



DEPARTMENT OF HEALTH AND HUMAN SERVICE

Southwest Region

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Food and Drug Administration
Denver District Office
Bldg. 20-Denver Federal Center
P.O. Box 25087
6th Avenue & Kipling Street
Denver, Colorado 80225-0087
Telephone: 303-236-3000
FAX: 303-236-3100

September 19, 2000

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mrs. Kay Summers
Owner
Summer Sprout
5151 West 925 North,
Hooper, UT 84315

Ref. #: DEN-00-41

Dear Mrs. Summers:

Our Investigator inspected your alfalfa sprout production facility at the above address on August 10 & 11, 2000. We found that you have failed to adopt effective preventative controls to reduce the risk of raw sprouts serving as a vehicle for foodborne illness and to assure that sprouts are not adulterated under the food safety provisions of the Federal Food, Drug, and Cosmetic Act (the Act).

Specifically, 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 adopted and implemented by your sprouting facility, and an effective alternative is not in place.

We may take further action if you do not promptly correct this violation. For example, the agency can take further action to seize products and/or enjoin firms from operating under conditions that are in violation of the law and present a potential health risk to consumers. Recent outbreaks of illness due to *Salmonella* and *Escherichia coli* 0157:H7 have been traced to sprouts.

It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date you receive this letter as to the steps you are taking to correct the problem. We also ask that you explain how you plan to prevent this violation from happening again. If you need more time, please explain the reason for your delay, and when you expect the corrections to be completed.

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This letter may not list all the violations at your facility. It is your responsibility to make sure you follow all the requirements of the Act and associated regulations. For your information, I have included with this letter copies of the following industry guidance documents: “Reducing Microbial Food Safety Hazards for Sprouted Seeds,” and “Sampling and Microbial Testing of Spent Irrigation Water During Sprout Production.” These documents, which were also provided to you during the inspection, are intended to assist the sprout industry in producing safe products.

Your reply should be sent to the attention of H. Tom Warwick, Compliance Officer, at the above address. You may contact Mr. Warwick at (303) 236-3054 if you have any questions regarding this letter.

Sincerely yours,


Thomas A. Allison
District Director

Enclosures: As Stated

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