



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

May 14, 1999

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 99-19

Tamotsu Nakamura, President
Shining Ocean, Inc.
2440 West Commodore Way
Seattle, Washington 98199

WARNING LETTER

Dear Mr. Nakamura:

On February 12 and 16, 1999, the Food and Drug Administration (FDA) conducted an inspection of your firm located at 2440 West Commodore Way, Seattle, Washington. At the conclusion of the inspection, Ray B. McCready, Quality Assurance 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 vacuum packaged, frozen imitation crab meat manufactured 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. The HACCP plan did not address the food safety hazard of post pasteurization pathogen contamination. 21 CFR Part 123.6(c)(1) requires you to list in your HACCP plan the food safety hazards that are reasonably likely to occur and therefore must be controlled. The need to address post pasteurization pathogen contamination was brought to your attention as a result of the April 30 and May 4, 1998, inspection. In a letter to the FDA, dated August 7, 1998, Mr. McCready promised correction of this deficiency.
2. The HACCP plan did not include critical limits for package thickness. Package thickness is a critical factor that directly affects pathogen survival at the pasteurization step. 21 CFR Part 123.6(c)(3) requires you to list critical limits that must be met for each critical control point.
3. Since the previous inspection, your firm has installed a new (#2) pasteurizer. According to your HACCP plan, you were applying the same critical limits (water temperature, core temperature, and belt speed) to the new pasteurizer as are assigned to your original (#1) pasteurizer. Pasteurizer (#2) operates differently than pasteurizer (#1), in that [REDACTED]. Additionally, the product passes through pasteurizer (#2) [REDACTED] 21 CFR

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Part 123.6(c)(3) requires you to list appropriate critical control limits at each critical control point. 21 CFR Part 123.8(a)(1) requires you to reassess your HACCP plan whenever processing methods or systems change.

4. The critical limits for the east cooler critical control point are not adequate to control the food safety hazard of *Clostridium botulinum* growth and toxin formation in product that cannot be run through the freezer immediately. 21 CFR Part 123.6(c)(3) requires you to list appropriate and adequate critical control limits at each critical control point. 21 CFR Part 123.8(a) requires you to verify that your HACCP plan is adequate to control food safety hazards that are reasonably likely to occur.
5. Review of eight temperature records found at least five instances where the hot water temperature critical limit of > [REDACTED] degrees Celsius was not met. 21 CFR Part 123.7(a) requires you to take a corrective action whenever a critical limit is not met. This deficiency was brought to your attention as a result of the April 30 and May 4, 1998, inspection. In a letter to the FDA, dated August 7, 1998, Mr. McCready promised correction of this deficiency.
6. The pre-determined corrective actions at the pasteurization and tote in east cooler critical control points are not adequate in that they do not address the safety of the product affected by the deviation, nor do they address the cause of the deviation. When a deviation from a critical limit occurs you must accomplish two things. 21 CFR Part 123.7(b)(1) requires you to ensure products injurious to health do not enter interstate commerce. 21 CFR Part 123.7(b)(2) requires you to ensure the cause of the deviation is corrected.
7. There were no records indicating that your firm monitors the following four of eight areas of sanitation:
 - a. prevention of cross contamination;
 - b. protection from adulterants;
 - c. proper storage, use and labeling of toxic compounds; and
 - d. control of employees with adverse health conditions.

21 CFR Part 123.11(c) requires you to maintain records of sanitation monitoring and any correction made as a result of that monitoring. This deficiency was brought to your attention as a result of the April 30 and May 4, 1998, inspection. In a letter to the FDA, dated August 7, 1998, Mr. McCready promised correction of this deficiency.

8. Our investigator noted the sanitation deficiencies listed below.
 - a. The outside of the splitter drip tank was soiled. Condensate from the outside of the drip tank ran continuously on product and the conveyor belt.

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- b. There was no soap or paper towels at the hand wash station by the steamer machine.
- c. There was a large amount of uncovered trash in the dry ingredient storage area.

21 CFR Part 123.11(b) requires that eight areas of sanitation be monitored and corrective action be taken whenever a sanitation problem is found. The above observations demonstrate that you are not adequately monitoring the prevention of cross contamination or the maintenance of hand washing stations.

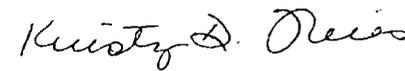
The above HACCP violations are not meant to be an all-inclusive list of deficiencies in your plant. Other violations can subject the food to legal action. It is your responsibility to assure that all of your products are in compliance with applicable statutes enforced by the FDA. You should take prompt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

9. The HACCP plan did not address the food safety hazards listed below:

- a. *Staphylococcus aureus* growth and toxin formation in product held for re-work; and
- b. the potential for undeclared allergenic ingredients, including egg whites and soy protein.

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 23rd Drive SE, Bothell, Washington 98021-4421.

Sincerely,


for Roger L. Lowell
District Director

Enclosures:

Form FDA 483

21 CFR PART 123

Section 402 of the Federal Food, Drug, and Cosmetic Act

cc: WSDA with disclosure statement