

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER 1201 Harbor Bay Parkway Alameda, CA 94502-7070 (510) 337-6700 Fax: (510) 337-6702		DATE(S) OF INSPECTION 1/27/2026-2/20/2026* FEI NUMBER 2939502	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Matthias (NMI) Heil, Factory Manager			
FIRM NAME Dreyer's Grand Ice Cream, Inc.		STREET ADDRESS 7301 District Blvd	
CITY, STATE, ZIP CODE, COUNTRY Bakersfield, CA 93313-2042		TYPE ESTABLISHMENT INSPECTED Manufacturer	
This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.			
DURING AN INSPECTION OF YOUR FIRM WE OBSERVED: OBSERVATION 1 You did not implement your sanitation monitoring and corrective action procedures. Specifically, Your firm manufactures frozen ready-to-eat (RTE) ice cream, dairy and nondairy desserts (eg. ice cream cones, sandwiches, bars, and fruit bars). Your hazard analysis for "Round Top Drumsticks, (b) (4) (b) (4) dated 11/22/25 identified the hazards: "Pathogen Contamination: Listeria" and "Pathogen Contamination: Salmonella" from the (b) (4) steps to the (b) (4) steps where RTE products are exposed to the environment and are handled by your employees. Recontamination with environmental pathogens is a foreseeable hazard at these steps requiring sanitation preventive controls. Your written sanitation procedures (eg. Pathogen Monitoring Program Procedure, Pathogen Monitoring Adaptation, Bakersfield Sanitation Procedure, line specific sanitation procedures, and Production Listeria Treatment Form (also called Listeria clean)) were not implemented to control <i>Listeria</i> contamination because your environmental monitoring records continue to show confirmed positive for <i>L. monocytogenes</i> in zones (b) (4) and (b) (4) throughout the production and auxiliary areas as summarized in the table below. Zone (b) (4) may be 1.5 feet away from exposed products (eg. (b) (4) (b) (4) cart) and Zone (b) (4) may be 6-7 feet away from exposed products.			
SEE REVERSE OF THIS PAGE		EMPLOYEE(S) SIGNATURE Muoi N Hoang, Investigator Tomanik'E C Howard, Investigator Jane G Choi, Investigator Theresa T Zhao, Microbiologist	
		Muoi N Hoang Investigator Signed By: 2004126894 Date Signed: 02-20-2026 00:03:33 X _____	DATE ISSUED 2/20/2026

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Year	Total environmental swabs taken	Total confirmed (+) for <i>Listeria</i> spp.	Total confirmed (+) for <i>L. monocytogenes</i>
1/1/26 – 2/5/26	(b) (4)		
2025			
2024			
2023			
2022			
2021			

You did not implement your Corrective Action procedure indicated in your "Pathogen Monitoring Program Procedure" which states "If an area is having repeat positives, a team must be formed to investigate the issue. The team will consist of (b) (4) (b) (4). (b) (4) should be used in the investigation. Root cause and corrective actions will be documented using (b) (4)." You did not implement corrective actions in (b) (4) or your "Corrective and Preventative Action" procedure. Your corrective action is to (b) (4) for presumptive or confirmed positive for *Listeria* spp. or *L. monocytogenes*.

You did not implement your employee monitoring procedure regarding employee practices as evident by your written sanitation preventive control called "Zoning and Good Manufacturing Practices Procedure". It explained the procedures for Hand Washing Guidelines and use of Gloves. "When working in a product contact or open product environment hands must be wash and/or sanitized after touching anything unsanitary (b) (4)" "(b) (4)

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handling contaminated material, such as (b) (4)
(b) (4). "Employees to wear disposable (b) (4) gloves when (b) (4)
(b) (4)
(b) (4). "Gloves must be changed after touching the (b) (4)
(b) (4)."
"Gloves must be (b) (4)
(b) (4). Frequent replacement
of (b) (4) gloves is recommended." " (b) (4) reusable gloves are not permitted for direct
product handling but may be (b) (4)."
• On 1/28/26 during the manufacturing of Nestle Toll House Minis Chocolate Chip Vanilla Sandwich
12ct with manufacturing code (b) (4) on Line [®], I observed
employee 1, who was wearing (b) (4) reusable (b) (4) gloves, touching nonfood contact surfaces
(eg, opening and breaking down boxes of cookies and touching the trash bin liners as he was
discarding trash) and then touching food contact surfaces (eg, inside the (b) (4) liner containing the
cookies in the box) and food (eg, cookies for the sandwich) and handed the food (eg, cookies for the
sandwich) to employee 2 who was placing the cookies on the line. Employee 1 repeated the process of
touching nonfood contact surfaces and then food contact surfaces and food wearing the same (b) (4)
(b) (4) reusable (b) (4) gloves and did not wash and sanitize his hands or change to disposable (b) (4)
gloves.
• On 1/28/26 during the manufacturing of Nestle Vanilla Sandwich 24ct with manufacturing code (b) (4)
(b) (4) on Line [®], I observed your employee with (b) (4) disposable
(b) (4) gloves touching nonfood contact surfaces (eg, cardboard boxes of (b) (4) while opening and
breaking down, wiping his hands on his uniform from removing jammed (b) (4) on the line, inside
lined trash bins as he was discarding the sleeves), then food contact surfaces (eg. clear plastic sleeves
holding the (b) (4) when he was opening the sleeves), and then food (eg. (b) (4) when he was

