



DEPARTMENT OF HEALTH AND HUMAN SERVICE

34623d

Southwest Region

Food and Drug Administration  
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Denver, Colorado 80225-0087  
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**WARNING LETTER**

May 21, 2003

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

Mr. Jay D. Terrell, President  
Curtell's Specialty Breads, Inc.  
1241 Major Street  
Salt Lake City, Utah 84111

Dear Mr. Terrell:

On February 20-21, 2003, the Food and Drug Administration (FDA) inspected your food processing plant, located at 1241 Major Street, Salt Lake City, Utah. As a result of this inspection, we have determined that certain products manufactured at this facility fail to comply with sections 402(a) and 403(r) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §§ 342(a), 343(r)) and Title 21, Code of Federal Regulations, Part 110 (21 C.F.R. Part 110). The specific violations are identified and explained below. You can find the Act and FDA's regulations through links in FDA's home page, located at <http://www.fda.gov>.

During the inspection, our investigator collected labels for some of your products, including your "HOMESTYLE SOUR 3/8" SLICE LOW CARB." bread. We have determined that this product's label causes the product to violate the Act and FDA's regulations. Specifically, your "HOMESTYLE SOUR 3/8" SLICE LOW CARB." bread product is misbranded under section 403(r)(1)(A) of the Act because its label bears the nutrient content claim "LOW CARB," which has not been authorized by FDA.

In addition, our inspection of your facility revealed multiple violations of FDA's Current Good Manufacturing Practice (GMP) regulations (21 C.F.R. Part 110). As you may recall, many of these violations were brought to your attention during past FDA inspections conducted on June 17-18, 2002; April 28, 1999; November 1, 1996, and May 13, 1996. These violations make your products adulterated under section 402(a)(4) of the Act, in that the food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. 21 U.S.C. § 342(a)(4). The following conditions in your facility violate GMPs and adulterate your food products under section 402(a)(4) of the Act:

- Failure to fit the refrigerator used to store eggs, milk, and cheese, with an indicating thermometer, temperature-measuring device, or temperature-recording device installed so as to show the temperature accurately in the cold storage compartment. 21 C.F.R. § 110.40(e). Our investigator verified that a new thermometer was placed in the refrigerator on the second day of the inspection, February 21, 2003. We remind you that it is particularly important to control the temperature of cold storage compartments used to store food such as eggs, milk, and cheese, because these foods are capable of supporting growth of microorganisms. You were notified of a similar violation during our inspection on May 13, 1996.
- Failure to store finished product and raw materials in a manner that protects against contamination. 21 C.F.R. § 110.80(b)(7). For example, there were crates and boxes of finished product stored directly on the floor, bins of flour and base mixes left uncovered, an open box of raisins, and pieces of onion and a pan of margarine left uncovered in the freezer. Uncovered bins and containers of raw materials and finished product were stored in such a manner whereby they may become contaminated with filth or attract pests such as insects, rodents, or birds. You were notified of the same and similar violations during our inspections on June 17-18, 2002, and May 13, 1996.
- Failure to provide adequate screening or other protection against pests. 21 C.F.R. § 110.20(b)(7). There are gaps in the closure of the side exit door and the bottom of the dock door (both located in the raw materials storage area), and the door located in the shipping/packaging area. In addition, the side exit door was left open. These conditions allow pests such as insects, rodents, and birds to access the facility and adulterate your raw materials and finished products. You were notified of the same and similar violations during our inspections on June 17-18, 2002, and May 13, 1996.
- Failure to clean food-contact surfaces, including utensils and food-contact surfaces of equipment, to protect against contamination of food, and failure to maintain equipment during storage in a manner that protects against contamination. 21 C.F.R. § 110.35(d) and § 110.80(b)(7), respectively. For example, stored bread pans were discovered to contain residue of old product debris. You were notified of the same and similar violations during our inspections on June 17-18, 2002, and May 13, 1996.
- Failure to provide sufficient space for placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations and the production of safe food. 21 C.F.R. § 110.20(b)(1). For example, you stored bread pans against the facility walls in the production area. This condition prevents adequate cleaning in the production area which could lead to contamination of your products. You were notified of this violation during our inspections on June 17-18, 2002, and April 28, 1999.
- Failure to maintain buildings, fixtures, and other physical facilities of the plant in a sanitary condition and in sufficient repair to prevent food from becoming adulterated within the meaning of the Act. 21 C.F.R. § 110.35(a). For example, you failed to clean

