



M39091

One Montvale Avenue  
Stoneham, Massachusetts 02180  
(781) 279-1675  
FAX: (781) 279-1742

**WARNING LETTER  
NWE-32-00W**

June 28, 2000

**VIA FEDERAL EXPRESS**

Mr. Pak Lam Tam  
Co-owner  
Ho Kong Bean Sprout Co., Inc.  
370 Harrison Ave.  
Boston, MA 02118

Dear Mr. Tam:

Our investigators conducted an inspection of your manufacturing facility, located at 370 Harrison Ave., Boston, MA between May 18-26, 2000. This inspection disclosed practices at your facility that concern us and that cause your mung bean sprouts to be in violation of the Federal Food, Drug and Cosmetic Act (the Act).

Specifically, our inspection revealed that 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 implemented at your facility.

This violation is not intended to be an all-inclusive list of violations at your facility. It is your responsibility to ensure compliance with all applicable laws and regulations.

You should take prompt action to correct this deviation. Failure to promptly correct this deviation may result in regulatory action without further notice. This may include seizure and/or injunction. During the inspection, our investigators provided you with copies of two guidance documents intended to assist the bean sprout industry in producing safe products, "Sampling and Microbial Testing of Spent Irrigation Water During Sprout Production," and "Reducing Microbial Food Safety Hazards for Sprouted Seeds." To address our concerns, you could follow the guidance provided in these

documents or establish an alternative approach that satisfies the requirements of the Act and regulations.

You should notify this office in writing, within fifteen (15) working days of receipt of this letter, of the steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within fifteen (15) working days, state the reason for this delay and the time within which the corrections will be completed.

Your response should be directed to David K. Elder, Compliance Officer, U.S. Food & Drug Administration, One Montvale Avenue, Stoneham, MA 02180. Should you have any questions concerning the contents of this letter, please contact Mr. Elder at (781) 279-1675 Ext. 125.

Sincerely,



Gail T. Costello  
District Director  
New England District Office

Cc: Ms. Lillian Tam  
Co-Owner  
Ho Kong Bean Sprout Co., Inc.  
370 Harrison Ave.  
Boston, MA 02118