



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration
Denver District Office
Building 20 – Denver Federal Center
P.O. Box 25087
Denver, Colorado 80225-0087
TELEPHONE: 303-236-3000

August 26, 1999

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

James J. Emmons, Owner
Rainbow Sprouts
209 S. 15th St.
Grand Junction, CO 81502

**REVIEWED
NOTHING PURGED**

Dear Mr. Emmons:

Representatives from the Food and Drug Administration (FDA), Center for Disease Control and Prevention (CDC), Colorado Department of Public Health and Environment (CDPHE) and the Mesa County Health Department inspected your sprout growing facility on May 21, 1999. Health officials linked consumption of your sprouts to an outbreak of *Salmonella* serotype Typhimurium in Colorado.

During the inspection, we collected three samples of sprouts (i.e., clover sprouts, clover & radish sprouts, and alfalfa & clover sprouts), a sample of crimson clover seed, and a set of environmental swabs. Our microbiological analysis of these samples revealed that your clover sprouts and your alfalfa & clover sprouts were contaminated with *Salmonella*. These sprouts are adulterated under section 402(a)(1) of the Federal Food, Drug and Cosmetic Act (the Act) because they are contaminated with the pathogenic bacteria *Salmonella* which may render the sprouts injurious to health. Delivery of, or causing the delivery of, adulterated foods into interstate commerce is prohibited by section 301(a) of the Act.

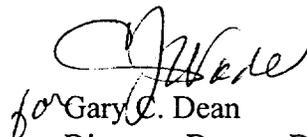
The inspection also revealed your operations are in serious violation of the Federal Regulations for Good Manufacturing Practices (GMP's) which are established in Title 21, Code of Federal Regulations, Part 110 (21 CFR 110). The maintenance of your equipment and processing areas and the employee practices observed, are inadequate to prevent foods from becoming contaminated with filth or with pathogenic bacteria. The Colorado Department of Public Health and Environment issued you a report outlining the deficiencies observed during the inspection on May 21, 1999. Additionally, on June 3, 1999, we issued you a Form FDA-483, Inspectional Observations also outlining conditions needing correction. Adulteration of food while held for sale after shipment in interstate commerce is prohibited by Section 301(k) of the Act.

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This list is not meant to be an all-inclusive list of violations. It is your responsibility to ensure that all of your operations are in compliance with applicable State and Federal requirements. Moreover, it is your responsibility to produce products that are safe for consumption. You should promptly correct these deficiencies. FDA may initiate regulatory action without further notice if you do not implement lasting corrections. Regulatory action may include product seizure and/or injunction of your firm. You should seek advice from a recognized authority on the proper methods of preparing and handling raw material seed, in-process and finished sprouts, as it is clear from our observations and laboratory analyses that your current methods are inadequate to prevent contamination of your finished product with pathogenic bacteria.

Please notify this office in writing, within 15 working days of receipt of this letter, of the current status of your corrective actions and the specific steps you have taken to correct the noted violations. Additionally, and most importantly, please include an explanation of each step being taken to prevent future contamination of your products. Your response should be directed to Tom Warwick, Compliance Officer, at the address indicated on the letterhead.

Sincerely,


for Gary C. Dean
Director, Denver District

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