



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

Telephone: 425-486-8788  
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April 10, 2001

**VIA CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

In reply refer to Warning Letter SEA 01-46

William Terhar, President  
Ocean Beauty Seafoods, Inc.  
1100 West Ewing Street  
Seattle, Washington 98144

**WARNING LETTER**

Dear Mr. Terhar:

We inspected your firm located at 4800 Irving Street, Boise, Idaho, on February 28, 2001, and found that you have serious deviations from Title 21 of the Code of Federal Regulations (21 CFR) Part 123 - Fish and Fishery Products (Seafood HACCP regulations). A FDA 483 form (copy enclosed) listing the deviations was presented to Jon W. (J. B.) Alexander, at the conclusion of the inspection. These deviations, some of which were previously brought to your attention, cause your whole cooked crab and fresh tuna, 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:

You must implement the monitoring procedures listed in your HACCP plan, to comply with 21 CFR 123.6 (b). However, your firm did not follow the monitoring procedures or frequency of monitoring the core temperatures of scrombroid species or for Cooked Ready to Eat of 38° F listed in your HACCP plan. In addition, you must implement the record keeping system listed in your HACCP plan, to comply with 21 CFR 123.6 (b). Examples of these failures are as follows:

- Your HACCP plan at the receiving fresh step for scrombroid species shows that core temperature is to be 40° F or less, that the gel pack is to be frozen, and that ice is still present. Your corrective action(s) show that you will reject product: "1). If core temperature is above 40° F. 2). If frozen gel-packs, surrounding product, are thawed. 3). If ice surrounding product, is thawed. 4). Find out what caused problem." The record section of this part of your HACCP plan states: "1). Record on B.O.L. & Q. C. Report. 2). Temperature log records." There are no records showing if frozen gel-packs are frozen or thawed, the records do not show if ice is still present or not, and the records do not show

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what caused the problem when temperatures were found to be at or above 40° F as was noted on at least six occasions (December 11, 19, 20, 21, 22, 2000 and January 1, 2001).

- Your HACCP plan at the receiving step for Cooked Ready to Eat products, which includes cooked whole crab, shows the critical limits as: “1). Core Temperature not to exceed 38° F. 2). Gel Pack remains frozen. 3). Ice still present.” Your corrective actions state “Reject product: 1). If core temperature is above 38° F. 2). If frozen gel packs, surrounding product, are thawed. 3). If ice surrounding product, is thawed. 4). Find out what caused problem.” Your HACCP plan also shows the records documenting these values are on the Bill of Lading (B.O.L.), the Q.C. Report and the Temperature log records. Your records do not document if the gel pack remains frozen, nor do they record if ice is still present, nor did they determine what caused the problem. On December 11, 19, 20, 21, 22, 2000, and January 1, 2001, your log shows that temperatures exceeded 38° F yet no determination was made of “What caused the problem”. In addition, your records do not show how long the product was above the critical limit, and the products were not rejected as called for in the plan.

You must take an appropriate corrective action when a deviation from a critical limit occurs, to comply with 21 CFR 123.7 (a). However, your firm did not take a corrective action to control the hazards of “bacterial pathogens and histamine development” when your process for scrombroid species deviated from your critical limit at the cooler and processing storage steps in that:

- Your temperature records for December 2000 and January 2001 show six instances where temperatures exceeded your critical limit of 38° F (12/11, 12/19, 12/20, 12/21, 12/22/2000 and 1/2/2001).
- Your temperature recordings do not show the time the temperature was taken and no follow-up temperatures were taken to document the length of time the product was above the critical limit.
- No corrective action was taken, and documented, although your HACCP plan requires that product above the critical limit be either isolated and monitored, or destroyed, depending on the length of time the product was exposed to temperatures above the critical limit.

In addition, your firm did not take a corrective action to control the hazards of bacterial pathogens when your critical limits for ready to eat product was exceeded on December 11, 19, 20, 21, 22, 2000, and January 2, 2001. Your HACCP plan does not specify whether the Critical Limit of 38° F is a core temperature or a cooler temperature. In either event your records show that the cooler temperature was at least 40° F for an unspecified length of time. Your records do not show how long the temperature was at or above 40° F.

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Since you chose to include corrective actions in your HACCP plan, your described corrective actions must be appropriate to comply with 21 CFR 123.7 (b). However, your corrective action plan for scrombroid species at the processing storage critical control point to control the hazards of bacterial pathogens is not appropriate in that:

- The Corrective action listed in item #1 only addresses temperatures within the range of 40-45° F, for less than two hours, when the critical limit is 38° F or above.
- The Corrective action plan list temperatures in the range of 40-45° F for over two hours, but does not address corrective actions when temperatures go above 45° F or product at 39° F for over two hours, or a cumulative time/temperature standard.

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 Federal Food, Drug, and Cosmetic Act and all applicable regulations.

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.

Please send your reply to the Food and Drug Administration, Attention: Bruce Williamson, Compliance Officer, 22201 23<sup>rd</sup> Drive SE, Bothell, Washington 98021. If you have questions regarding any issue in this letter, please contact Mr. Williamson at (425) 483-4976.

Sincerely,



Charles M. Breen  
District Director

Enclosures:

Form FDA 483

21 CFR PART 123

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

cc: ISDH with disclosure statement