

17071  
5-10-01  
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 27, 2001

**VIA CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

In reply refer to Warning Letter SEA 01-89

Ernest Spada, Jr., President  
Duck Delivery Produce, Inc.  
8448 N. E. 33<sup>rd</sup> Drive, Suite 120  
Portland, Oregon 97211-2162

**WARNING LETTER**

Dear Mr. Spada:

We inspected your firm, Duck Delivery Produce, Inc., Portland, Oregon, on July 5, 2001. As part of this inspection, a finished product sample of "Spring Salad" with lot code "use by 7/11/01" was 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 July 6, 2001, you were sent reports of sample analysis signed by Cheryl Eklund, Acting Director of Microbiology, informing you of these results.

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 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 (the 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.

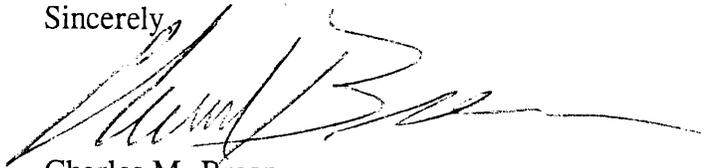
Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as your revised HACCP plan and copies of your monitoring records,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

Ernest Spada, Jr., President  
Duck Delivery Produce, Inc.  
Portland, Oregon 97211  
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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: 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 Ms. Elrand at (425) 483-4913.

Sincerely,

A handwritten signature in black ink, appearing to read "Charles M. Breen", written over a horizontal line.

Charles M. Breen  
District Director

Enclosures:  
Form FDA 483

cc: OSDA with disclosure statement