



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

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

September 24, 2002

**VIA CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

In reply refer to Warning Letter SEA 02-63  
Gary L. Gerontis, President  
Johnny's Seafood Company, Inc.  
1199 Dock Street  
Tacoma, Washington 98402

**WARNING LETTER**

Dear Mr. Gerontis:

We inspected your firm located at 1199 Dock Street, Tacoma, Washington, on July 16, 2002, 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 Robert R. Iverson, Vice President. These deviations, some of which were previously brought to your attention, cause your seafood operation 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). Our office has received your response dated August 26, 2002.

The deviations are as follow:

Domestic Seafood HACCP plans:

1. You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur, and you must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6 (a) and (b). Your firm does not have a HACCP plan for cooked ready-to-eat seafood products (for example, whole cooked Dungeness crab and refrigerated canned crabmeat) to control the food safety hazard of pathogens and/or *Clostridium botulinum*. You must conduct a hazard analysis for all seafood products you receive and implement a HACCP plan when necessary.

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2. You must have a HACCP plan that lists monitoring procedures for each critical control point, to comply with 21 CFR 123.6(c)(4). Your firm's HACCP plan for Scrombroid Species lists a monitoring procedure and frequency that is not adequate to control the hazard of histamine formation. Your plan lists that you will monitor your cooler temperature with visual checks. FDA does not consider periodic checks of cooler temperatures or internal product temperatures an adequate safety control for the storage of histamine forming species. Since one of your coolers is not equipped with a continuous temperature monitoring device, you should alter your plans to accommodate the possibility of scrombroid species being stored in that cooler. If you determine to keep your scrombroid species in the cooler with the continuous temperature recording device, your plan should reflect that the temperature will be monitored continuously with a daily visual check of the device.

Imported Seafood:

1. You must have product specifications that are designed to ensure that the fish and fishery products you import are not adulterated under section 402 of the Act because they may be injurious to health or may have been processed under insanitary conditions, to comply with 21 CFR 123.12 (a)(2)(i). Your firm does not have a product specification for the aquacultured Atlantic salmon you import from Canada.
2. You must implement an affirmative step which ensures that the fish and fishery products you import are processed in accordance with the seafood HACCP regulation, to comply with 21 CFR 123.12(a)(2)(ii). Your firm did not perform an affirmative step for the aquacultured Atlantic Salmon processed by [REDACTED] in Canada.

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. We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

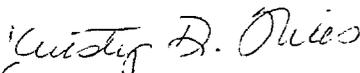
Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as your revised HACCP plan and copies of your monitoring records, 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

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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: Lisa M. Elrand, Compliance Officer, 22201 23<sup>rd</sup> Drive SE, Bothell, Washington 98021. If you have questions regarding any issue in this letter, please contact CO Elrand at (425) 483-4913, or email her at [lelrand@ora.fda.gov](mailto:lelrand@ora.fda.gov).

Sincerely,

  
for Charles M. Breen  
District Director

Enclosures:  
Form FDA 483

cc: WSDA with disclosure statement