



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

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

April 8, 2002

WARNING LETTER

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

In reply refer to Warning Letter SEA 02-39

Due T. Tran, President
VW Asian Food Company, Inc.
270 South Hanford Street, Building B
Seattle, Washington 98134

Dear Mr. Tran:

The Food and Drug Administration (FDA) conducted an inspection of your warehouse located at 270 South Hanford Street, Building B, Seattle, Washington, on February 28, March 1, 4, and 6, 2002. The inspection revealed numerous deviations from the Good Manufacturing Practice (GMP) regulations, Title 21, Code of Federal Regulations (21 CFR) Part 110 and (21 CFR) Part 123-Seafood HACCP regulations. At the conclusion of the inspection, you were issued a Form FDA-483 (copy enclosed) which delineated a number of insanitary conditions observed in your warehouse at the time of the inspection. These conditions cause the food products stored in your warehouse to be adulterated within the meaning of Section 402(a)(4) (copy enclosed) of the Federal Food, Drug, and Cosmetic Act (the Act), in that they were prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth. You can also find links to the Act at FDA's website at www.fda.gov.

The following insanitary conditions were observed by the investigators during the inspection:

1. Rodent activity in the warehouse:
 - a. A lot of [REDACTED] approximately 6 lb. boxes of instant rolled rice pancake stored on [REDACTED] pallets in the southwest corner of the southwest storage room had hundreds of rodent excreta pellets on the box surfaces, urine stains, and many rodent gnawed holes that penetrated into the product.

- b. A lot of 20 lb. paper bags of panko (Japanese style bread crumbs) stored on two pallets under the loft area of the main warehouse had a rodent gnawed hole that penetrated through to the product of one bag, several urine stains on box surfaces, and numerous rodent excreta pellets.
- c. Rodent excreta pellets were found in numerous areas around the warehouse as evidenced by the following:
 - At least fifty rodent excreta pellets were found at the floor/wall juncture of the north wall in the main warehouse, and at least fifty rodent excreta pellets beneath pallets of canned calamansi drink and canned coconut nectar stored in the middle of the warehouse at the west end of the aisle.
 - At least twenty-five rodent excreta pellets were found beneath a pallet of garlic stored near the south wall of the small storage area.
 - A total of thirty rodent excreta pellets were found at the floor/wall juncture of the west wall of the rice storage room, and southwest corner of the main warehouse.
3. Structural deficiencies included a large hole (approximately 2" X 2") at the floor/wall juncture of the west wall of the main warehouse that penetrates to the outside of the building, and a gap beneath the east end loading door.
4. You must have written verification procedures, product specifications to preclude safety hazards, and affirmative steps, in order to comply with 21 CFR 123.12(a)(2). Your firm did not have written verification procedures for imported frozen mackerel. You have not been following the affirmative steps you have chosen for this product.

The above violations are not meant to be an all-inclusive list of deficiencies in your facility. Other violations can subject the food to legal action. It is your responsibility to assure that all of your products are in compliance with the Act. You should take prompt action to correct the violations observed during FDA's most recent inspection. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

Please respond in writing within fifteen (15) days from your receipt of this letter. Your response should include each step that has been taken to completely correct the current violations and to prevent the recurrence of similar violations, the time within which correction will be completed, and any documentation necessary to show that correction has been achieved. If you cannot complete all corrections before you respond, please explain the reason for your delay and state when you will correct any remaining deviations.

Duc T. Tran, President
VW Asian Food Company, Inc., Seattle, Washington
Re: Warning Letter SEA 02-
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Please send your reply to the Food and Drug Administration, Attention: Lisa M. Elrand, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421. If you have questions regarding any issue in this letter, please contact Lisa Elrand, Compliance Officer at (425) 483-4913.

Sincerely,

A handwritten signature in black ink, appearing to read "Charles M. Breen", with a long horizontal flourish extending to the right.

Charles M. Breen
District Director

Enclosures:

Form FDA 483
21 CFR PART 110 and 123.12
Section 402(a)(4) of the FD&C Act

cc: WSDA with disclosure statement