

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
738

Refer to: 1120998

Baltimore District
900 Madison Avenue
Baltimore, Maryland 21201
Telephone: (410) 962-4012

December 17, 1997

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Coleman Pressman, Owner
Gourmet Bakery Shoppes, Incorporated
6101 Oakleaf Avenue
Baltimore, Maryland 21215

Dear Mr. Pressman:

During an inspection of your firm conducted by the Food and Drug Administration (FDA) from December 11-12, 1997, numerous insanitary conditions were observed throughout the facility. For example:

- (1) Two live birds were observed in the storage areas.
- (2) Rodent excreta pellets (too numerous to count) were noted throughout the facility.
- (3) Custard used to fill eclairs was left unrefrigerated in excess of 24 hours.
- (4) Holes were noted in the south outside wall of the building.
- (5) The door to the warehouse was left open during the inspection.
- (6) Uncovered finished product was observed in the coolers exposed to condensate from the condenser.

Preparing, packing, or holding food under insanitary conditions renders the food adulterated under Section 402(a)(4) of the Food, Drug, and Cosmetic Act (Act), in that the food may become contaminated with filth. Adulterated food is subject to seizure under the Act. The

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regulations regarding preparing, packing, and holding food are located in the Code of Federal Regulations, Title 21, Part 110, and are enclosed for your reference.

The above violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to insure that your facility is operated in a sanitary manner.

At the conclusion of the inspection, the FDA investigator presented to you a list of deficiencies (FDA-483). You should take prompt action to correct these violations. Failure to do so may result in regulatory action without further notice, such as seizure and/or injunction.

You should notify this office in writing, within 15 days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent recurrence of similar violations.

Your reply should be sent to the Food and Drug Administration, at the above address, to the attention of Mr. Wiley T. Williamson, III, Compliance Officer. Mr. Williamson can be reached at 410-962-4366, Extension 136.

Sincerely,



Elaine Knowles Cole
Director, Baltimore District

Enclosure