



DEPARTMENT OF HEALTH AND HUMAN SERVICES

94758d

Food and Drug Administration  
Los Angeles District  
Pacific Region  
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Irvine, CA 92612-2445

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**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

May 19, 2004

W/L 39-04

Luke Yam, President  
San Diego Soy Dairy  
1330 Hill St., Suite B  
El Cajon, CA 92020-5735

Dear Mr. Yam:

On April 1 – 5, 2004 your firm located at 1330 Hill St., Suite B, El Cajon, California was inspected by representatives of the U.S. Food and Drug Administration (FDA). Our inspection found that you did not follow food Good Manufacturing Practices (GMP's) as described in Title 21, Code of Federal Regulations, Part 110 (21 CFR 110). Listed below are the conditions observed by FDA during the inspection. These conditions cause food products manufactured by your firm to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act) because they were prepared, packed or held under insanitary conditions whereby they may have been contaminated with filth, or whereby they may have been rendered injurious to health.

The following deviations from food GMP's were observed during your inspection:

1. Employees did not wash and sanitize hands thoroughly in an adequate hand-washing facility after each absence from the work station and at any time their hands may have become soiled or contaminated [ref. 21 CFR 110.10(b)(3)]. Specifically, you, as the president of the company while working in the production room, were observed touching your face and mouth covering prior to processing /cutting ready to eat tofu. In addition, another employee, while moving between the production room and the outside of the facility, was observed using an iodine hand dip without first washing his hands.
2. All reasonable precautions are not taken to ensure that production procedures do not contribute contamination from any source [ref. 21 CFR 110.80]. Specifically,
  - a) The top of a tofu pressing tray was placed with the edge directly on the floor of the processing room between uses.

- b) Two white five gallon buckets filled with water were used as weights on top of a wet cutting board to press tofu blocks prior to vacuum packing. The buckets were observed with dirt and residue on the exterior surfaces.
  - c) Cheese cloth used to strain soy emulsion in the curd vats was observed hanging over pipes along the wall of the processing room between uses. The cloth was re-used throughout the processing shift.
3. Failure to clean and sanitize utensils and food-contact surfaces of equipment in continuous wet-processing operations as necessary [21 CFR 110.35(d)(2)]. Specifically, food contact surfaces such as tofu molds, cutting boards and rolling carts are used for over four hours during processing at temperatures above 70 degrees F without cleaning and sanitizing.
  4. Failure to take necessary precautions to protect against contamination of food contact surfaces with microorganisms and foreign substances [21 CFR 110.10(b)(9)]. Specifically, finished food packaging was observed uncovered and exposed to the environment in the attic and in the kitchen area.
  5. Failure to maintain equipment, containers and utensils used to convey, hold, and store food in a manner that protects against contamination [21 CFR 110.80(b)(7)]. Specifically,
    - a) Flaking paint and greasy debris was observed on both of the one pound tofu packing machines directly above the area where food is exposed during packing.
    - b) White five gallon buckets used to store bulk tofu in plastic bags had residue on the outer surfaces and were stacked together
    - c) A tank used to cool finished packages of tofu was patched on the inner surface with duct-tape.
    - d) Duct tape was used to repair a hose at the tofu cooling area.
  6. Gloves used in food handling are not maintained in an intact, clean, and sanitary condition [21 CFR 110.10(b)(5)]. Specifically, gloves worn by employees working at the tofu curd stations had black residue along the cuff areas and food residue on the exterior surfaces.
  7. The procedure used for cleaning and sanitizing of equipment and utensils had not been shown to provide adequate cleaning and sanitizing treatment [21 CFR 110.35(d)(5)]. Specifically,
    - a) Cutting boards which are placed directly on top of blocks of tofu were not sanitized after cleaning prior to use.

