



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

June 7, 1999

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

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 99-23

Gregory F. Baker, President  
Westward Seafoods, Inc.  
1111 3<sup>rd</sup> Avenue, Suite 2250  
Seattle, Washington 98101

WARNING LETTER

Dear Mr. Baker:

On January 27 and 28, 1999, the Food and Drug Administration (FDA) conducted an inspection of your plant at One Mile Captains Bay Road, Dutch Harbor, Alaska. At the conclusion of the inspection, John D. Nordin, Production Manager, 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 cooked opilio crab sections 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.

Your firm did not have a HACCP plan for cooked crab sections to address the food safety hazard of pathogen survival at the cook step. 21 CFR Part 123.6(a) requires you to conduct a hazard analysis to determine if there are food safety hazards that are reasonably likely to occur for this product. The FDA acknowledges that you did conduct a hazard analysis for this product; however, we do not agree that this product is free of food safety hazards. Pathogen survival at the cook step is a food safety hazard that is reasonably likely to occur. Based on this, 21 CFR Part 123.6(b) requires you to have and implement a HACCP plan for this product.

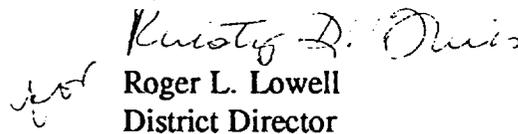
The above HACCP violation is not meant to be an all-inclusive list of deficiencies in your plant. Other violations can subject the food to legal action. It is your responsibility to assure that all of your products are in compliance with applicable statutes enforced by the FDA. You should take prompt action to correct the violation noted in this letter. Failure to promptly correct this violation may result in regulatory action without further notice, such as seizure and/or injunction.

Gregory F. Baker, President  
Westward Seafoods, Inc., Seattle, WA  
Re: Warning Letter SEA 99-23  
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One deficiency with your Surimi, Raw, Frozen HACCP plan was a discrepancy between the critical limit and that which is monitored. The critical limit listed "No detectable fragments in finished product" while "presence of metal fragments 0.3 inches or larger dimension in finished product" is listed under what monitored. This deficiency is not considered to be a serious deviation from the HACCP Regulation. However, it is important that you make the necessary corrections to resolve the discrepancy between these two statements.

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: Janelle K. Main, Compliance Officer, 22201 23<sup>rd</sup> Drive SE, Bothell, Washington 98021-4421.

Sincerely,

  
Roger L. Lowell  
District Director

3 Enclosures:  
Form FDA 483  
21 CFR PART 123  
Section 402 of the Federal Food, Drug, and Cosmetic Act

cc: ADEC with disclosure statement