DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768	7/19/2022-9/1/2022*
	FEI NUMBER 3004654033

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
David S. Peachey, Co-Owner and President

FIRM NAME	STREET ADDRESS
Big Olaf Creamery LLC dba Big Olaf	2001 Cattlemen Rd Unit 123
CITY, STATE, ZIP CODE, COUNTRY Sarasota, FL 34232-6247	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 have a written food safety plan.

Specifically,

You have not developed a Food Safety Plan as a manufacturer of over 94 RTE ice cream products with common post pasteurized ingredients (which includes the allergen of milk) and unique product specific inclusions (the allergen of tree nuts, peanuts, milk) all of which have been implicated in an outbreak of *L. monocytogenes* confirmed through laboratory testing. These analytical findings resulted in a recall and destruction of every ice cream flavor you manufactured.

You have not developed a written hazard analysis for any of your manufactured products to address the potential hazards present in your operations; including contamination with environmental pathogens throughout and postproduction, allergen cross contact, and undeclared allergens, to determine if any require a preventive control during the processing steps of mixing, addition of flavors and inclusions, packaging and labeling of RTE ice cream product.

Additionally, you do not have a trained Preventive Control Qualified Individual (PCQI) for preventive control oversight in your RTE ice cream manufacturing process.

<u>Environmental Pathogens</u>

You did not identify and establish controls related to the hazard of recontamination with

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	David P King, Investigator Megan K Otero, Investigator Tracy L Reed, Investigator Carol S Davis, Investigator X David P King Investigator Signed By 1300179742 Date Signed 09-01-2022 15 13 41	9/1/2022

environmental pathogens at your facility. This lack of control was evidenced by recontamination with environmental pathogens during environmental testing on 7/14/22 when (b) (4) sample sites tested positive for *L. monocytogenes* including the (b) (4) and the (b) (4). These samples were collected by a third-party lab contracted by you who collected the samples on 7/14/22. Subsequent environmental testing on 8/10/22 by the same third-party laboratory found at least 25 positive results for *L. monocytogenes* in the processing room, processing equipment, and warehouse area. The processing equipment which tested positive (b) (4), which included the ice cream mix (b) (4) and immediate surrounding area and (b) (4) (b) (4). This equipment was confirmed positive for *L. monocytogenes* on 7/26/22 and 8/4/22 by your contract laboratory and was used to manufacture all RTE ice cream products, including but not limited to Cookies and Cream, Kahlua Krunch and Plantation Praline ice cream flavors.

You have not established an environmental sampling program at your facility for verifying the adequacy of cleaning and sanitation processes for the control of environmental pathogens.

Allergen Control

You do not have controls in place for monitoring allergen cross-contact when processing RTE ice cream products with multiple allergens on shared equipment. These allergens are not limited to tree-nuts, peanuts, and milk.

Furthermore, you have not established written procedures for sequencing products with unique allergens in a formulation and any procedures related to equipment sanitation during product changeovers.

Additionally, there are no written procedures to establish labeling accuracy when handling RTE ice cream containing ingredients such as tree nuts and peanuts as a verification step in your process.

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Supply chain program

You did not establish an appropriate supplier verification procedure to ensure that environmental pathogens such as *Salmonella spp.* and mycotoxins for inclusions and other hazards, are controlled by you suppliers. Furthermore, you do not require any documentation such as a supplier COA to demonstrate control of potential hazards were controlled. However, during the inspection we observed a record accompanying incoming documentation of ingredients, from an ingredient supplier which was a COA, and you stated that you were not aware of what this document referenced.

During the inspection and while these observations were discussed with you. You provided a draft SOP to address the operational procedures requiring food safety preventive controls. However, these procedures have not been adequately developed to demonstrate control of the potential food safety hazards associated with your manufacturing operations. Such procedures not addressed; temperature monitoring at receiving, holding, processing, and storage steps, sanitation activities, as well as corrective action when deviations from the established critical limits are observed.

OBSERVATION 2

You did not ensure individuals were qualified to perform their assigned duties and have records documenting food hygiene and food safety training.

Specifically,

During the inspection, although it was noted that you were not in production, it was observed that there was no handwash sink outside of the production area for employees to wash and sanitize hands before entering the production room. You stated that employees are not required to change their shoes worn from outside production room areas (such as the rest room) into the production room, there was no sanitizing footbath provided, or dedicated employee changing area.

Additionally, there are no records showing employee practices and overall sanitation conditions are

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monitored at appropriate intervals during production or that employees demonstrated knowledge of food safety, personal hygiene, and sanitation as evidenced by the lack of employee training.

***DATES OF INSPECTION**

7/19/2022(Tue), 7/20/2022(Wed), 7/21/2022(Thu), 7/22/2022(Fri), 7/26/2022(Tue), 8/02/2022(Tue), 8/03/2022(Wed), 8/04/2022(Thu), 8/05/2022(Fri), 8/08/2022(Mon), 8/15/2022(Mon), 8/26/2022(Fri), 8/30/2022(Tue), 9/01/2022(Thu)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	David P King, Investigator Megan K Otero, Investigator Tracy L Reed, Investigator Carol S Davis, Investigator	X David P King Investigator Signed By 1300179742 Date Signed 09-01-2022 15:13:41	9/1/2022

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."