



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

m39417

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

VIA FEDERAL EXPRESS

Our Reference: 2936174

June 21, 2000

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

WARNING LETTER

Dear Mr. Kong:

The U.S. Food and Drug Administration (FDA) conducted an inspection of your facility located at 2863 Larkin Avenue, Clovis, California on May 24 and 26, 2000.

The inspection revealed lack of implementation of the recommended practice of microbial testing of spent irrigation water from your sprout processing and the failure to adequately disinfect mung beans for sprouting. This causes your firm's sprouts to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act) because they are produced under insanitary conditions that may render them injurious to health. The conditions under which the sprouts are produced are considered insanitary since effective preventive controls, particularly microbial testing of spent irrigation water, have not been adopted and implemented by your firm.

Furthermore, the inspection revealed insanitary practices and conditions which cause all foods to be adulterated within the meaning of Section 402(a)(4) of the Act because they have been prepared, packed or held under insanitary conditions whereby they may have been contaminated with filth.

The following is a list of the insanitary practices, conditions, and findings observed by Investigators Helen J. Hamaoka and Christopher J. Lee:

BEAN SPROUT PROCESSING

1. FAILURE TO PERFORM MICROBIAL TESTING OF SPENT IRRIGATION WATER: 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.

2. **FAILURE TO ADEQUATELY DISINFECT MUNG BEANS FOR SPROUTING:** Please note that FDA currently recommends the treatment of pre-washed seed with 2% (20,000 ppm available chlorine) calcium hypochlorite solution for 15 minutes at room temperature with continuous agitation. The ratio of five (5) pounds of seed in one gallon 2% calcium hypochlorite solution is recommended. See enclosed EPA Reg. #1258-427. Note that the ultra-Clorox that your firm uses is 6% sodium hypochlorite.
3. **RUST BUILD-UP WAS NOTED INSIDE AND OUTSIDE OF A PIPE ELBOW USED AS A WATER FAUCET:** As a result, water from this pipe elbow may be contaminated with rust. Since sprouts are washed with this water, the sprouts may, in turn, be contaminated with rust. In addition, the linoleum-type material in area above the sink was noted to be peeling.
4. **SANITRON UV LAMP SHOULD BE REPLACED ANNUALLY:** The UV lamp, which is used for treating sprout irrigation water, has not been replaced since October 20, 1998. The labeling for the lamp recommends annual replacement.
5. **DRIED SPROUT PRODUCT WAS FOUND ADHERING TO THE TILE WALL OF THE SPROUT WASHROOM:** Washed bean sprouts come into direct contact with this wall during processing.
6. **INADEQUATE SPACE IN STORAGE AREAS PREVENTING ACCESS TO AND MAINTENANCE OF PEST TRAPS:** The storage of raw materials against the walls prevents access to setting and maintaining pest traps and spraying for pests.
7. **INSECTS FOUND IN STORAGE AREAS:** Five dead insects were found on the floor at the northwest side of the raw materials storage area, and one dead cricket was found along the wall at north end of the raw materials storage area.
8. **NO SYSTEM IN PLACE TO PROTECT FOOD PRODUCTS FROM CONTAMINATION BY EXTRANEEOUS MATERIALS.**
9. **POOR EMPLOYEE PRACTICES:**
 - a. Failure of employees to wear suitable outer garments to protect against contamination of food.
 - b. Failure of employees to wear mustache coverings or hair restraints.
 - c. An employee was observed to handle a wooden broom and then handle food product without washing and sanitizing hands. An employee's bare arms were observed to come into direct contact with food.

At the conclusion of the inspection, the insanitary practices and conditions and the lack of implementation of currently recommended practices were listed on Form FDA 483 (Inspectional Observations) and discussed with you. A copy of this form is enclosed for your ready reference. This list is not meant to be an all-inclusive list of violations.

You should take prompt action to correct the violations. Failure to promptly correct these violations may result in regulatory action without further notice. These include seizure and/or injunction. FDA will consider enforcement actions against any party who does not have effective preventive controls in place with respect to sprouts, in particular, effective microbial testing.

Please advise FDA in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within 15 days, state the reasons for the delay and the time at which the corrections will be completed.

Your response should be directed to: Ms. Harumi Kishida, Compliance Officer, U.S. Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502-7070.

Sincerely,


Darrell Lee
Acting District Director
San Francisco District

Enclosures:

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

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

EPA REG. #1258-427

Form FDA 483