you have any questions regarding any issue in this letter, please contact Lisa M. Elrand at (425) 483-4913.

Sincerely,



for Charles M. Breen
District Director

Enclosures:
Form FDA 483
21 CFR Part 123
21 CFR Part 101.4
Section 402 of the Federal Food, Drug, and Cosmetic Act