



DEPARTMENT OF HEALTH & HUMAN SERVICES

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May 12, 2000

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

VIA FEDERAL EXPRESS

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

In reply refer to Warning Letter SEA 00-44

David M. Crum, President
Pacific Harvest Products, Inc.
13405 SE 30th Street, Suite 1C
Bellevue, Washington 98006

Warning Letter

Dear Mr. Crum:

We inspected your firm located at 13405 SE 30th Street, Suite 1C, Bellevue, Washington, on March 27 and April 4, 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 FDA 483 form (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 seafood base products 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.

The deviations were as follows:

You must have a HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(b). Your firm does not have a HACCP plan for any of the following products to control for the food safety hazard of metals.

- Premier clam soup base
- Premier lobster base
- Premier crab base
- Premier shrimp base
- Premier fish base

The above HACCP violation is not meant to be an all-inclusive list of deficiencies in your plant. It is your responsibility to assure that all of your products are in compliance with applicable statutes enforced by the FDA, including the Seafood HACCP regulations and the Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food regulations in 21 CFR 110. 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. Pertinent sections of the Act and regulations are enclosed for your review.

David M. Crum, President
Pacific Harvest Products, Inc., Bellevue, WA
Re: Warning Letter SEA 00-44
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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.

For your information, our investigator also noted during the inspection that your HACCP plan did not list the critical control point of label review for controlling the food safety hazard of allergens (clams, dairy ingredients, corn and wheat gluten) in your seafood base products. Our Center for Food Safety and Applied Nutrition (CFSAN) and Office of Seafood are currently in the process of clarifying their position on this issue and a formal policy has not been issued.

Please send your reply to the Food and Drug Administration, Attention: Lisa M. Elrand, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421. If you have any questions regarding any issue in this letter, please contact Lisa Elrand at (425) 483-4913.

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: WSDA with disclosure statement