



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

Telephone: 425-486-8788  
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December 11, 2002

**VIA CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

In reply refer to Warning Letter SEA 03-07

Hiromi Yagishita, President  
Y & L Washington, Inc.  
398 South Kalorama Street  
Ventura, California 93001-2933

**WARNING LETTER**

Dear Mr. Yagishita:

We inspected your firm, Y & L Washington, Inc., 401 East 25<sup>th</sup> Street, Tacoma, Washington, on August 26, 27, and 28, 2002, and found you have serious deviations from Title 21 of the Code of Federal Regulations (21 CFR) Part 123 - Fish and Fishery Products (Seafood HACCP regulations) and 21 CFR Part 101 – Food Labeling. A FDA 483 form (copy-enclosed) listing the deviations was presented to Juan B. Mercado, Production Supervisor, at the conclusion of the inspection. In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part renders the fish or fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). Accordingly, your sea urchin roe and imported sea urchins are adulterated, in that the products have been prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health. Additionally, our review of your labels and labeling found your products to have serious labeling deficiencies in violation of Section 403 of the Act. You can find this Act, the Seafood HACCP regulations, and the food labeling regulations, through links in FDA's homepage at [www.fda.gov](http://www.fda.gov).

The deviations are as follows:

1. You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and have a HACCP plan that, at a minimum, lists the food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(a) and (c)(1). A food safety hazard is defined in 21 CFR Part 123.3(f) as "any biological, chemical, or physical property that may

cause a food to be unsafe for human consumption." However, your firm's HACCP plan for Sea Urchin Roe does not list the food safety hazard of pathogen growth through temperature abuse at the receiving critical control point. The product is considered ready-to-eat since the only additional processing will be brining. Therefore, control of this food safety hazard, the monitoring steps, and the required records, should be listed in your HACCP plan.

2. You must have a HACCP plan that, at a minimum, lists the critical limits that must be met, to comply with 21 CFR 123.6(c)(3). A critical limit is defined in 21 CFR Part 123.3(c) as "the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard." However, your firm's HACCP plan for Sea Urchin Roe does not list critical limit(s) at the "cold storage prior to packing" and "completed trays are placed in styrofoam cases in cooler" critical control points that are adequate to control pathogen growth through temperature abuse. The FDA Fish & Fishery Products Hazards & Controls Guidance, Third Edition, recommends that ready-to-eat products be maintained at temperatures below 40°F. In addition, the aforementioned guidance recommends that the temperatures be monitored continuously with a device that generates a record (log) of the storage temperature during the entire storage cycle.
3. You must adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR 123.11(b). Your firm did not monitor the following areas with sufficient frequency:
  - Prevention of cross-contamination in that food contact surfaces and product packaging for sea urchin roe exhibited dried food product particles.
  - Exclusion of pests in that the truck bay door was observed to be open throughout the inspection; rodent excreta pellets were observed on shelving units and in the corners of the packaging room; and rodent excreta pellets were observed on light fixtures in the packaging room.

Moreover, you must maintain sanitation control records that, at a minimum, document monitoring and corrections, to comply with 21 CFR 123.11(c). However, your firm did not maintain sanitation monitoring records for the prevention of cross contamination; the proper labeling and storage of toxic compounds; and the exclusion of pests from the food plant.

4. You must have written verification procedures that are designed to ensure the fish and fishery products you import are not adulterated under section 402 of the Act and were processed in accordance with the Seafood HACCP regulation, 21 CFR 123.12(a)(2). Your firm does not have written verification procedures that include, at a minimum, product specifications (21 CFR 123.12(a)(2)(i)) and an

affirmative step (21 CFR 123.12(a)(2)(ii)). Your firm is the importer for five shipments of live sea urchins in April 2002. These shipments were received from [REDACTED]

5. Labels for your sea urchin roe product were collected during the inspection. Our review of these labels found the following deviations. Your product is misbranded within the meaning of Section 403(e) of the Act in that it does not contain the place of business of the manufacturer, packer, or distributor in accordance with 21 CFR 101.5(d) and it does not contain the declaration of net quantity of contents in accordance with 21 CFR 101.105. It is further misbranded within the meaning of Section 403(i) of the Act in that it does not contain the common or usual name of each ingredient in accordance with 21 CFR 101.3 and 21 CFR 101.4. Finally, it is misbranded within the meaning of Section 403(q)(1) of the Act in that it does not contain Nutritional Labeling in accordance with 21 CFR 101.9(a).

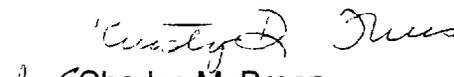
This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations, and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures 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 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, revised labeling, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect 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: Lisa M. Althar, Compliance Officer, 22201 23<sup>rd</sup> Drive SE, Bothell, Washington 98021-4421. If you have questions regarding any issue in this letter, please contact Lisa M. Althar at (425) 483-4940.

Sincerely,

  
for Charles M. Breen  
District Director