



19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

WARNING LETTER

AUG 31 2000

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

W/L 78-00

Kieu Huynh
President
Calco Bean Sprouts, Inc.
7835 Silverton Avenue
San Diego, CA 92126

Dear Mr. Huynh:

The U.S. Food and Drug Administration (FDA) conducted an inspection of your facility located at 7835 Silverton Avenue, San Diego, CA on June 29 and 30, 2000. The inspection revealed that your sprouts are adulterated within the meaning of 402 (a)(4) of the Federal Food, Drug and Cosmetic Act (the Act) in that they have been prepared, packed or held under insanitary conditions whereby they may have been contaminated with filth or whereby they may have been rendered injurious to health. The sprouts are considered adulterated since effective controls, particularly microbial testing for pathogens, have not been adopted and implemented by your firm.

In the case of ready-to-eat sprouts, the agency has determined that microbial testing for *Salmonella* and *Escherichia coli* 0157:H7 is necessary and should be conducted (and found negative) prior to release of these food products into domestic commerce, and that this testing is an appropriate quality control operation. Our current guidance recommends that this testing should be conducted on the spent irrigation water used in the production of each lot of sprouts at specific growing periods, and is the most effective means to detect these harmful bacteria in the food. A production lot or batch is defined as sprouts from a single lot of seed that was started at the same time in a single growing unit (e.g. a single drum, or rack of trays).

Furthermore, our inspection revealed additional insanitary conditions that could constitute the products processed under such conditions to be adulterated. These conditions and practices included:

1. Failure to clean and sanitize equipment and utensils adequately, as evidenced by:
 - The sprout washing equipment had remnant organic material (bio-film) build up on the sides of the water reservoir and on the food contact surfaces.

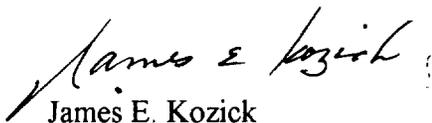
- No sanitizer is used on processing equipment and utensils.
 - The brush used in the cleaning procedure was covered with organic material (bio-film).
2. The walls of the processing room are not constructed of a suitable material that can be easily cleaned and kept in good repair. These walls appeared to be constructed of "dry wall" material which is porous. These walls exhibited significant staining from what appeared to be water splash from the sprout irrigation and cleaning operations conducted by your firm.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice, such as seizure and/or injunction.

Please notify this office in writing, within 15 working days of receipt of this letter, of specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your written reply should be directed to the Director, Compliance Branch, U.S. Food & Drug Administration, 19900 MacArthur Blvd, Suite 300, Irvine, CA 92612-2445.

Sincerely,



James E. Kozick
Acting District Director

cc: California Department of Health Services, Food & Drug Branch
601 N. 7th Street
Sacramento, California 94234-7320
Attn: Stuart Richardson, Jr., Chief