DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

M2078N

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

HAND DELIVERED

September 29, 1998

Darrell Kong, Owner
Darrell Kong Bean Sprout and Noodle Manufacturing
2863 Larkin Ave.
Clovis, CA 93612

WARNING LETTER

Dear Mr. Kong,

An inspection of your sprout growing and noodle manufacturing facility in Clovis, CA on August 18 & 19, 1998 by Food and Drug Administration Investigator Helen J. Hamaoka, revealed numerous continuing insanitary conditions which cause your products to be adulterated under the Food, Drug, and Cosmetic Act. A number of these conditions have previously been brought to your attention following inspections of your facility in March 1997 and October 1991.

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. Failure to follow good manufacturing practices as outlined in Title 21, *Code of Federal Regulations*, Part 110, has contributed to your products becoming adulterated.

Among the conditions and insanitary practices which were observed during the inspection were:

- The production process includes direct hand contact by employees in the harvesting, washing and packaging steps. No sanitizing hand dips were in use in those areas. Employees were observed handling telephones, freezer door handles, and mold and slime contaminated tub handles. Employees then returned to handling sprout products with their bare hands, without washing their hands after touching those insanitary surfaces.

- No testing procedures were in place to examine finished product for microbial, pesticide, or extraneous material contaminants.

- Plastic tubs used to hold and transport sprouts between processing steps were nested together and placed in direct contact with the floor. During use they were observed to be restacked with the tub previously in contact with the floor now in contact with the food contact surface of a second tub. An examination of the plastic tubs handles revealed a

slimy surface and mold-like growth, indicating inadequate cleaning and sanitizing of the equipment.

- Water hoses directly above the exposed, growing sprouts had a brownish-black mold-like growth ranging from ⅓" thick and up to 18" long. Hoses lacked backflow prevention devices, and if left submerged in water could create the potential for backflow of contaminated water into your water supply.

- Transportation of the packed finished product is at non-refrigerated temperatures for more than two hours in some cases. This could allow the growth of pathogenic bacteria if present in the product.

A food is adulterated within the meaning of Section 402(a)(4) of the Act if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

This list is not meant to be an all-inclusive list of violations. It is your responsibility to ensure that all requirements of the Act and regulations promulgated thereunder are being met. Failure to achieve prompt corrective action may result in enforcement action without further notice, including seizure and/or injunction.

This letter is being hand delivered to you by Investigator Hamaoka. Please advise her of your responses to the conditions cited and the measures you have taken and will take to preclude adulteration of foods. Include a proposed time line for accomplishment of those measures. On or about October 16, 1998, please advise this office in writing of your progress in making the necessary improvements at your plant. Your response should be directed to Mr. Randall J. Plunkett, Acting Compliance Officer.

Sincerely,

Wayne L. Vaundell for PCZ
Acting District Director

Patricia C. Ziobro
District Director
San Francisco District