



DEPARTMENT OF HEALTH & HUMAN SERVICES

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San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

VIA FEDERAL EXPRESS

Our Reference: 2917492

August 9, 2000

Mr. Paul S. Louie, President
Silver Sprouts, Ltd.
1069 Pennsylvania Street
San Francisco, California 94107

WARNING LETTER

Dear Mr. Louie:

The U.S. Food and Drug Administration (FDA) conducted an inspection of your facility located at 1069 Pennsylvania Street on June 19-21, 2000.

The inspection revealed lack of implementation of the recommended practice of microbial testing of spent irrigation water from your sprout processing. This causes your firm's sprouts to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act) because they are produced under insanitary conditions that may render them injurious to health. The conditions under which the sprouts are produced are considered insanitary since effective preventive controls, particularly microbial testing of spent irrigation water, have not been adopted and implemented by your firm.

Furthermore, the inspection revealed a significant deviation from the Current Good Manufacturing Practices, codified in Title 21, Code of Federal Regulations, Part 110, in that your firm stores bags of mung beans and soybeans stacked directly against the walls. The floor areas near the walls often become harborage areas for pests and vermin. The practice of storing products against the walls prevents cleaning of the floor areas near the walls. This causes the foods to be adulterated within the meaning of Section 402(a)(4) of the Act because they have been held under insanitary conditions whereby they may have been contaminated with filth.

A copy of the guidance document, "Sampling and Microbial Testing of Spent Irrigation Water During Sprout Production," is enclosed. This guidance document is intended to assist sprout manufacturers in implementing one of the principal recommendations in the guidance document, "Reducing Microbial Food Safety Hazards For Sprouted Seeds," which is also enclosed.

At the conclusion of the inspection, the insanitary practices and conditions and the lack of implementation of currently recommended practices were listed on Form FDA 483 (Inspectional Observations) and discussed with you. A copy of this form is enclosed for your ready reference. This list is not meant to be an all-inclusive list of violations.

You should take prompt action to correct the violations. Failure to promptly correct these violations may result in regulatory action without further notice. These include seizure and/or injunction. FDA will consider enforcement actions against any party who does not have effective preventive controls in place with respect to sprouts, in particular, effective microbial testing.

Please advise FDA in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within 15 days, state the reasons for the delay and the time at which the corrections will be completed.

Your response should be directed to: Ms. Harumi Kishida, Compliance Officer, U.S. Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502-7070.

Sincerely,



Mary H. Woleske
Acting District Director
San Francisco District

Enclosures:

Guidance for Industry Document, "Sampling and Microbial Testing of Spent Irrigation Water During Sprout Production"

Guidance for Industry Document, "Reducing Microbial Food Safety Hazards For Sprouted Seeds"

Form FDA 483