



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

COPY

November 1, 1999

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 00-11

David Underwood, General Manager
Quinault Tribal Enterprises
100 West Quinault Street
Taholah, Washington 98587

WARNING LETTER

Dear Mr. Underwood:

On August 9-11, 1999, the Food and Drug Administration (FDA) conducted an inspection of Quinault Tribal Enterprises located at 100 West Quinault Street, Taholah, Washington. At the conclusion of the inspection, you were 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 low acid canned food, fresh and frozen Dungeness crab, and hot smoked vacuum packaged salmon processed by your firm are adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act) and 21 CFR Part 123.

LACF OBSERVATIONS

1. Upon review of your processing records since January 1, 1999, our investigator noted only 18 days of visual seam inspection and double seam examinations for [redacted] days of production. 21 CFR Part 113.60(a) requires that a visual examination of can seam closures shall be made by a qualified person at intervals of sufficient frequency to ensure proper closure.
2. Our investigator noted that your daily processing records were not routinely dated. 21 CFR Part 113.100(a) requires you to enter processing and production information at the time it is observed. This regulation requires you to list all information provided in that section including the date of processing.
3. Review of your double seam teardown records by our investigator revealed that production codes and day codes are not routinely recorded on your forms. 21 CFR 113.100(c) requires that written records of all container closure examinations shall specify the product code, the date and time of container closure inspections, the measurements obtained, and all corrective actions.

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taken. In addition, our investigator noted that the manufacturer's specifications were not available for review as a comparison to your firm's teardown measurements.

4. Your firm does not maintain a process deviation file as observed by our investigator. 21 CFR Part 113.89 requires that each processor maintain a separate file or log detailing all process deviations and the actions taken. A process deviation occurred on July 31, 1998 in retort # at your firm. This was addressed in a letter to you from the FDA dated April 14, 1999. This is one example of a process deviation, which occurred in the past, and for which no documentation was found by our investigator.

HACCP OBSERVATIONS

1. In reviewing both of your HACCP plans for Dungeness crab and hot smoked fish, it appears that you do not have a separate written HACCP plan for each of the products processed at your plant. 21 CFR Part 123.6(b)(2) requires you to have a separate HACCP plan for each fish and fishery product processed at your facility. You may only group fish and fishery products together, if the food safety hazards, critical control points, critical limits, and procedures required to be identified and performed in 21 CFR Part 123.6(c) are identical for all fish and fishery products so grouped.

2. Your written HACCP plan for ready to eat cooked Dungeness crab does not identify pathogen survival in the cook step as a critical control point to control the hazard of pathogen survival through cooking. In addition, your written HACCP plan for Dungeness crab does not identify the receiving step as a critical control point to control the hazard of natural toxins. 21 CFR Part 123.6(c)(2) requires you to list the critical control points for each identified food safety hazard that is reasonably likely to occur for your processes.

3. Our investigator noted that the HACCP monitoring and verification records have not been completed for hot smoked vacuum packaged salmon and Dungeness crab processes for the 1999-processing year. 21 CFR Part 123.6(c)(7) requires you to provide for a record keeping system that documents the monitoring of the critical control points. The records shall contain the actual values and observations obtained during monitoring.

4. Your HACCP plan for hot smoked vacuum packaged salmon and Dungeness crab have not been signed and dated by a responsible individual onsite or by a higher level official. 21 CFR Part 123.6(d) requires the signing and dating of all HACCP plans used at your facility.

5. In your HACCP plan for hot smoked vacuum packaged salmon, the critical control points of brining, smoking/drying/heating, cooling, and storage do not specifically address *Clostridium botulinum* toxin as the food safety hazard that is reasonably likely to occur for your process. 21

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CFR Part 123.6(c)(1) requires you to specifically list the food safety hazards that are reasonably likely to occur.

6. The critical control point of brining in your HACCP plan for hot smoked vacuum packaged salmon does not identify the specific critical limits for brine time and brine strength that must be met in order to achieve a minimum water salt phase level of 3.5% in your finished product. 21 CFR Part 123.6(c)(3) requires you to do so. In addition, the process schedule referred to in your plan does not appear to exist, as observed by our investigator. 21 CFR Part 123.6(c)(6) also requires you to list the verification procedures and frequency thereof, that the processor will use in accordance with 21 CFR Part 123.8(a), *overall verification*. No mention of quarterly water phase salt analysis is mentioned in your plan as a means of verifying brining as a critical control point.

7. The critical control point of smoking/cooking in your HACCP plan for hot smoked vacuum packaged salmon does not specify the critical limits for "time/center temp as per process schedule." 21 CFR Part 123.6(c)(3) requires you to list the critical limits that must be met at each critical control point to control the food safety hazard that is reasonably likely to occur. The internal temperature of the fish must be maintained at or above 145° Fahrenheit throughout the fish for at least thirty minutes, in order to control the formation of *Clostridium botulinum* toxin.

8. The critical control point of cooling in your HACCP plan for hot smoked vacuum packaged salmon does not specify the critical limits that must be met for the cooling process. Your HACCP plan states "maximum cooler temperature." The product must not be exposed to temperatures above 50° Fahrenheit for more than 12 hours nor to temperatures above 70° Fahrenheit for more than 4 hours, excluding time above 140° Fahrenheit, in order to control the formation of *Clostridium botulinum* toxin. 21 CFR Part 123.6(c)(3) requires you to list the critical limits that must be met in order to control your identified food safety hazard. There is also no mention of the procedures, and frequency thereof, that will be used to monitor this critical control point. 21 CFR Part 123.6(c)(4) requires you to list this to ensure compliance with the critical limits.

9. Sanitation issues that were observed in a previous inspection that occurred on September 1-3, 1998, still continue to exist at your facility. This was brought to your attention in a letter dated April 14, 1999. In a written response to FDA on May 10, 1999, you explained that these sanitation violations had been corrected. Our investigator found the same violations during her recent inspection. These conditions are indicative of sanitation failures in your plant. We remind you that all of the requirements in 21 CFR Part 110, Good Manufacturing Practice Regulations (GMPs) apply in your facility. 21 CFR Part 123.5 specifies that Part 110 (GMPs) apply in determining whether the facilities, methods, practices, and controls used to process fish

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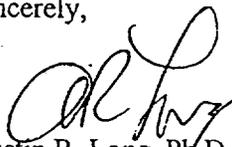
and fishery products are safe, and whether these products have been processed under sanitary conditions.

During the previous inspection, on September 1-3, 1998, and in a letter from the FDA, dated April 14, 1999, you were notified of many of the same deficiencies described in the numbered points discussed in 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 thirteen 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 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,



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