



DEPARTMENT OF HEALTH AND HUMAN SERVICES

940817

REF: 3000204825

Food and Drug Administration
Baltimore District Office
Central Region
6000 Metro Drive, Suite 101
Baltimore, MD 21215
Telephone: (410) 779-5454
FAX: (410) 779-5707

May 9, 2002

02-BLT-16

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ms. Gina Chin, President
Donald Chin Supply Company
1323 4th Street, N.E.
Washington, D. C. 20002

Dear Ms. Chin:

The Food and Drug Administration (FDA) conducted an inspection of your food storage warehouse located at 1323 4th Street, N.E., Washington, D.C. on March 18-20 and 25-26, 2002. The inspection revealed numerous deviations from the Good Manufacturing Practice (GMP) regulations, Title 21, Code of Federal Regulations (CFR), Part 110. At the conclusion of the inspection, you were issued a Form FDA 483, Inspection Observations (copy enclosed), which described the insanitary conditions observed in your warehouse. The deviations cause the food stored in your warehouse to be adulterated within the meaning of Section 402(a)(4) of the Food, Drug, and Cosmetic Act (FD&C Act). The conditions observed included:

- A live rodent was observed in the retail product display area of the warehouse (see 21 C.F.R. §§ 110.20, 110.35);
- Rodent excreta pellets were observed throughout the facility, including on the surface of pallets holding bags of Monosodium Glutamate stored along the east wall of the first floor, on the surface of a pallet holding bulk drums of Monosodium Glutamate stored in the loft area on the second floor; on boxes containing wrapped blocks of cheese stored in the walk-in cooler located on the first floor, and on the floor behind pallets holding food items stored along the north wall of the third floor storage area (see 21 C.F.R. §§ 110.20, 110.35, 110.80, 110.93);
- Live birds were observed flying in the rafters located on the first, second, and fourth floors of the warehouse (see 21 C.F.R. §§ 110.20, 110.35);
- Bird excrement was observed in various areas of the warehouse including on a pallet containing a bag of potato starch and on another pallet containing miscellaneous food service items stored on the second floor, and in the loading dock area located along the east wall of the first floor storage area (see 21 C.F.R. §§ 110.20, 110.35, 110.93);
- Three loading dock doors remained open for long periods of time when not in use (see 21 C.F.R. §§ 110.20, 110.35, 110.93);
- Holes and/or gaps were observed in various areas, including a 4' x 3' hole along the outside portion of loading dock door #3, leading directly into the main storage area of the warehouse (see 21 C.F.R. §§ 110.20, 110.35, 110.93), and

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- Empty pallets and pallets holding food items were stored outside, directly against the east wall of the warehouse, in the immediate area of the loading dock doors that remained open during the inspection (see 21 C.F.R. §§ 110.20, 110.35, 110.93.).

During the inspection, you admitted to an ongoing rodent infestation problem, a fact that was confirmed not only by the current inspection but by our two prior inspections on 5/27/97 and 3/4/99. It is your responsibility to have an effective, ongoing sanitation and pest-control program for your facility that eliminates the observed insanitary conditions, as well as prevents new infestations. The above list of objectionable conditions observed in your warehouse is not all-inclusive. You should take prompt action to correct all the deviations. Failure to do so may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, or prosecution.

Please notify this office in writing, within 15 working days of receipt of this letter, of the steps you have taken to correct the violations and to prevent recurrence. 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 the Food and Drug Administration, 6000 Metro Drive, Suite 101, Baltimore, Maryland 21215, Attention: Rosalie Bucey, Compliance Officer. Ms. Bucey may be reached at (410) 779-5417.

Sincerely,



Lee Bowers
Director, Baltimore District

Enclosure