



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

November 24, 1999

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

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 00-20

Howard Garcia, Owner  
Native American Shellfish Company  
3622 Lummi Shore Drive  
Bellingham, Washington 98225

WARNING LETTER

Dear Mr. Garcia:

On June 23, 1999, the Food and Drug Administration (FDA) conducted an inspection of your firm at 3622 Lummi Shore Drive, Bellingham, 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 Regulations). A copy of Form FDA 483 is enclosed for your review. By virtue of these deficiencies, the cooked dungeness crab meat processed by your firm is adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act) due to violations of 21 CFR Part 123.

1. Your firm was not maintaining sanitation monitoring records for all the days in which you processed. The records you have do not include safety of processing water, prevention of cross contamination, proper labeling, storage, and use of toxic compounds, control of employees with adverse health conditions, and exclusion of pests.

21 CFR Part 123.11(b) requires you to monitor the conditions and practices during processing that relate to the eight areas of sanitation. 21 CFR part 123(c) requires that you maintain records of that monitoring and any correction made as a result of that monitoring.

During the previous inspection, on June 11-12, 1998, and in a letter from the FDA, dated August 18, 1998, you were notified of the above deficiency. During the inspection, and in the letter, the FDA explained that you would need to take steps to correct this deficiency. The FDA is concerned that in twelve months time your firm has not taken action to correct this deficiency.

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

Howard Garcia, Owner  
Native American Shellfish Co, Bellingham, WA  
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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: Lisa M. Elrand, Compliance Officer, 22201 23<sup>rd</sup> Drive S.E., Bothell, Washington 98021-4421.

Sincerely,

*Bruce W Williamson*  
for 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  
WSDA