



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration  
Baltimore District Office  
Central Region  
6000 Metro Drive, Suite 101  
Baltimore, MD 21215  
Telephone: (410) 779-5454  
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04-BLT-16

March 9, 2004

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Mr. Rafee Karapetian, President  
Mama Lavash, Inc.  
2190 A Pimmit Drive  
Falls Church, VA 22043-2806

Dear Mr. Karapetian,

On December 16-18, 2003, the Food and Drug Administration (FDA) inspected your food manufacturing facility located at 2190 A Pimmit Drive, Falls Church, VA. The inspection revealed numerous deviations from the current Good Manufacturing Practice (cGMP) regulations for Manufacturing, Packing, or Holding Human Food, Title 21, Code of Federal Regulations (CFR), Part 110, which cause your products to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act).

The observations of concern to us included:

1. Your firm failed to take effective measures to exclude pests from the food processing areas and protect against the contamination of food on the premises by pests [21 CFR 110.35(c)]. Specifically, live roaches were observed crawling on the eastern and western terminals of the mister; and a live roach was observed crawling in the manufacturing area, near the [REDACTED] oven. Numerous pathogens recovered from foods and food-contact surfaces have been traced to various kinds of pests, including cockroaches.
2. Your firm failed to have an accurate indicating thermometer, temperature measuring device, or temperature recording device in each freezer and cold storage compartment used to store food capable of supporting growth of microorganisms [21 CFR 110.40(e)]. Specifically, the upright refrigerator in the processing area, used for storing [REDACTED] did not have an indicating thermometer to monitor refrigeration temperature.
3. Your firm failed to provide its employees with adequate, readily accessible toilet facilities [21 CFR 110.37(d)(3)], in that the toilet facility failed to have a self-closing door to provide a barrier between potential contamination from the restroom to the production area.

4. Your firm failed to post readily, understandable signs directing employees handling unprotected food, unprotected food packaging materials, of food-contact surfaces to wash and, where appropriate, sanitize their hands before they start work, after each absence from post of duty, and when their hands may have become soiled or contaminated [21 CFR 110.37(e)(5)].

5. Your firm's bread, labeled in part, "Mama Lavash, Inc, BREAD NET WT. 16OZ. (1LB.)..." is misbranded under Section 403(i)(2) of the Act, in that the ingredient statement fails to bear the common or usual name of all ingredients in the bread. Title 21, CFR 101.4(b)(2) requires that all ingredients must be declared, including the sub-ingredients of ingredients which themselves contain two or more ingredients. For example, our investigators observed that you use the ingredient "[REDACTED]" in the manufacturing of your bread. The ingredient statement on the [REDACTED] indicates that it is composed of whey and l-cysteine hydrochloride; however, you failed to list these ingredients on the label of your bread. Declaration of the whey sub-ingredient is of particular concern because it is a milk based ingredient, which is an allergenic substance. For sensitive individuals, the presence of undeclared allergens in food is potentially life-threatening.

The above violations are not meant to be an all-inclusive list of your cGMP and labeling deficiencies. It is your responsibility to ensure that all of your products are manufactured and labeled in compliance with all applicable requirements of 21 CFR Part s 101, 110, and the Act.

You should take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action by FDA without further notice. Such action includes seizure and/or injunction.

We request that you notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action can not be completed within 15 working days, state the reason for the delay and the time within which corrections will be completed.

Your reply should be directed to Ms. Vinetta Howard-King, Compliance Officer, U.S. Food and Drug Administration, 6000 Metro Drive, Suite 101, Baltimore, Maryland 21215. If you have any questions, please do not hesitate to contact Ms. Howard-King at (410) 779-5454, extension 413.

Sincerely,



Lye Bowers  
Director, Baltimore District