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

October 7, 1999

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

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 00-05

Dan O'Neil, Owner  
Northern Lights Smokeries  
501 Noseeum Street  
Petersburg, Alaska 99833

WARNING LETTER

Dear Mr. O'Neil:

On August 7, 1999, the Food and Drug Administration (FDA) conducted an inspection of your facility located at 501 Noseeum Street, Petersburg, Alaska. At the conclusion of the inspection, [REDACTED] 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 hot-smoked, vacuum-packed salmon processed by your firm is 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 firm's HACCP plan for hot-smoked, vacuum-packed salmon does not list *Clostridium botulinum* as the specific significant hazard most reasonably likely to occur for your process. As our investigator explained, "bacterial pathogens" encompasses a wide range of organisms, and it is important to list the specific pathogen being controlled in your HACCP plan. 21 CFR Part 123.6(c)(1) requires you to list, at a minimum, the food safety hazards that are reasonably likely to occur.

2. In your HACCP plan for hot-smoked, vacuum-packed salmon, brining is not listed as a critical control point. Our investigator also noted that there appears to be a discrepancy between your response letter to FDA received on April 13, 1999, and actual procedures followed at your firm. 21 CFR Part 123.6(c)(2) requires you to list the critical control points for each identified food safety hazard. In addition, 21 CFR Part 123.16 requires you to include in your HACCP plan how you are controlling the food safety hazard associated with the formation of toxin produced by *Clostridium botulinum* for at least as long as the shelf-life of the product under normal and moderate abuse conditions. Brining, as a critical control point, addresses both of these issues.

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3. In your HACCP plan, calibration of thermometers is not listed as a verification procedure. 21 CFR Part 123.6(c)(6) requires you to list the verification procedures, and frequency thereof, that the processor will use in accordance with 21 CFR Part 123.8(a)(2)(ii), on-going verification activities.
4. During the inspection, our investigator observed that there is no record showing that a visual check is made at the start and end of your cook step. 21 CFR Part 123.6(c)(7) requires you to provide for a record keeping system that documents the monitoring of critical control points. Further, the records shall contain the actual values and observations obtained during monitoring.
5. During the inspection, our investigator noted that recording thermometer charts are not signed and dated, indicating they were reviewed. 21 CFR Part 123.8(a)(3)(i) requires a review of critical control point monitoring records. The purpose of this review is to ensure that records are complete and to verify that values are within critical limits. This procedure shall include review, signing, and dating of documents within one week of the day that the records are made. An individual trained in HACCP must conduct these procedures.

During the previous inspection, on August 13, 1998, and in a letter from the FDA, dated March 30, 1999, you were notified of the same deficiencies described in points numbered 1 through 5 of this letter. During the inspection, and in the letter, the FDA explained that you would need to take steps to correct those deficiencies. The FDA is concerned that in fourteen months time your firm has not taken action to correct these deficiencies.

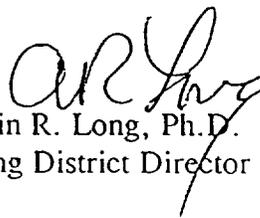
The above HACCP violations are not meant to be an all-inclusive list of deficiencies in your plant. Other violations can subject the food to legal action. It is your responsibility to assure that all of your products are in compliance with applicable statutes enforced by the FDA. You should take prompt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

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

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the corrections will be completed. Pertinent sections of the Act and the Regulations are enclosed for your review. Your reply relating to these concerns should be addressed to the Food and Drug Administration, Attention: Diane J. Englund, Acting Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421.

Sincerely,

A handwritten signature in black ink, appearing to read "AR Long".

Austin R. Long, Ph.D.  
Acting 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