



1990 MacArthur Blvd., Ste 300  
Irvine, California 92612-2445  
Telephone (949) 798-7600

**WARNING LETTER**

**AUG 31 2000**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

W/L 80-00

Mr. Johng W. Kim, Partner  
Ms. Hyon Soon Han, Partner  
Pear Garden Produce  
250 N. Juanita Street  
Los Angeles, CA 90004

Dear Mr. Kim and Ms. Han:

The U.S. Food and Drug Administration (FDA) conducted an inspection of your facility located at 250 N. Juanita Street, Los Angeles, CA on June 28, July 5 and 18, 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).

A copy of the guidance document, "Sampling and Microbial Testing of Spent Irrigation Water During Sprout Production," is enclosed. This guidance document is intended to assist sprout manufacturers in implementing one of the principal recommendations in the guidance document, "Reducing Microbial Food Safety Hazards For Sprouted Seeds," which is also enclosed.

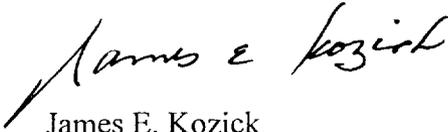
You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice, such as seizure and/or injunction.

Letter to Mr. J. Kim, Pear Garden Produce, Los Angeles, CA - Page 2

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

Enclosures:

Guidance to Industry Document, "Sampling and Microbial Testing of Spent Irrigation Water During Sprout Production"

Guidance to Industry Document, "Reducing Microbial Food Safety Hazards For Sprouted Seeds"

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