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Food and Drug Administration
Baltimore District Office
Central Region
900 Madison Avenue
Baltimore, MD 21201-2199
Telephone: (410) 962-3396
FAX: (410) 962-2307

August 27, 1999

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Chun Tack Chin, President
Hanmi, Incorporated
6560 Dobbin Road
Columbia, Maryland 21045

Dear Mr. Chin:

The Food and Drug Administration (FDA) conducted an inspection of your food storage warehouse on August 3 & 5, 1999. The inspection revealed deviations from the Good Manufacturing Practice (GMP) Regulations, Title 21, CFR, Part 110. The deviations cause the food products stored in your facility to be adulterated within the meaning of Section 402(a)(4) of the Food, Drug, and Cosmetic Act (FD&C Act), in that they were prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth.

The deviations observed included: a live mouse, rodent excreta pellets on the floor, live birds in the warehouse, holes in walls, and loading dock doors remaining open all day when not in use. A bag by bag examination of 10/50 pound bags of Pressed Barley revealed rodent excreta pellets on the surfaces of all 10 bags, gnawed holes in 3 of 10 bags, and fluorescent stains indicative of rodent urine on 4 of 10 bags. A copy of the FDA-483, Inspectional Observations, is enclosed for your information.

The above list is not intended to be an all-inclusive list of deficiencies observed at your facility. It is your responsibility to assure that your establishment is in compliance with all the requirements of the FD&C Act. Failure to do so may result in regulatory action being taken by the FDA without further notice, such as seizure or injunction.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations and to prevent their recurrence.

Your response should be addressed to Rosalie Bucey, Compliance Officer, U.S. Food and Drug Administration, 900 Madison Avenue, Baltimore, Maryland 21201, telephone number 410/962-3591, Ext. 143.

Sincerely,



James E. Strachan
Acting District Director

Enclosure: FDA-483