

FDA Closes Puerto Rico Bakery for Multiple Violations

SILVER SPRING, Md. (FDA) — Los Genuinos, Inc., a Bayamon, Puerto Rico, food manufacturer, has agreed under terms of a court order not to process or distribute food until it addresses the unsanitary conditions found by [U.S. Food and Drug Administration](#) [1] investigators. The company must also correct its product labels to accurately reflect the ingredients used in its products.

Los Genuinos manufactures a variety of non-filled sweet bakery products and distributes these products locally to supermarkets, small grocery stores, general stores, pharmacies, bakeries and cafeterias.

Los Genuinos and its owner, Nicolas Rivera Berrios, have failed to adequately implement corrective and preventive actions to address current Good Manufacturing Practice (cGMP) requirements and labeling violations.

“The company’s failure to correct these problems puts the health of consumers at risk, which is unacceptable,” said Melinda K. Plaisier, associate commissioner for regulatory affairs, FDA. “The FDA will continue to take enforcement action against firms that violate our manufacturing requirements.”

The FDA has conducted multiple inspections of the company’s facility and has repeatedly observed violations, including failing to follow cGMP requirements and misbranding violations. In addition, in June 2011, the FDA issued a [warning letter](#) [2] to Los Genuinos, warning the company that an FDA inspection revealed that bakery items had been prepared, packed or held under unsanitary conditions and labels failed to declare a food allergen and unsafe color additive.

During the FDA’s most recent inspection, agency investigators found that Los Genuinos had failed to take effective measures to protect food against contamination from pests, adequately clean and sanitize equipment and utensils and properly store cleaning compounds away from food and manufacturing areas. Investigators also observed that Los Genuinos did not accurately declare ingredients on product labels.

Before it will be allowed to resume operations, Los Genuinos must hire an independent sanitation expert to help the company develop and implement a written sanitation control program, review all product labeling to ensure it complies with the Federal Food, Drug and Cosmetic Act and conduct an independent audit of the company’s operations and labeling.

No illnesses have been reported to the FDA associated with Los Genuinos’ products. Consumers can report problems to their appropriate FDA [District Office Consumer Complaint Coordinator](#) [3].

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For more information:

[Your Guide to Reporting Problems to the FDA](#) [4]

[Warning letter to Los Genuinos, Inc., June 2, 2011](#) [2]

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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Links:

[1] <https://twitter.com/FDAfood>

[2]

<http://www.fda.gov/iceci/enforcementactions/warningletters/2011/ucm260354.htm>

[3] <http://www.fda.gov/Safety/ReportaProblem/ConsumerComplaintCoordinators/default.htm>

[4] <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm095859.htm>