



DEPARTMENT OF HEALTH AND HUMAN SERVICES

M 35531

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

March 14, 2000

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 00-32

John P. Kaney, Owner  
Newport Seafoods, Inc.  
927 South Homer  
Seattle, Washington 98108

**WARNING LETTER**

Dear Mr. Kaney:

We inspected your firm, located at 927 South Homer, Seattle, Washington, on January 13, 2000, 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 form FDA 483 (copy enclosed) listing the deviations was presented to you at the conclusion of the inspection. These deviations, some of which were previously brought to your attention, cause your cooked Dungeness crab, live Dungeness crab, fresh mahi mahi and other scombroid fish species 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 have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, in order to comply with 21 CFR 123.6(b). Your firm does not have a HACCP plan for fresh mahi mahi, and other scombroid species your firm processes to control the food safety hazard of scombrototoxin formation. This deviation was previously brought to your attention during the June 2-4, 1999, inspection, and in our letter of September 10, 1999.

Your firm does not have a HACCP plan for cooked, refrigerated, whole Dungeness crab to control the food safety hazard of pathogens.

Your firm does not have a HACCP plan for live, whole Dungeness crab to control the food safety hazard of natural environmental toxins and chemical hazards.

Your firm does not have a HACCP plan for fresh, cooked, ready-to-eat crustaceans to control the food safety hazard of pathogens.

John P. Kaney, Owner  
Newport Seafoods, Inc., Seattle, WA  
Re: Warning Letter SEA 00-32  
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We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product and/or enjoin your firm from operating.

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. Please include in your response HACCP plans for all of the products processed by your firm and any 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.

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 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations. Pertinent sections of the Act and regulations are enclosed for your review.

Please send your reply to the Food and Drug Administration, Attention: Robert L. Wesley, Compliance Officer, 1000 2<sup>nd</sup> Avenue, Suite 2400, Seattle, Washington 98104. If you have questions regarding any issues in this letter, please contact Robert Wesley at 206/553-7001, extension 57.

Sincerely,

A handwritten signature in black ink, appearing to read 'Charles M. Breen', written over a horizontal line.

Charles M. Breen  
District Director

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

cc: WSDA with disclosure statement