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aligning the (b) (4) on the feeder) and repeating the whole process again without changing his gloves or washing and sanitizing his hands.

- On 2/11/26 during the manufacturing of Outshine Mini Fruit Pops Cherry, Tangerine, Grape 12ct with manufacturing code (b) (4) on Line (b) (4), I observed your employee's ungloved hands touching multiple nonfood contact surfaces (eg. cardboard boxes, stair railings, inside the lined garbage bin to move the bin, trash on the floor, and the bottom of the (b) (4) wet waste bin that is used as a stool to position it in place for sitting while changing the film roll) and then touching food contact packaging when he changed the packaging film roll and repeating the process during subsequent film roll changes without washing his hands, sanitizing his hands, or wearing gloves. The food packaging film roll was used to individually wrap and seal the frozen fruit pop.
- On 2/13/26 during the manufacturing of Nestle Variety Pack, Vanilla Fudge, Vanilla Caramel, and Vanilla 16ct containing chopped peanuts with manufacturing code (b) (4) (b) (4) on Line (b) (4), I observed your employee's gloved hands touching nonfood contact surfaces (eg. inside the trash liner as he was disposing the empty peanut packaging, handle on the (b) (4) cart that was also touched by a different employee's gloved hands, bottom of the (b) (4) bins with apparent brown residues, handle on the hopper lid) and then touching food contact surfaces (eg. inside the peanut packaging bag, inside the (b) (4) bins containing the peanut) and food (eg. (b) (4) peanuts as he was leveling the peanuts on the hopper before closing the lid) and repeating this process of filling the hopper with (b) (4) peanuts from the bag or the bin without changing his gloves or washing and sanitizing his hands.

Additionally, you stated that (b) (4) were used to control pathogen contamination into production area, but they were not adequate to control *Listeria* contamination because your environmental monitoring records continue to show confirmed positive for *L. monocytogenes* in zones (b) (4) and (b) (4). Your

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“Hygienic Zoning (b) (4) Sanitizer Map” shows locations for (b) (4) and (b) (4) sanitizers. However, I did not observe any (b) (4) sanitizers being used (b) (4) or per the map. Your “Bakersfield Sanitation Procedure” states that “(b) (4), were (b) (4), and will be tested (b) (4) for the correct concentration”. There is no written procedure for its use or records to document the testing.

(b) (4) are not an adequate sanitation control because they are not (b) (4) are not (b) (4) as

evident by:

- On 1/27/26, 2/5/26, 2/10/26, and 2/12/26 the (b) (4) in the (b) (4) area was placed on the (b) (4) (b) (4) and not (b) (4). Employees and pallet jacks wheels were observed exiting the (b) (4) area and into production without (b) (4). The (b) (4) was observed to be (b) (4).
- There are no (b) (4) from the warehouse into the production area. On 2/10/26, employees were observed pushing wheeled carts and pulling pallet jacks entering the production area from the warehouse.
- On 2/10/26, the (b) (4) in the (b) (4) rooms (b) (4) were placed next to the (b) (4) (b) (4). Your employees were observed not (b) (4) prior to entering production area. Additionally, there was a large black plastic sheet partially covering the (b) (4) next to the (b) (4) in (b) (4).

OBSERVATION 2

Your written sanitation preventive control procedures were not appropriate to significantly minimize or prevent the hazard requiring a preventive control.

Specifically,

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***DATES OF INSPECTION**

EMPLOYEE(S) SIGNATURE

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Investigator
Signed By: 2004126894
Date Signed: 02-20-2026
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FORM FDA 483 (09/08)

PREVIOUS EDITION OBSOLETE

INSPECTIONAL OBSERVATIONS

PAGE 6 of 6 PAGES

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) 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. A copy of such report shall be sent promptly to the Secretary."