



Food and Drug Administration  
Seattle District  
Pacific Region  
22201 23rd Drive S.E.  
P.O. Box 3012  
Bothell, WA 98041-3012

Telephone: 425-486-8788  
FAX: 425-483-4996

March 29, 1999

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 99-12

Brian Phuong, President  
Happy Tofu, Inc.  
6113 NE 92<sup>nd</sup> Drive  
Portland, Oregon 97220

WARNING LETTER

Dear Mr. Phuong:

On January 21, 22, 25, 27, and 29, 1999, the United States Food and Drug Administration (FDA) conducted an inspection of your firm located at 6113 NE 92<sup>nd</sup> Drive, Portland, Oregon. The inspection was conducted to evaluate your firm's compliance with FDA's good manufacturing practice (GMP) requirements for foods (21 CFR 110). At the conclusion of the inspection, our investigators issued you a Form FDA 483 (copy attached) which delineated a number of gross insanitary conditions present in your firm at the time of the inspection. These conditions cause the products being prepared at your firm to be adulterated within the meaning of Section 402(a)(4) (copy attached) of the Federal Food, Drug, and Cosmetic Act (the Act).

The following is a list of insanitary conditions observed by our investigators during the inspection.

1. Heavy rodent activity was observed at your firm as evidenced by:
  - a. Six (6) entry holes were found along a 25-foot section of the east wall in the bagged soybean and dry storage area. Numerous rodent excreta, ranging from 10 to 30 pellets, were located at the entrances to each of these holes.
  - b. Spilled [REDACTED] bait and an empty paper bait box were found behind the soybean storage pallets along the north wall of the soybean and dry storage area. Rodent activity was apparent from a rodent gnaw hole on one soybean bag and rodent excreta pellets on the floor under the pallet.

- c. Suspect rodent nesting material, comprised of shredded blanket fabric, and rodent excreta pellets were observed along the north wall of the dry storage area.
  - d. Four (4) rodent excreta pellets were found along the north wall of the miscellaneous storage area, approximately 15 feet from the pasteurizer.
  - e. During tofu production, one (1) live rat was observed at the base of the soybean-soaking tote in the processing area.
  - f. An approximate two (2) inch by three (3) inch gap was found at the bottom right side of the west loading dock door, approximately 15 feet from the pasteurizer and approximately 10 feet from the rodent excreta pellets described in item D.
2. Excessive mold was observed at your firm as evidenced by:
- a. Mold was found on soybeans inside bags and on the outer surfaces of bags of soybeans. Condensate was evident on the inner surface of shrink-wrap that was around palletized bags of soybeans, stored against the north wall in the northeast corner of the dry storage area.
  - b. Mold had accumulated on all processing equipment, food contact utensils, work surfaces, concrete walls, metal loading doors, floors, drains, and cleaning implements.
  - c. Rolls of label film were stored on mold-covered surfaces above the heat-sealing equipment.
  - d. Moldy, shredded plastic bags were used as covers for electrical control panels for the processing equipment.
3. Our investigator noted several practices and conditions, listed below, which may lead to the cross contamination of products.
- a. Condensation was dripping into the processing area and onto work surfaces from the ceiling and water pipes.
  - b. Buckets, containing ground soybeans used in the production of product, were stored directly on the floor of the processing area. These buckets were located in approximately one-half inch of standing water.
  - c. Employees were observed placing the stainless steel lids from the tofu pressing pans directly on the floor during production.

- d. Hoses in the processing area were stored on the floor with the nozzles contacting the floor. Floor splash and hose over-spray came into contact with the product in buckets being stored on the floor in the processing area.
  - e. Cheesecloth, used in the tofu pressing process, was used multiple times without being cleaned and sanitized. Employees were observed removing the cheesecloth from the tofu press, using it to wipe off work surfaces, and then returning it to the tofu press.
  - f. No towels were found in the handwash station in the processing area.
  - g. Employee personal items including coffee cups, food, deodorant, coins, and clothing were stored in the processing area.
  - h. Employees handling finished product on the packing line were wearing bracelets, necklaces, and earrings.
4. The following practices, which could lead to product adulteration, were observed:
- a. Cleaning supplies and soft tofu dry ingredient ( [REDACTED] ) were stored together in a utility cabinet. The cleaning granules were spilled on the shelf above an opened bag of [REDACTED].
  - b. Empty coded plastic tofu trays were stored adjacent to non-food grade chemicals.
  - c. Non-food grade chemicals including ink, acetone, brake fluid, cleaning compounds, lubricant, and car batteries were stored in the processing area.
  - d. Unshielded fluorescent lights were observed in the processing and dry storage areas.

During the inspection, our investigators collected samples to document the conditions at your firm and our laboratory analysis confirmed our investigators' observations.

5. During the inspection, our investigators noted that you did not have controls in your manufacturing process to minimize the growth of microorganisms and contamination of your product. As an example, your firm did not identify time and temperature of the pasteurization step as controls that must be monitored. As suggested by the Oregon State Department of Agriculture (OSDA) inspector, present during the inspection, your firm needs to establish that your pasteurization process is adequate to control pathogens of concern. Once your pasteurization process is established, you need to monitor both the time and temperature of your pasteurization process.

Brian Phuong, President  
Happy Tofu, Inc., Portland, OR  
Re: Warning Letter SEA 99-12  
Page 4

6. During the inspection, Tan Nguyen, Plant Manager, told our investigators that your cold water tanks are drained and fresh water added several times a day. In the five (5) days our investigators were present at your firm the water was not changed during the processing day. Your firm should be changing the water with greater frequency.

This inspection, coupled with your firm's inspectional history, demonstrates to FDA that you have an ongoing problem with sanitation issues and pest control. On January 25, 1999, a Food Safety Specialist from OSDA joined our inspection and confirmed our observations. It is your responsibility to have an effective, ongoing sanitation program for your facility, which eliminates the insanitary conditions observed at your firm.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action, such as seizure or injunction, without further notice.

You should notify this office in writing within 15 working days of the receipt of this letter of the specific steps that you have taken to correct the noted violations. If correction cannot be completed within fifteen working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply relating to these concerns should be directed to the Food and Drug Administration, Attention: Janelle K. Main, Compliance Officer, 22201 23<sup>rd</sup> Drive SE, Bothell, WA 98021-4421. If you have any questions concerning this letter, you may contact me at (425) 483-4928.

We look forward to working with you to achieve a successful corrective program in your plant.

Sincerely,



Roger D. Lowell  
District Director

3 Enclosures:  
Form FDA 483  
Section 402 Of the Act  
21 CFR Part 110

cc: With Disclosure Statement  
OSDA