the floor of your facility, which was littered with various finished product, raw materials, and other debris. You were notified of this violation during our inspections on June 17-18, 2002, April 28, 1999, and November 1, 1996. In addition, your facility’s insulation is torn in several places and was observed hanging from the ceiling over uncovered finished food product. You were notified of this violation during our inspections on June 17-18, 2002, and May 13, 1996. The litter and exposed, torn insulation contribute to insanitary conditions in your facility and can lead to contamination of your food products.

- Failure to convey, store, and dispose of rubbish and any offal so as to minimize the potential for waste becoming an attractant and harborage or breeding place for pests, and protect against contamination of food, food-contact surfaces, water supplies, and ground surfaces. 21 C.F.R. § 110.37(f). For example, trash containers were discovered within the immediate proximity of finished food product and production equipment. The proximity of these trash containers and their contents to food and food contact surfaces can lead to contamination of your food products.
- Failure to locate and operate fans and other air-blowing equipment in a manner that minimizes the potential for contaminating food and food-contact substances. 21 C.F.R. § 110.20(b)(6); 110.35(d)(3). For example, the blades of your industrial floor fan used to cool finished product were covered with dust and debris. This fan was located within 12 inches of finished food product. In addition, the overhead air duct/ventilation system used in your facility to cool finished food product has no screening device. This may expose food to dust or other debris and provide direct access to open space in the facility’s ceiling that could become an harborage for pests. You were notified about the filth on the floor fan during a past FDA inspection on June 17-18, 2002. You were similarly notified about the missing screen for the overhead ventilation system during our inspections on June 17-18, 2002, and April 28, 1999.
- Failure to properly store equipment and remove litter and waste within the immediate vicinity of your facility that may constitute an attractant, breeding place, or harborage for pests. 21 C.F.R. § 110.20(a)(1); 110.37(f). For example, your facility has extensive litter, including pallets, plastic crates, bread storing racks, and bread pans, on the north, west, and east sides of the outside of your building. This litter, combined with the open entryways into your facility and the uncovered raw materials and finished product, creates conditions that are likely to lead to serious pest infestation and contamination of food. You were notified of this violation during our inspection on June 17-18, 2002.
- Finally, failure to conform to hygienic practices to the extent necessary to protect against contamination of food, including failure to store personal belongings in areas other than where food is exposed or where equipment or utensils are washed. 21 C.F.R. § 110.10(b)(7). For example, personal items such as plastic beverage containers, aluminum soda cans, and a pack of cigarettes were discovered in your facility in the raw materials storage area and on the table used for weighing product ingredients. The presence of these personal belongings can lead to contamination of food in these areas.

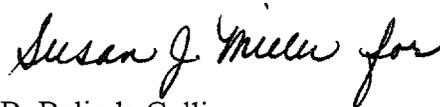
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The violations listed above are not meant to be an all-inclusive list of deficiencies in your facility or product labeling. It is your responsibility to ensure that all of your food products are manufactured and labeled in accordance with applicable statutes and regulations. We advise you to take prompt action to correct any violations, including those identified in this letter. Failure to promptly correct violations may result in regulatory action without further notice, such as an action to seize your products or enjoin your firm's operations.

Please respond in writing within fifteen (15) working days of receipt of this letter. Your response should outline the specific steps you have taken to correct the noted violations. 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 deficiencies.

Your reply should be sent to Shelly L. Maifarth, Compliance Officer, at the address provided in the letterhead. If you have any questions concerning this letter, you may contact Ms. Maifarth at (303) 236-3046.

Sincerely,



B. Belinda Collins  
District Director