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December 10, 1999

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

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

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 00-23

Alan D. Otness, President  
Tonka Seafoods, Inc.  
22 Sing Lee Alley  
Petersburg, Alaska 99833

WARNING LETTER

Dear Mr. Otness:

We inspected your firm located at 22 Sing Lee Alley, Petersburg, Alaska on August 5, 1999, and found that you have serious deviations from the Seafood HACCP regulations, Title 21 of the Code of Federal Regulations Part 123 (21 CFR 123) which were listed on Form FDA 483 (copy enclosed) presented to you at the conclusion of the inspection. These deviations, some of which were previously brought to your attention, cause your vacuum packed hot 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, in order to comply with 21 CFR 123.6(c). Specifically, 21 CFR 123.16 requires that processors of smoked and smoke-flavored fishery products include in their HACCP plan how they are controlling the food safety hazard associated with the formation of toxin by *Clostridium botulinum* (*C. botulinum*). However, your firm's HACCP plan for vacuum packed hot smoked salmon does not specifically list the food safety hazard related to *C. botulinum* and its toxin formation.
2. You must have a HACCP plan that lists the critical control points in order to comply with 21 CFR 123.6(c)(2), as well as the corresponding critical limits that must be met in order to comply with 21 CFR 123.6(c)(3). However, your firm's HACCP plan for vacuum packed hot smoked salmon does not list the critical control point of brining (with an appropriate corresponding critical limit of 3.5 water phase salt) for controlling the food safety hazard related to *C. botulinum*.

Alan D. Otness, President  
Tonka Seafoods, Inc., Petersburg, AK  
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According to the *Fish and Fisheries Products Hazards and Controls Guide* (Chapter 13: *Clostridium botulinum* Toxin and Formation) control of water phase salt is critical to the safety of all smoked fish and fishery products. A water phase salt level adequate for inhibiting toxin formation must be achieved during the brining step. This was brought to your attention as a result of the August 8 and 10, 1998, inspection and in a letter dated January 26, 1999. You have not taken any steps to correct this deficiency since this notification. The agency is currently unaware of any method to control *C. botulinum* growth and toxin formation, other than controlling the brining process to achieve a final water phase salt level of 3.5 (when no nitrites are used), in conjunction with the smoking process. We have no data or information to support that the smoking (cook) process alone is an adequate control strategy.

3. You must have a HACCP plan that lists monitoring procedures for each critical control point, in order to comply with 21 CFR 123.6(c)(4). However, your firm's HACCP plan for vacuum packed hot smoked salmon lists a monitoring frequency at the "refrigerate or freeze" critical control point that is not adequate to control *C. botulinum*.

21 CFR Part 123.6(c)(4) requires that you list, in your HACCP plan, the procedures, and frequency thereof, that will be used to monitor each of the critical control points to ensure compliance with the critical limits. You state in your HACCP plan you will monitor refrigeration or freezing once per day, but you will take corrective action if the temperature is above 38° Fahrenheit for more than 2 hours. This deficiency was also brought to your attention as a result of the August 8 and 10, 1998, inspection and in a letter dated January 26, 1999, and you have not made any corrective action in 8 months time.

4. You are not maintaining a record keeping report to document your monitoring of refrigeration or freezing as stated in your HACCP plan. You must have monitoring records which contain the actual values and observations obtained during monitoring, in order to comply with 123.6(b) and (c)(7).

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.

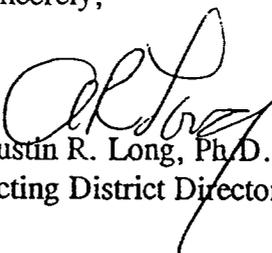
Alan D. Otness, President  
Tonka Seafoods, Inc., Petersburg, AK  
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Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may 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.

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 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 23<sup>rd</sup> Drive SE, Bothell, Washington 98021-4421. If you have any questions regarding any issue in this letter, please contact Lisa Elrand at (425) 483-4913.

Sincerely,



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: With Disclosure Statement  
ADEC