



DEPARTMENT OF HEALTH & HUMAN SERVICES

HFI-35 (1400000/28)
LINDA LOW R. J. H.

Public Health Service D1253B
Food and Drug Administration

San Francisco District
1431 Harbor Bay Parkway
Alameda, California 94502
Telephone (510) 337-6700

CERTIFIED MAIL
RETURNED RECEIPT REQUESTED

March 12, 1997

Sap Trinh, Owner
Fay Wong Tofu Co.
4128 Franklin Blvd.
Sacramento, CA 95820

WARNING LETTER

Dear Ms. Trinh.

An inspection of your tofu manufacturing facility on January 27, 28, 31, and February 5, 1997, by Food and Drug Administration Investigator Lorna F. Jones revealed **significant insanitary** conditions which may cause your products to be adulterated under the **Food, Drug, and Cosmetic Act** (the Act). Among the conditions noted during the inspection were:

- Live cockroaches were observed on stored tofu in the production room and in the storage room.
- Mold and food residues were observed on walls and equipment, and mold was observed on the ceiling above the tofu production area.
- The doorways leading from the outside of the production area remained open during the manufacturing process.
- Power steering fluid and bearing grease were stored next to bags of raw soy beans.
- There was no backflow preventer on the hose in the processing room, which could lead to contamination of your potable water system.
- The floor in the processing room is not constructed properly which causes a build up of standing water in the processing area.

WARNING LETTER

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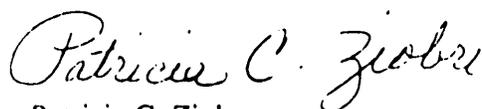
- Employees who handled ready-to-eat tofu did not wash or sanitize their hands following operations in which their hands may have become contaminated. For example, an employee who was slicing the tofu held the telephone, and then she returned to slicing the tofu without washing and sanitizing her hands.
- Plastic totes, buckets and other equipment used in the manufacturing of tofu are not sanitized.

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.

At the conclusion of the inspection, the insanitary conditions were listed on Form FDA 483 (Inspectional Observations) and discussed with you. A copy of this is enclosed for your ready reference. 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

Please advise us in writing within fifteen (15) working days of receipt of this letter about the measures you have taken to preclude adulteration of foods. Your response should be directed to Mr. Charles D. Hoffman, Compliance Officer.

Sincerely,



Patricia C. Ziobro
District Director

(enclosure)