



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Baltimore District Office
6000 Metro Drive
Suite 101
Baltimore, MD 21215-3215
Telephone: (410) 779-5454

04-BLT-06

January 30, 2004

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Daniel A. Albisu, President
S & F Enterprises D.B.A. Ziggy's Finest
35 New York Avenue NE
Washington, DC 20002

Dear Mr. Albisu:

The Food and Drug Administration (FDA) inspected your food storage warehouse located at 35 New York Avenue NE Washington, DC 20002 on October 29 and 31st, 2003. 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 Federal Food, Drug, and Cosmetic Act. Effective measures are not being taken to protect against the contamination of food on the premises by pests, in violation of 21 CFR 110.35(c). Specific examples include:

- A live mouse observed inside a box of [REDACTED] Macaroni stored on top of the cooler in the northeast part of the warehouse;
- Two dead mice observed on a glue trap by the front door under a pallet of canned product at the northeast corner of the warehouse;
- A cardboard box of [REDACTED] Macaroni had a hole at the bottom left side. Six 1 pound inner packages also had holes varying from 3" by 2" at the largest to 1" by 3/4" at the smallest. Holes in food packaging allow the food inside to be accessed by pests, thereby giving rise to an insanitary condition;
- A cardboard box of [REDACTED] Macaroni had a hole at the bottom right side. Twelve 1 pound inner packages also had holes varying from 5" by 4" at the largest to 3/4" by 3/4" at the smallest sizes;
- A case of Pepperoncino located at the northwest side of the warehouse had a hole 4" by 7";
- Rodent excreta pellets were observed in eight different areas of the warehouse. Numbers of pellets ranged from 33 to 7. Four of the sites were in proximity to stored food articles.

The investigator also noted failure to maintain buildings in repair sufficient to prevent food from becoming adulterated, in violation of 21 CFR 5 110.35(a). Specifically,

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- A hole in the wall/floor juncture of the second floor stairway landing along the northwest side of the warehouse;
- A hole in the wall by the window frame along the second floor, southeast side of the warehouse.

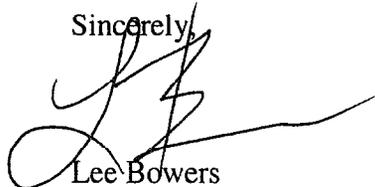
You should take prompt action to correct these deviations. Failure to do so may result in regulatory action being initiated by the FDA without further notice, including seizure and/or injunction.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your facility operates in compliance with the Act and the Good Manufacturing Practice regulations, 21 CFR Part 110. You are responsible for implementing procedures to prevent further violations of the Act and all applicable regulations.

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. Your response should outline the specific things that you are doing to correct these deviations. You should include in your response documentation and written verification procedures or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

Your reply should be sent to the Food and Drug Administration, 6000 Metro Drive, Suite 101, Baltimore, Maryland 21215, Attention: Elizabeth Laudig, Compliance Officer. Ms. Laudig can be reached at (410) 779-5441.

Sincerely,

A handwritten signature in black ink, appearing to read 'Lee Bowers', with a long horizontal flourish extending to the right.

Lee Bowers

Baltimore District Director