



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

M37510

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

VIA FEDERAL EXPRESS

May 12, 2000

Pengxiang Lin, Owner
Wa Heng Dou Fu Soy Sauce Int Enterprises
2451-26th Avenue, #1
Sacramento, CA 95822

WARNING LETTER

Dear Mr. Lin:

The U.S. Food and Drug Administration (FDA) conducted an inspection of your facility located at 2451-26th Avenue, #1, Sacramento, CA on February 14, 29, and March 2, 2000. The inspection revealed significant insanitary practices and conditions which cause products stored in your facility to be adulterated within the meaning of Sections 402(a)(3) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act).

The following is a list of the insanitary practices and conditions observed by Investigator Joan T. Briones:

- Rodent Infestation
Serious rodent infestation as evidenced by (1) penetrating and non-penetrating gnaws, rodent stains, and rodent excreta pellets found in the lot of forty-two 50-lb bags of salt in the storage room; and (2) rodent excreta pellets found on the floor adjacent to the northwest wall and on the floor near pallet racks in the storage room.
- Insect Infestation
Serious insect infestation as evidenced by (1) trails of live ants near food, food ingredients, and packaging materials; and (2) a live spider and webbing observed in an uncovered drum of fermented soy beans and webbing observed in seven other drums of fermented soy beans.

- **Rodent and Insect Infestation**

The samples of fermented soybean and soy sauce collected for FDA analysis indicates that the twenty-four 55-gallon plastic drums of product in the production room are grossly adulterated by insects and insect fragments, rat/mouse hair and hair fragments, and feather barbule fragments.

- **Poor Employee Practices**

(1) The 5-gallon pails used to transfer fermented soy beans were observed to be directly on the floor so that they are in direct contact with the floor and standing water. (2) An employee was observed covering a hole in a dou-fu press cloth with a piece of paper torn from an empty soy bean bag. (3) You were observed in the production room without a hair restraint during processing of product. (4) An employee was observed hose-spraying the floor within two feet of dou-fu product which was being held on the bottom shelf of a stainless steel rack. (5) The nozzles of hoses used to deliver water used in processing were observed to be in direct contact with standing water on the production room floor. (6) Kettles containing cooking oil were observed to be stored directly on the floor. The lids were coated with accumulated oil and food debris. (7) A case of 12-ft fluorescent light bulbs were observed to be stored across the top of five uncovered drums of fermented soy beans.

At the conclusion of the inspection, the insanitary conditions and 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.

A food is adulterated within the meaning of Section 402(a)(3) of the Act if it consists in whole or in part of any filthy substance or is otherwise unfit for food. 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.

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.

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,



Charles D. Moss
Acting District Director
San Francisco District

Enclosure: Form FDA 483