



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
New England District

M3907M

One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 279-1675
FAX: (781) 279-1742

WARNING LETTER
NWE-31-00W

June 26, 2000

VIA FEDERAL EXPRESS

Marcel Roberge
President
Curran Beansprout Co., Inc.
271 Mill Street
Auburn, ME 04210

Dear Mr. Roberge:

Our investigator conducted an inspection of your manufacturing facility, located at 271 Mill Street, Auburn, ME on June 5-7, 2000. This inspection disclosed practices at your facility that concern us and that cause your mung bean sprouts to be in violation of the Federal Food, Drug and Cosmetic Act (the Act).

Specifically, our inspection revealed that your sprouts are adulterated within the meaning of section 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 implemented at your facility.

This violation is 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.

You should take prompt action to correct this deviation. Failure to promptly correct this deviation may result in regulatory action without further notice. This may include seizure and/or injunction. For your information, I've enclosed 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 an alternative approach that satisfies the requirements of the Act and regulations.

You should notify this office in writing, within fifteen (15) working days of receipt of this letter, of the steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within fifteen (15) working days, state the reason for this delay and the time within which the corrections will be completed.

Your response should be directed to David K. Elder, Compliance Officer, U.S. Food & Drug Administration, One Montvale Avenue, Stoneham, MA 02180. Should you have any questions concerning the contents of this letter, please contact Mr. Elder at (781) 279-1675 Ext. 125.

Sincerely,

A handwritten signature in black ink, appearing to read "Gail T. Costello", with a long horizontal flourish extending to the right.

Gail T. Costello
District Director
New England District Office

Enclosure