



01-BLT-25

March 21, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Gilberto A. Gonzalez, President
International Wholesalers Corporation
1238 W Street, N.E.
Washington, D.C. 20018

Dear Mr. Gonzalez:

The Food and Drug Administration (FDA) conducted an inspection of your food storage warehouse located at 1238 W Street, N.E., Washington, D.C., on March 6-8, 2001. 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", Inspectional Observations (copy enclosed), which describes the insanitary conditions observed in your firm during the inspection. These conditions cause the products stored in your facility to be adulterated within the meaning of Section 402(a)(4) of the Food, Drug, and Cosmetic Act (the Act). The conditions observed include:

- A dead rodent on the floor in the coffee/juice room.
- Examination of a co-mingled lot containing bagged wheat, cornmeal, and potato starch revealed:
 - rodent excreta pellets inside a bag of Semolina wheat,
 - over one hundred rodent excreta pellets on bags of rice, in spilled product and on the pallet surface holding the bags,
 - bird droppings on a box of cornmeal and a bag of potato starch.
- Rodent nesting material and rodent excreta pellets on a pallet holding canned egg plant.
- Rodent excreta pellets in the spice room.
- Rodent excreta pellets along the floor/wall areas of the Jalapeno room.
- Rodent excreta pellets on the floor in the flour room.

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- Rodent excreta pellets, damaged and spilled product, and bits of insulation adjacent to a hole in the outside wall of the cooler.
- A live bird in the flour room.
- Bird excrement on spilled product, on pallet surfaces and storage racks, and on boxes containing ██████████ Flour.
- Ten dead adult and 5 moth larvae on spilled product from an unlabeled, damaged box in the Spice Room.
- Product spillage throughout the facility (Jalaepno, Spice, Flour and Coffee/Juice rooms).
- Storage of products against walls, no aiseways between products, clutter, debris, machinery, and metal parts stored along various walls.
- Gaps measuring 1 to 2 inches in length along the base of the outer bay doors.
- Thermometers in the walk-in freezers have not been calibrated or tested for accuracy.

The above items are not intended to be an all-inclusive list of the objectionable conditions and/or practices in your facility. You should take prompt action to correct all deviations from the GMP regulations. 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 and/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 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 reply should be sent to the Food and Drug Administration, 900 Madison Avenue, Baltimore, Maryland 21201, to the attention of Rosalie Bucey, Compliance Officer. Ms. Bucey can be reached at 410/962-3591, extension 143.

Sincerely,



for Lee Bowers
Director, Baltimore District

Enclosure