



Department of Health and Human Services

Public Health Service
Food and Drug
Administration
Atlanta District Office
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Atlanta, GA 30309
Telephone: 404-253-1200
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January 27, 2010

VIA FEDERAL EXPRESS

A.D. David Mackay, President & CEO
Kellogg Company
1 Kellogg Square
Battle Creek, MI 49017

**WARNING LETTER
(10-ATL-07)**

Dear Mr. Mackay:

On October 22-29, 2009, the U.S. Food and Drug Administration (FDA) conducted an inspection of your frozen food manufacturing facility located at 5601 Bucknell Drive, SW, Atlanta, GA 30336. The inspection was initiated in response to a notification from the Georgia Department of Agriculture (GDA) on August 31, 2009, of a positive test for *Listeria monocytogenes* in your Eggo Buttermilk Waffles identified with a Better If Used Before date beginning with NOV17 10 EAAM1. During the inspection, we collected a variety of samples consisting of finished products, in-process products, and environmental swabs. FDA laboratory analyses of the environmental swabs collected during this inspection also found the presence of the pathogen *Listeria monocytogenes* in your facility. In addition, we found that you have significant deviations from the current Good Manufacturing Practice (CGMP) regulations for food manufacturers, Title 21, Code of Federal Regulations, Part 110 (21 CFR 110). These violations and the results of the laboratory analyses cause the foods manufactured at your facility to be adulterated within the meaning of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 342(a)(4)] in that they were prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health. You may find the Act and FDA's regulations through links in FDA's home page at <http://www.fda.gov>.

Listeria monocytogenes (*L. monocytogenes*) is a pathogenic bacterium that is widespread in the environment and may be introduced into a food processing facility. *L. monocytogenes* can contaminate foods, resulting in a mild illness (called listerial gastroenteritis) or a severe, sometimes life-threatening, illness called invasive listeriosis. Listeriosis is an atypical foodborne illness of major public health concern because of the severity of the disease, a high case-fatality rate, a long incubation and a predilection for individuals with underlying conditions.

During the FDA inspection, investigators collected environmental samples from various areas in your facility. Five environmental swabs tested positive for *L. monocytogenes*. Pulsed Field Gel Electrophoresis (PFGE) testing results determined that three of the environmental swabs had a PFGE pattern that was indistinguishable from the positive sample collected by the GDA. This is significant because these three swabs were taken from three different locations in your facility and the swabs' indistinguishable PFGE pattern was found in your firm's finished product, Eggo Buttermilk Waffles. The PFGE results reveal that *L. monocytogenes* may have been transported throughout your facility and may have established niche areas to colonize. One of the aforementioned environmental swabs was taken from the wheels on a forklift observed in the packaging area. The presence of *L. monocytogenes* on the wheels of a forklift is a concern as the organism is likely to spread when the forklift moves throughout the facility.

Two of the positive environmental swabs had PFGE patterns that were distinguishable from the other three environmental swabs and the positive sample collected by the GDA. One of these samples was collected from the floor at the walk-through door to the battery changing room. The other sample was collected from the bottom of a grey tote located at the end of the **(b)(4)** conveyor.

Bacteria may enter and/or be transported through a food plant by a variety of routes that include, but are not limited to: roof leaks; the shoes of employees, contractors, and visitors; the wheels of fork lifts, pallet movers, and moveable equipment; soiled pallets; soiled raw material packaging; raw ingredients; and by rodent vectors. Once established on production area floors, the pathogen may contaminate food and food-contact surfaces through either human or mechanical means. *L. monocytogenes* differs from most other foodborne pathogens because it is widely distributed, resistant to diverse environmental conditions, including low pH and high NaCl concentrations, and grows under refrigeration conditions.

During our inspection, we documented conditions and practices that may lead to the contamination of your products with pathogens such as *L. monocytogenes*. Specifically, our inspection of your facility revealed the following sanitation violations:

1. To comply with section 21 CFR 110.35(a), you must clean and sanitize utensils and equipment in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials. However, our investigators observed that employees in the mixing room were using high pressure water to clean equipment near exposed raw materials. The investigators also observed the cleaning water splashing

near the exposed raw ingredients, which could lead to contamination of your food products.

2. To comply with section 21 CFR 110.37(f), you must convey, store, and dispose of rubbish and any offal in a manner that protects against contamination of food. However, our investigators observed that an uncovered cart containing trash was located within close proximity (approximately six inches) of exposed raw materials in the mixing room. The proximity of the trash container and its contents to food and food contact surfaces could lead to contamination of your food products.

3. To comply with section 21 CFR 110.20(b)(4), your plant and facilities must be constructed so that drip or condensate from fixtures, ducts, and pipes does not contaminate food, food-contact surfaces, or food-packing materials. However, our investigators observed condensate and drippage in the waffle production area above lines

(b)(4) which were transporting exposed products; above the conveyors transporting exposed in-process products to the spiral freezer; and above wheel **(b)(4)** and an uncovered cinnamon feeder containing raw ingredients. Condensate is not potable water and it is likely to be contaminated with harmful bacteria, which could contaminate the finished product.

4. To comply with section 21 CFR 110.10(b), all persons working in direct contact with food, food-contact surfaces, and food-packaging materials must conform to hygienic practices to protect against contamination of food. These methods include but are not limited to the following:

- Taking necessary precautions to protect against contamination of food, food-contact surfaces, or food packaging materials with micro-organisms [21 CFR 110.10(b)(9)]. However, our investigators observed a maintenance employee, who was not wearing gloves, touching exposed finished product and food-contact surfaces on equipment while using tools to fix an infrared sensor on line **(b)(4)**
- Washing hands thoroughly (and sanitizing if necessary to protect against contamination with undesirable microorganisms) before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated [21 CFR 110.10(b)(3)]. Our investigators observed two employees donning shoe covers after washing their hands, and an employee touching his nose and mustache, after washing his hands, and not using sanitizer or re-washing his hands before he returned to the work area.

We acknowledge receipt of your response (updated November 18, 2009) in response to FDA's positive *L. monocytogenes* environmental swabs. Although your response lists a number of corrective actions directly associated with the positive test results, including sanitizing certain equipment and limiting employee access to certain processing areas, it

is essential to identify all areas of your facility where *L. monocytogenes* is able to grow and survive (niche areas) and to take such corrective actions as necessary to control the organism. In addition, FDA recommends that your sanitation controls include effective environmental monitoring programs designed to identify and eliminate and/or control pathogens such as *L. monocytogenes* in and on surfaces and areas in the facility where contamination could result in food product contamination. Finally, your response does not address the CGMP deviations identified in this letter.

This letter is not intended to be an all-inclusive list of violations that may exist at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act and applicable regulations. You should take prompt action to correct these violations. We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

You should respond, in writing, within fifteen (15) working days from receipt of this letter. Your response should outline specific actions you are taking to correct these violations. You should include documentation that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, you should explain the reason for your delay and state when you will correct any remaining violations.

Please send your reply to Derek C. Price, Compliance Officer, Food and Drug Administration, 60 Eighth Street, NE., Atlanta, GA 30309. If you have any questions about the content of this letter, please contact Mr. Price at 404-253-2277.

Sincerely yours,
/S/

LaTonya M. Mitchell
Acting District Director
Atlanta District Office

cc: Michael A. Jones, Plant Director
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cc: Daryl Riley, Vice President Global Quality
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