



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region M40371

Telephone (973) 526-6010

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

August 3, 2000

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Daniel Paolicelli, Owner
LushLife Gardens
202 Mt. Nebo Road
Milford, New Jersey 08848

FILE NO.: 00-NWJ-47

Dear Mr. Paolicelli:

An inspection of your sprout growing operation, located at 202 Mt. Nebo Road, Milford, NJ, was conducted on July 13, 2000. During this inspection, we found the conditions under which the sprouts are being grown are not sanitary, because your facility has not adopted and implemented effective preventive controls. In particular, we found that your firm did not have a program to test the spent irrigation water for microbial contaminants such as Salmonella and Escherichia Coli 0157:H7. This type of testing is necessary to help assure that the sprouts are safe and free from human pathogens.

The sprouts produced by your firm are considered to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act ("the Act"), because failure to test the irrigation water for microbial contaminants is considered to be an unsanitary condition that may cause the sprouts to be injurious to the health of consumers.

The violation listed above is not intended to be an all-inclusive list of deficiencies at your firm. You should take prompt action to correct all deviations and to assure adherence with each requirement of the Good Manufacturing Practice Regulations. Failure to correct the deviation promptly could result in regulatory action without further notice.

During the inspection, you promised correction of each of the observations by September 15, 2000. Please notify this office within 15 working days of receipt of this letter outlining the specific steps you have taken to correct the violation noted above as well as the additional deviations cited on the FDA-483. If corrective actions cannot be completed within 15 working days, state the reason for the delay and the time needed to complete the correction.

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Please submit your response to: U.S. Food and Drug Administration, 10 Waterview
Boulevard, 3rd Floor, Parsippany, New Jersey 07054, Attn.: Sarah A. Della Fave,
Compliance Officer.

Sincerely,



Douglas I. Ellsworth
District Director
New Jersey District