



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

July 2, 2002

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

In reply refer to Warning Letter SEA 02-54

Robert J. Miller, President
The Bread Garden, Ltd.
1001 South 344th
Federal Way, Washington 98003

WARNING LETTER

Dear Mr. Miller:

The Food and Drug Administration (FDA) conducted an inspection of your bakery located at 1001 South 344th, Federal Way, Washington, on June 3, 2002. The inspection revealed numerous deviations from the Good Manufacturing Practice (GMP) regulations, Title 21, Code of Federal Regulations (21 CFR) Part 110. At the conclusion of the inspection, you were issued a Form FDA-483 (copy enclosed) which delineated a number of gross insanitary conditions present in your bakery at the time of the inspection. These conditions cause the food products stored in your bakery to be adulterated within the meaning of Section 402(a)(4), (copy enclosed) of the Federal Food, Drug, and Cosmetic Act (the Act), in that they were prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth. You can find this Act through links in FDA's homepage at www.fda.gov.

The following is a list of the insanitary conditions observed by our investigators during the inspection:

1. Insect activity in the processing area and equipment:
 - a. Numerous live and dead beetles were observed in and around the secondary proofer unit used for the Pita bread line. Specifically, at least ten live beetles were found in flour residue on the ledges that hold the top panels of the proofer. At least six of these beetles were approximately three inches from the top conveyor belt that comes in contact with product. Also, at least five live beetles were found in the interior base frame of the proofer.

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- b. At least six live beetles were found in flour dust at the base of the electrical panel on the north orange top mixer on the west wall of the breakroom. Near this area were also about 50 beetles and larva in product residue at the juncture of the base and backside of the same electrical panel.
 - c. Two live beetles and three dead beetles were found in product residue in the upper compartment of the rectangular metal storage bin by the oil storage rack on the north side of the mix area.
2. Poor practices in maintaining and cleaning equipment, containers, and utensils used to hold or store food:
- a. Ten ingredient barrels in the raw material storage area were soiled with product residue on the lid exterior and interior, and interior contact surfaces.
 - b. Scoops were being stored in a bucket containing old product residue. Another scoop was being stored on the soiled lid of a barrel of food product.
 - c. Old product residue was found on baking pans stored on the South wall of the processing area.
 - d. The area under the perforated metal sheet on the exit chute from the Pita bread cooling conveyor had an accumulation of dusty product residues.
 - e. The wall behind the scaling bench and west wall of the facility had a build up of what appeared to be mold.
 - f. Loose staples were found on the edge of the juncture of the conveyor belt between the divider and overhead proofer of the Pita bread line. Also, the conveyor belts between the molder and secondary proofer on the Pita bread line had frayed and torn edges leaving material up to three inches hanging in some places.

Our inspection has revealed that you have a serious pest infestation problem in your facility. It is your responsibility to have an effective, ongoing sanitation program that eliminates the insanitary conditions we have observed.

The above violations are not meant to be an all-inclusive list of deficiencies in your facility. Other violations can subject the food to legal action. It is your responsibility to assure that all of your products are in compliance with applicable statutes enforced by the FDA. You should take prompt action to correct all of the violations noted in this letter. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

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Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. 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.

Please send your reply to the Food and Drug Administration, Attention: Lisa M. Elrand, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421. If you have questions regarding any issue in this letter, please contact Lisa Elrand, Compliance Officer at (425) 483-4913 or via e-mail at leland@ora.fda.gov.

Sincerely,

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

Charles M. Breen
District Director

Enclosures:

Form FDA 483 -6/3/02-6/6/02
21 CFR PART 110 and 123.11(b)
Section 402 (a)(4) of the Federal Food, Drug, and Cosmetic Act

cc: WSDA with disclosure statement