



Department of Health and Human Services

Public Health Service
Food and Drug
Administration
New Orleans District
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Nashville, TN 37217
Telephone: (615)366-
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May 29, 2009

WARNING LETTER NO. 2009-NOL-10

**FEDERAL EXPRESS
DELIVERY SIGNATURE REQUESTED**

Tian G. Zheng, Owner
Won Feng Trading, Inc.
2728 Eugenia Avenue, Suite 103
Nashville, Tennessee 37211

Dear Mr. Zheng:

The U.S. Food and Drug Administration (FDA) conducted an inspection of your food storage warehouse and cooked cabbage operation, located at 2728 Eugenia Avenue, Suite 103, Nashville, Tennessee, from February 23-27, and March 2, 2009. During the inspection, FDA investigators documented serious violations of the Current Good Manufacturing Practice (CGMP) regulation for foods, Title 21, *Code of Federal Regulations*, Part 110 (21 CFR 110). The inspection revealed the conditions in your food processing and warehouse facility have caused the foods stored there to be adulterated under Section 402(a)(4) [21 United States Code (USC) 342(a)(4)] of the Federal Food, Drug, and Cosmetic Act (the Act) because they have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth.

On March 2, 2009, at the conclusion of the inspection, FDA investigators issued a Form FDA 483, Inspectional Observations, to Xin "Evan" Zheng, Manager, which described a number of significant objectionable conditions relating to your facility's compliance with CGMP.

The following significant deviations were observed during the inspection:

1. Per 21 CFR 110.3 5(c), no pests shall be allowed in any area of a food plant; further, effective measures shall be taken to exclude pests from the processing areas and to protect against the contamination of food on the premises by pests. However, FDA investigators observed the following conditions at your facility:

DRY STORAGE ROOM 2

AISLE 3:

- Four rodent excreta pellets and apparent rodent urine stains on two cases of one lot of chili garlic sauce;
- On a pallet containing Dried Star Aniseed and Solo cup lids, multiple rodent excreta pellets and rodent nesting material were found on and around the pallet, and there were apparent rodent urine stains on multiple cases;
- One rodent excreta pellet on a case of Vermicelli Sticks and one rodent excreta pellet under a pallet containing cases of Tung Kow Vermicelli Sticks, Squid Fish Sauce, Instant Noodles, and Stew Pork Flavor;
- At least 10 rodent excreta pellets on a pallet containing cartons of dry minced garlic;
- Multiple rodent excreta pellets and rodent urine stains on one case held on a pallet containing 21 cases of bagged garlic spice;
- On a pallet containing 49 bags of G&L Cracker Meal, FDA investigators found one cast insect skin, more than 100 rodent excreta pellets on six bags, rodent gnawed bags, and urine and blood stains on at least five bags;
- Six rodent excreta pellets on and between the pallets containing cracker meal and dry minced garlic;

AISLE 4:

- Twenty-nine rodent excreta pellets under a pallet containing cartons of cayenne pepper sauce and one pellet adhering to the bottom of one box on the pallet;
- At least 12 rodent excreta pellets and spilled rice on a pallet containing cartons of Ajax Oxygen Cleanser;
- At least seven rodent excreta pellets under a pallet containing cartons of Knorr Chicken Broth;

AISLE 5:

- At least 48 rodent excreta pellets on floor along the north wall perimeter rack, the northeast corner, and the south end of east wall of this warehouse area;

AISLE 2:

- At least 100 insects - alive and dead - on bags of Kokhuro rice;

DRY STORAGE ROOM I:

- Three decomposed rodents in a mouse trap between the dry storage rooms 1 and 2;

CHICKEN COOLER:

- One rodent excreta pellet found on a pallet containing Long Prairie Packing beef product;

PRODUCE COOLER:

- Two rodent excreta pellets on a pallet of King's Pastry Product; and,

PRODUCE STORAGE AREA OUTSIDE FREEZER DOOR:

- On February 26,2009, two live birds flying in the produce storage area and observed occasionally landing on boxes of eggs and produce.

2. Per 21 CFR 110AO(a), your plant equipment and utensils shall be so designed as to be adequately cleanable and shall be properly maintained. However, your cabbage dryer, cabbage transport bin, and cabbage processing bins are not constructed in a way which would make them easily cleanable. Specifically, the design of the dryer does not allow proper access for thorough cleaning of all interior surfaces, particularly the interior walls and the floor lining beneath the spinning drum; the use of octagonal nuts and bolts in the bottom of the transport bin results in gaps and corners which are difficult to clean; and the interior surfaces of the processing bins have pitted and dented surfaces and rough seams which are difficult to clean effectively. Furthermore, FDA investigators observed foul-smelling residues and apparent mold growth beneath the spinning drum in the cabbage dryer.

3. Per 21 CFR 110.10(b)(1), all persons working in direct contact with food, food-contact surfaces, and food-packaging materials shall wear outer garments suitable to protect against the contamination of the food, food-contact surfaces, and food-packaging materials. However, FDA investigators observed the primary employee handling cooked cabbage during cooking, cooling, drying, and hand packaging not wearing suitable outer garments to cover apparent street clothes worn throughout the facility.

This letter is not intended to be an all inclusive review of your manufacturing practices. It is your responsibility to ensure all products marketed by your firm comply with the Act and the applicable regulations. You should take prompt action to correct the violations addressed in this letter. Failure to promptly correct these violations may result in regulatory action being initiated by the FDA without further notice.

These actions include, but are not limited to, seizure and/or injunction.

(b)(3)

We acknowledge your voluntary destruction of a number of products, including 49 bags of G&L Cracker Meal, five bags of Kokhuro rice, and four cases of minced garlic, on March 2, 2009, at the conclusion of the inspection. You signed a Form FDA 463a, Affidavit, to document this voluntary destruction. However, you appear to have an

ongoing rodent problem in your facility, as evidenced by rodent excreta pellets, urine stains, and nesting materials found on site.

Please notify this office in writing within fifteen (15) working days from the date you receive this letter of the specific steps you have taken to correct the noted violations, including an explanation of how you plan to prevent these violations, or similar violations, from occurring again. Include documentation of the corrective action you have taken. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to: U.S. Food and Drug Administration, Attention: Kari L. Batey at the address above. If you have any questions about the content of this letter, please contact Ms. Batey at (615) 366-7808.

Sincerely,

/s/

H. Tyler Thornburg

District Director
New Orleans District

Enclosure: Form FDA 483

cc: Mr. Xin "Evan" Zheng, Manger
Won Feng Trading, Inc.
2728 Eugenia Avenue, Suite 103
Nashville, Tennessee 37211