



DEPARTMENT OF HEALTH AND HUMAN SERVICES

HFI-35

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Refer to: 3003067452

**Food and Drug Administration  
Baltimore District Office  
Central Region  
900 Madison Avenue  
Baltimore, MD 21201-2199  
Telephone: (410) 962-3396  
FAX: (410) 962-2307**

September 7, 2000

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Mrs. Eun Ja Yoon, Owner  
Rainier Sprouts  
7954E Twist Lane  
Springfield, Virginia 22153

Dear Mrs. Yoon:

The Food and Drug Administration (FDA) conducted initial and follow-up inspections of your sprout manufacturing facility located in Springfield, Virginia on July 17 and 19, 2000 and August 16 and 18, 2000, respectively. These inspections revealed insanitary conditions in the manufacture of soy bean sprouts in violation of the Food, Drug and Cosmetic Act (FD&C Act). Specifically, the sprouts are adulterated within the meaning of Section 402(a)(4) of the FD&C Act, in that they are being produced under insanitary conditions that may render them injurious to health. These conditions are considered insanitary since effective preventative controls, particularly microbial testing of spent irrigation water, have not been implemented by your facility.

The following is a list of additional insanitary conditions observed by our investigators during the initial and follow-up inspections:

- Major construction was being conducted at the firm without an intervening barrier to isolate associated dust, dirt, and debris from the sprout manufacturing area.
- Food contact surfaces can not be or were not adequately sanitized, e.g., wood, unsealed concrete, unsealed cinder block, and a pitch fork used in processing with a wooden handle and rusted tines.
- Numerous building and facility construction and maintenance deficiencies were noted, including holes in walls, gaps under exterior doors, standing water, inadequate floor drains, hose bibs without backflow prevention, broken floor tiles in the bathroom, inadequate lighting for cleaning, opening in top re-circulated cooling water tank, and a malfunctioning water heater that could not produce warm water for hand washing and other cleaning functions.

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- Facilities were not maintained in a clean and orderly manner, i.e., numerous cobwebs throughout the plant, spilled soy bean seeds on floor, and unused equipment and personal items in the manufacturing area.
- Poor employee practices were observed, i.e., employees did not wash hands or wear hair restraints while working with product, and meals were eaten immediately adjacent to the manufacturing area.

The deficiencies noted are not intended to be an all-inclusive list of violations at your facility. It is your responsibility to ensure compliance with all applicable laws and regulations.

Corrections of deviations noted on the FDA-483 for the July 17 & 19, 2000 inspection were promised by August 15, 2000. During the August 16 & 18, 2000 inspection, it was verified that only one deficiency had been corrected (i.e., the leaking toilet was repaired).

You should take prompt action to correct the deviations noted above. Failure to do so may result in regulatory action being taken without further notice. This may include seizure and/or injunction.

Enclosed is a copy of a recently published FDA guidance document entitled "Sampling and Microbial Testing of Spent Irrigation Water During Sprout Production." To address our concerns, you may wish to establish a program as described in the guidance document, or use an alternative approach that satisfies the requirements of the FD&C Act and pertinent regulations.

Please notify us in writing, within 15 working days of receipt of this letter, of the field-testing program and other corrections you plan to implement. Your reply should be sent to the U.S. Food and Drug Administration, 101 West Broad Street (Suite 400), Falls Church, Virginia 22046-4200, to the attention of Gerald W. Miller, Compliance Officer. Mr. Miller can be reached at 703-235-8440, extension 504.

Sincerely,



Roberta F. Wagner  
Acting District Director

Enclosure