



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

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

M40127

July 28, 2000

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 00-67

Ronald D. Huegli, Manager  
Living Sprouts Company  
12506 NE 151<sup>st</sup>  
Brush Prairie, Washington 98606

WARNING LETTER

Dear Mr. Huegli:

We inspected your firm located at 12506 NE 151<sup>st</sup>, Brush Prairie, Washington, on June 21, 2000, and found that you have serious deviations from Title 21 of the Code of Federal Regulations (21 CFR) Part 110 – Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food. A FDA 483 form (copies enclosed) listing the deviations was presented to you at the conclusion of the inspection on June 21, 2000. These deviations cause your sprouts to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act through links in FDA's homepage at [www.fda.gov](http://www.fda.gov).

Your firm's sprouts are adulterated within the meaning of 402(a)(4) of the Act because they are being produced under insanitary conditions that may render the sprouts injurious to health. The conditions under which the sprouts are being produced are considered insanitary since effective preventive controls, particularly microbial testing of spent irrigation water, have not been adopted and implemented by your firm. In addition, an employee wearing gloves took a hose tip that was being stored on the floor and sprayed sprouts in the pre-germination room, then the same employee handled a growing tray and was touching sprouts without washing and sanitizing hands.

This letter may not list all the deviations in your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act 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.

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

Ronald W. Huegli, Owner  
Living Sprouts Company, Brush Prairie, WA  
Re: Warning Letter SEA 00-67  
Page 2

include in your response documentation 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: Lisa M. Elrand, Compliance Officer, 22201 23<sup>rd</sup> Drive SE, Bothell, WA 98021-4421. If you have questions regarding any issue in this letter, please contact Lisa Elrand, Acting Compliance Officer at (425) 483-4913 or via e-mail at [leland@ora.fda.gov](mailto:leland@ora.fda.gov).

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 dated June 21, 2000  
21 CFR PART 110  
Section 402 of the Federal Food, Drug, and Cosmetic Act

cc: WSDA with disclosure statement