



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  
FAX: 425-483-4996

June 16, 2000

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 00-50

Robert E. Seidel, President  
New West Fisheries, Inc.  
601 West Chestnut Street  
Bellingham, Washington 98225

WARNING LETTER

Dear Mr. Seidel:

We inspected your firm located at 601 West Chestnut Street, Bellingham, Washington, on May 2, 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 Kelly K. Lowry, HACCP Coordinator, at the conclusion of the inspection. These deviations, some of which were previously brought to your attention, cause your frozen roe herring 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 deviation was as follows:

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(b). Your firm does not have a HACCP plan for frozen roe herring to control the food safety hazard of scombrototoxin (histamine) formation. This deviation was previously brought to your attention during a meeting with FDA on December 15, 1998.

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. In addition, we may not provide certificates to your firm for export of your products to European Union (EU) countries if you do not

Robert E. Seidel, President  
New West Fisheries, Inc., Bellingham, WA  
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correct this deviation. Pertinent sections of the Act and regulations are enclosed for your review.

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: Barbara Pfrunder, Acting Compliance Officer, 22201 23<sup>rd</sup> Drive SE, Bothell, WA 98021. If you have questions regarding any issue in this letter, please contact Barbara Pfrunder at 425-483-4977.

Sincerely,

A handwritten signature in black ink, appearing to read "Charles M. Breen", written in a cursive style.

Charles M. Breen  
District Director

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

cc: ADEC with disclosure statement