



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

June 21, 2001

**VIA CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

In reply refer to Warning Letter SEA 01-62

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 April 17, 2001, 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, 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](http://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 refrigerated, vacuum packed picked crab does not list the food safety hazard of *Clostridium botulinum*.
2. 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 refrigerated, vacuum-packed, sockeye and halibut does not list the smoker cabinet temperature, rather it lists "temperature not to exceed 90 ° F." Your smokehouse manager reported that the firm probes the thickest fillet in the coldest part of the oven rather than the oven temperature in the warmest part of the oven to ensure they do not exceed the critical limit.
3. You must take an appropriate corrective action when a deviation from a critical limit occurs, to comply with 21 CFR 123.7 (a). Your firm did not take a corrective action, to control the hazard of *Clostridium botulinum*, when eight of your processing records from October through December 2000 failed to meet the critical limit of 90 ° F. According to your HACCP plan your corrective action for this critical limit is to "adjust smoking program" and to

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“record the corrective action on the corrective action report.” Neither of these steps was done on any of the eight occasions (11/16, 18, 23, 24/00 and 12/4, 8, 18, 20/2000). In addition, your dried jerky HACCP plan does not address both the affected product as well as the cause of the deviation. For your refrigerated, vacuum packed crab meat HACCP plan you do not address the affected product in your pre-planned corrective action only the cause of the problem. Your plan needs to address how you are going to prevent affected product from being distributed as well as how you plan to address the deviation itself.

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’s monitoring records do not address the eight points of sanitation which include:
  - a) The safety of the water that comes into contact with food or food contact surfaces, or is used in the manufacture of ice;
  - b) Conditions and cleanliness of food contact surfaces, including utensils, gloves, and outer garments;
  - c) Prevention of cross-contamination from insanitary objects to food, food packaging materials, and other food contact surfaces, including utensils, gloves and outer garments, and from raw product to cooked product;
  - d) Maintenance of hand washing, hand sanitizing, and toilet facilities;
  - e) Protection of food, food packaging material, and food contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate, and other chemical, physical, and biological contaminants;
  - f) Proper labeling, storage, and use of toxic compounds;
  - g) Control of employee health conditions that could result in the microbiological contamination of food, food packaging materials, and food contact surfaces; and
  - h) Exclusion of pests from the food plant.

In our Warning Letter dated May 5, 2000, you were notified of deficiencies similar to those described in this letter. During the inspection, the Food and Drug Administration (FDA) explained that you would need to take steps to correct those deficiencies. In letters from you dated May 24 and 25, 2000, 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.

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 April 16, 2001, inspection) of your frozen cold-smoked sockeye salmon product from lot “C079121” to attain acceptable water

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phase salt levels (WPS). For products without added nitrites, a minimum 3.5% WPS level is required to discourage the growth of pathogenic bacteria. One of the ten sub samples was found to have a WPS of 3.3, the average for the 10 sub samples collected was 3.98. Your sockeye lox had one out of ten packages with an inadequate WPS level (subsample #2, with 3.3 % WPS). This shows us that the 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 laboratory analysis (which takes longer and is not cost effective). Your HACCP plans must be revised or more closely followed 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.

Please send your reply to the Food and Drug Administration, Attention: Bruce Williamson, Compliance Officer, 22201 23<sup>rd</sup> Drive SE, Bothell, WA 98021-4421. If you have any questions regarding any issue in this letter, please contact Mr. Williamson at (425) 483-4976.

Sincerely,

  
for Charles M. Breen  
District Director

Enclosures:  
Form FDA 483

cc: ADEC with disclosure statement