- b) An employee was observed pouring an unmeasured quantity of iodine sanitizer into a tank full of water and processing equipment such as tofu molds and utensils. The water was not agitated or mixed after the addition of the iodine and there was an immeasurable concentration of iodine present in the water.
  - c) The container used to store knives in sanitizer during processing had an immeasurable concentration of iodine after roughly three hours of processing.
8. Failure to maintain buildings, fixtures, or other physical facilities in a sanitary condition [21 CFR 110.35(a)]. Specifically,
- a) There was dried food residue on the underside of tofu pressing tables directly above the shelf used to store tofu molds during processing.
  - b) Switches and control panels were observed with food residue on the surfaces.
  - c) Plastic sheeting installed along the wall behind the tofu curd vats had mold, standing water, and a slimy residue on some of the outer surfaces.
  - d) A plastic bag with food residue and debris was tied over the control panel of the soy fiber extractor.
  - e) An overhead fan in the production room that blows directly towards the tofu curd vats had dust and dirt on the fan blades and outer grate. The area around the ceiling exhaust fan above the soy grinding machine also had dust and dirt on the surfaces.
  - f) The ceramic drain in the production room had accumulated food residue and debris.
  - g) Ceiling paneling above working areas of the processing room was stained and discolored from water damage.
9. Failure to maintain buildings, fixtures, and physical facilities in repair sufficient to prevent food from becoming adulterated [21 CFR 110.35(a)]. Specifically,
- a) The wall behind the tofu curd vats and in other areas of the processing room is delaminated between the stainless steel sheeting and the plastic paneling. A tarp had been installed over the area. The tarp also had multiple holes and tears in it.
  - b) The floor in the kitchen and in the tofu processing room were cracked, chipped; could not be adequately cleaned; and were a point of accumulation for standing water.
  - c) The wall and door jamb between the kitchen and the hallway to the cooler were deteriorated and had holes in them.

10. Suitable outer garments were not worn that protect against contamination of food and food contact surfaces [21 CFR 110.10(b)(1)]. Specifically,
  - a) Employees were observed submerging their exposed arms into tofu cooling tanks.
  - b) Employee aprons were repaired with duct tape, which can not be adequately cleaned.
  - c) Employees were observed wearing soiled ball caps over their hair nets.
11. Plumbing was not adequately installed and maintained to provide adequate floor drainage [21 CFR 110.37(b)(4)]. Specifically, standing water which does not adequately drain was observed at the entrance to the processing facility, at the south east corner of the production room and at the area adjacent to the soy grinding machine.
12. Failure to provide hand washing facilities at each location in the plant where needed [21 CFR 110.37(e)(1)]. Specifically, there was no hand washing sink in the tofu processing room.
13. Lack of effective hand cleaning preparations [21 CFR 110.37(e)(2)]. Specifically, there was no hand washing soap available at the sink in the kitchen area.
14. Employees failed to remove unsecured jewelry or other objects which might fall into food, equipment, and containers (exhibit #20) [21 CFR 110.10(b)(4)]. Specifically, two employees were observed wearing earrings while processing tofu. One employee was observed processing tofu with a necklace dangling over exposed in-process product.
15. Appropriate training in food handling techniques and food protection principles had not been provided to food handlers [21 CFR 110.10(c)]. Specifically, the employee who was responsible for preparing and testing the adequacy of sanitizing solutions lacked the appropriate training and equipment. The employee was observed using pH test strips to determine iodine concentration in sanitizing solutions.

The above violations are not meant to be an all-inclusive list of deficiencies in your product and its labeling. It is your responsibility to ensure that all of your products are in compliance with the laws and regulations enforced by FDA. You should take prompt action to correct these deviations and prevent their future recurrence. Failure to make prompt corrections could result in regulatory action without further notice. Possible actions include seizure and/or injunction.

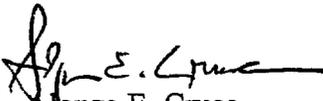
You should notify this office within fifteen (15) working days of the receipt of this letter of the specific steps you have taken to correct the violations noted above, including an explanation of each step taken to prevent the recurrence of similar violations. If corrective actions cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

Letter to Mr. Yam, San Diego Soy Dairy  
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Your written reply should be addressed to:

Pam Schweikert, Director of Compliance  
U.S. Food and Drug Administration  
19701 Fairchild  
Irvine, CA 92612

Sincerely,

A handwritten signature in black ink, appearing to read "Alnza E. Cruse". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Alnza E. Cruse  
District Director