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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

San Francisco District
1431 Harbor Bay Parkway
Alameda, California 94502

CERTIFIED MAIL
RETURNED RECEIPT REQUESTED

March 17, 1998

Paul Louie, President
Silver Sprouts, LTD
1069 Pennsylvania St
San Francisco, CA 94107

WARNING LETTER

Dear Mr. Louie:

An inspection of your sprout and tofu manufacturing facility on January 8, 9, 12 and 20, 1998, by Food and Drug Administration Investigators Marcia Madrigal and Lorna F. Jones revealed significant insanitary conditions which may cause your products to be adulterated under the Food, Drug, and Cosmetic Act (the Act). Among the conditions and insanitary practices noted during the inspection were:

The maintenance of the equipment and processing areas was inadequate to prevent conditions whereby the foods may have become contaminated with filth or rendered injurious to health.

- The steel prongs that are attached to the stainless steel wheel inside the sprout wash water bath, in direct contact with the bean sprouts, had black mold and a brown caked food residue build-up.
- Walls in both sprout growing rooms, upstairs and downstairs and in the tofu production area were observed to have black mold build-up.
- The sprout wash tank sanitizer delivery system was not functioning properly and consequently, the sprout wash water had no detectable residual chlorine when tested by the FDA investigators. Furthermore, the chlorine levels of the wash water were not routinely monitored.

- Loading doors into the sprout processing/packaging area and to the fresh produce warehouse were left open during production. Pigeons were observed using these doors as an entry way into the firm.

Numerous insanitary practices were observed, including:

- Employees use the same stainless steel tank to hold the blocks of tofu and to wash processing equipment. There are no separation barriers in the tank. At times this water is also used to fill finished product containers of tofu.
- Three employees were using their hands to scoop out the tofu cakes from the stainless steel tank. One of the three employees had a cold and used a handkerchief to blow his nose. He then continued working without washing his hands. This same employee covered his mouth while he coughed then placed that same hand into a yellow plastic barrel of fresh water that was poured into finished units of tofu. In addition, employees were observed eating in the tofu and sprout production areas.
- A thorough cleaning and disinfection of all equipment and surfaces that come into contact with finished product is not routinely done. This was observed in the sprout and tofu processing/packing areas.

A food is adulterated within the meaning of Section 402(a)(3) of the Act if it consists in whole or in part of any filthy substance or is otherwise unfit for food. A food is adulterated within the meaning of Section 402(a)(4) of the Act if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated.

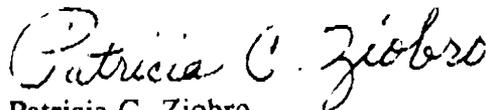
At the conclusion of the inspection, the insanitary conditions were listed on Form FDA 483 (Inspectional Observations) and discussed with you. A copy of this is enclosed for your ready reference. This list is not meant to be an all-inclusive list of violations. It is your responsibility to ensure that all requirements of the Act and regulations promulgated thereunder are being met. Failure to achieve prompt corrective action may result in enforcement action without further notice, including seizure and/or injunction.

Please advise us in writing within fifteen (15) working days of receipt of this letter about the measures you have taken to preclude adulteration of foods. Your response should be directed to Mr. Charles D. Hoffman, Compliance Officer.

Paul Louie, President, Silver Sprouts, LTD

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Sincerely,

A handwritten signature in cursive script that reads "Patricia C. Ziobro".

Patricia C. Ziobro
San Francisco District Director

Enclosure: FDA 483