DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Drive, Suite 205 Lenexa, KS 66214 (913)495-5100 Fax:(913)495-5115	5/16/2022-6/30/2022* FEI NUMBER 1921383

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Julie L Fry, Quality Manager

FIRM NAME	STREET ADDRESS
Dairy Farmers of America	211 N Central Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Allerton, IA 50008	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

Your written sanitation preventive control, monitoring, corrective action and verification procedures were not appropriate to significantly minimize or prevent the hazard requiring a preventive control.

Specifically,

1. On or about April 7, 2022 your firm manufactured approximately (b) (4) bags of (b) (4) (b) (4) with each bag weighing (b) (4) Your firm shipped a composite sample of the finished product (b) (4) (b) (4).

   Although your firm cleaned the wet processing equipment associated with the manufacture of infant formula ingredient (b) (4) your firm did not clean nor sanitize (b) (4) dryer (b) (4) which was used to dry the infant formula, nor did your firm clean and sanitize the product packaging room and associated equipment. Your firm did not investigate the (b) (4) dryer or packaging environment by conducting environmental monitoring (b) (4)

   Management personnel provided investigators with the (b) (4) dryer internal crack inspection and repair report for (b) (4) dryer (b) (4) which indicated the baghouse and chamber equipment had internal, micro-cracks, which were repaired. Your management personnel informed investigators these internal micro-cracks can cause niche environments for pathogenic microorganisms such as *Cronobacter* to grow and proliferate.

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EMPLOYEE(S) SIGNATURE
Michael A Feingold, Investigator
Elizabeth P Mayer, National Expert
Heath W Cartwright, Investigator
Melissa N Simanton, Investigator
Joselin P Baray-Alvarado, Investigator
Tristian E Strait, Investigator
Shaun M Stracener, Investigator
Avery J Dennis, Investigator

X Michael A Feingold Investigator Signed By: Michael Feingold -S Date Signed: 06-30-2022 12:00:48

DATE ISSUED
6/30/2022

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Your firm's internal environmental monitoring program identified and located *Cronobacter spp* in the environment around (b) (4) dryer (b) (4) dryer (b) (4) packaging tower, warehouses, walkways, and numerous locations in which roof rainwater leaked in dry production and storage areas. **Environmental monitoring conducted by FDA Investigators confirmed *Cronobacter sakazakii* in the environment around** (b) (4) **dryer** (b) (4) **and on** (b) (4) **dryer** (b) (4)

When questioned why your firm did not clean and sanitize spray dryer (b) (4) and the (b) (4) room after having positive product, positive environmental monitoring results in other areas of your facility, acknowledging equipment micro-cracks that provide niche growth areas for pathogenic microorganisms, and numerous roof leaks that intruded into processing areas, your firm management and corporate management personnel stated it takes approximately (b) (4) (b) (4) to fully clean and sanitize (b) (4) dryer (b) (4) and it is not firm policy to clean the (b) (4) dryer in these events.

From April 7, 2022 to May 16, 2022, your firm manufactured approximately (b) (4) dried infant formula and food products on (b) (4) dryer (b) (4) totaling (b) (4) without cleaning and sanitizing the equipment after finding *Cronobacter spp* in finished product. These products were shipped from DairiConcepts in Allerton, IA to (b) (4) (b) (4)

2. Review of the Manufacturing Batch Records and circular temperature charts for (b) (4) (b) (4) dated 4/7/22 indicated that for batches (b) (4) the recording chart temperature was higher than the indicating thermometer, which is the calibrated "official" thermometer. Your firm's CCP states that your products need to be held (b) (4). Your firm management stated the PCQI or operator does not measure the (b) (4) requirement with calipers or an equivalent measurement device.

Your firm's PCQI reviewed, verified, and signed off on records without conducting or documenting corrective actions.

OBSERVATION 2

A person who conducted an audit relating to quality control procedures was directly responsible for matters that the person was auditing.

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Specifically,

Your firm conducts quality audits (b) (4) These audits are performed by your firm's Quality Manager who has direct interest in the outcome of the audit.

In addition, your written quality audit procedure, "PRO-8-1-003 Batch Record Audit, effective date 6/10/22" does not thoroughly detail the methods, which are utilized to determine if your facility is operating in accordance with quality control procedures, which ensure that infant formula base powders are not adulterated.

OBSERVATION 3
An instrument you used to measure, regulate, or control a processing parameter was not properly maintained.

Your firm manufactures the infant formula base (b) (4) . A Manufacturing Batch Record is maintained for this base powder, which identifies the required ingredient weights at each process step to ensure that the final product formulation is achieved. However, the following measuring devices are not calibrated, which are used to verify that ingredient weights are accurate:

- The flow meter located on the product line between the (b) (4) silo and the (b) (4) tank.
- The (b) (4) located on the (b) (4) tank.
- The flow meter located on the product line between the (b) (4) tank and the liquefier.
- The flow meter located on the product line between the (b) (4) silo and the liquefier.

OBSERVATION 4
You did not maintain a building used in the manufacture, processing, packing or holding of infant formula in a clean and sanitary condition.

Specifically,

On 06/14/2022, on level (b) (4) of (b) (4) dyer (b) (4) standing water was observed in the following locations: under and

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adjacent to the (b) (4) air handling unit; under the dehumidifier of the (b) (4) air handling unit, and under the CIP system.

***DATES OF INSPECTION**

5/16/2022(Mon), 5/17/2022(Tue), 5/18/2022(Wed), 5/19/2022(Thu), 5/20/2022(Fri), 5/23/2022(Mon), 6/02/2022(Thu), 6/13/2022(Mon), 6/14/2022(Tue), 6/30/2022(Thu)

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Investigator
Signed By: Michael Feingold -S
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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."