



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

July 12, 2001

**VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

In reply refer to Warning Letter SEA 01-67

Frank Dulcich, President
Pacific Seafood Group
3220 S.W. First Avenue
Portland, Oregon 97201

WARNING LETTER

Dear Mr. Dulcich:

We collected samples of frozen shrimp processed by your firm, Depot Bay Fish Company, 617 S.W. Bay Blvd., Newport, Oregon, on May 16, 2001, at Columbia Colstor, Inc., Woodland, Washington. Those samples of cooked and peeled shrimp meat were collected and analyzed for Listeria monocytogenes (L. mono). The analysis revealed the product to be positive for L. mono. As a result, the product is adulterated within the meaning of Section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act (the Act), in that the bacterium L. mono may have rendered the food injurious to health. On or about May 25, 2001, June 4, 2001, and June 13, 2001, your firm was sent reports of sample analysis signed by Carlos Abeyta, Cheryl Eklund, Acting Director(s) of Microbiology, and/or Moises O'Neill, Microbiology Branch Chief, informing you of these results.

This letter may not list all the deviations at your facility, for example, the conditions that led to the adulteration of frozen shrimp with L. mono. 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. In addition, we may not provide certificates to your firm for export of your products to European Union (EU) countries if you do not correct these deviations.

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

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Pacific Seafood Group
Portland, Oregon
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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: Bruce Williamson, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021. If you have questions regarding any issue in this letter, please contact Mr. Williamson at (425) 483-4976.

Sincerely,

A handwritten signature in cursive script, appearing to read "Charles M. Breen".

Charles M. Breen
District Director

Enclosures:
Form FDA 483

cc: OSDA with disclosure statement