



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

94551d

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

VIA FEDERAL EXPRESS

Our Reference: 3004196693

February 17, 2004

Ping L. Kwan, Owner  
Wing Kee Foodstuff Co.  
717 Vallejo Street  
San Francisco, California 94133

**WARNING LETTER**

Dear Mr. Kwan:

The U.S. Food and Drug Administration (FDA) conducted an inspection of your facility located at 639 Vallejo Street on November 5, 6, 7, and 28, 2003. The inspection revealed numerous deviations from the Good Manufacturing Practice regulations, Title 21, Code of Federal Regulations (21 CFR), Part 110. At the conclusion of the inspection you were issued a Form FDA 483 (copy attached) which delineated a number of gross insanitary conditions present in your facility at the time of that inspection. These conditions cause the products stored in your facility to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), in that they were prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth.

The insanitary conditions observed by the FDA investigator are as follows:

1. Your firm failed to take effective measures to exclude pests from the storage facility and to protect against the contamination of food on the premises by pests [21 CFR Part 110.35(c)].
  - a. FDA found rodent and insect activity on and near food products, as follows:
    - (1) The cardboard cases of a lot of approximately [REDACTED] cases of red dates, located in the southwest corner of the storage facility, bore rodent pellets, rodent-gnawings, and mammalian urine stains.
    - (2) The cardboard cases of a lot of approximately [REDACTED] cases of Lotus Noodles, located in the southwest side of

- the storage facility, bore rodent pellets, mammalian urine stains, and rodent hairs.
- (3) The cardboard cases of a lot of approximately [REDACTED] cases of Lotus Noodles, located along the south side of the storage facility, bore rodent pellets, mammalian urine stains, and rodent hairs.
  - (4) The cardboard cases of a lot of approximately [REDACTED] cases of Lotus Noodles, located in the southeast side of the storage facility, bore rodent pellets and mammalian urine stains.
  - (5) The cardboard cases of a lot of approximately [REDACTED] cases of dried fungus, located along the southeast wall of the storage facility, bore rodent pellets and mammalian urine stains.
  - (6) The cardboard cases of a lot of approximately [REDACTED] lb.) cases of chicken powder, located in the northeast area of the storage facility, bore rodent pellets and mammalian urine stains.
  - (7) The cardboard cases of a lot of approximately [REDACTED] lb.) cases of white fungus, located along the northwest wall of the storage facility, bore rodent pellets.
  - (8) The cardboard cases of a lot of approximately [REDACTED] cases of Chinese Herbs, located along the northwest wall of the storage facility, bore rodent pellets.
  - (9) The cardboard cases of a lot of approximately [REDACTED] lb.) cases of Chinese herbs, located in the northeast area of the storage facility, bore mammalian urine stains and rodent hairs.
  - (10) The cardboard cases of a lot of approximately [REDACTED] cases of Chinese herbs located in the middle area of the storage facility, bore mammalian urine stains.
  - (11) The cardboard cases of a lot of approximately [REDACTED] lb) cases of dried black beans, located in the southern area of the storage facility, bore mammalian urine stains. We acknowledge that you voluntarily destroyed this lot of dried black beans.

(12) Three insects were also found in the facility. They were identified as:

- Erotylid beetle (*Dacne sp.*)
- Tineid moth adult (clothes moth)
- Maize weevil

b. FDA observed areas where pests were able to gain entry into the facility due to inadequate screening or repair, as follows:

- (1) Approximately 2" x 4" gaps between the ventilation blades of the fan located along the south wall of the storage facility.
  - (2) An approximately 3/4" gap underneath the door located along the south wall of the storage facility.
  - (3) Window above the front door of the facility.
  - (4) An open pipeline extending from the ceiling, located in the northeast corner of the storage facility.
  - (5) An open pipeline extending from the ceiling, located in the southwest corner of the storage facility.
  - (6) An approximately 4" x 6" hole in the wall located in the southwest corner of the storage facility.
  - (7) An approximately 2" x 12" hole in the wall located in the southwest corner of the storage facility.
  - (8) An approximately 5" x 5" hole in the wall, located in the southwest corner of the storage facility.
2. Your firm failed to provide sufficient space for such placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations [21 CFR Part 110.20(b)(1)]. Specifically, on November 5 and 6, 2003,
- a. FDA observed several cartons of food in close proximity to the walls of the storage facility.
  - b. FDA observed several cartons of food in direct contact with the floor of the storage facility.

The above is not meant to be an all-inclusive list of deficiencies in your facility. You are responsible for ensuring that your facility operates in compliance with the Act and the Current Good Manufacturing Practice regulations (21 CFR Part 110). You should take prompt action to correct these violations. Failure to promptly correct these violations may result in enforcement action, such as seizure and/or injunction, without further notice.

Please respond in writing within fifteen (15) working days of receipt of this letter. Your response should outline the specific steps you are taking to correct these deviations and prevent the occurrence of similar violations. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

Please send your reply to: Ms. Harumi Kishida, Compliance Officer, U.S. Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502-7070. If you have any questions regarding any issue in this letter, please contact Ms. Kishida at (510) 337-6824.

Sincerely,



Charles M. Breen  
Acting District Director  
San Francisco District

Enclosure:  
Form FDA 483