DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax:(313)393-8139	10/18/2023-11/27/2023* FEI NUMBER 1814412

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Robert L. West, Animal Nutrition Manager

FIRM NAME	STREET ADDRESS
Caledonia Farmers Elevator Company	146 E Main St SE
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Caledonia, MI 49316-9488	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 I OBSERVED:

OBSERVATION 1

You did not have a written food safety plan.

Specifically,

you do not have a written food safety plan which includes at a minimum a written hazard analysis identifying and evaluating any known or reasonably foreseeable hazards associated with your ingredients, manufacturing processes, and animal foods of which you manufacture, process, pack, or hold.

OBSERVATION 2

You did not evaluate the raw materials susceptible to contamination with mycotoxins or other natural toxins in a manner that does not result in animal food that can cause injury or illness to animals or humans.

Specifically,

- ☐ You do not routinely test for Fumonisin, Aflatoxin, or Trichothecene "T2" mycotoxins commonly found in corn.
- ☐ Your bulk raw ingredient collection methods do not produce a statistically representative sample of the entire load.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Christi L Bellmore, Investigator	X Christi L Bellmore Investigator Signed By: Christi Bellmore -S Date Signed: 11-27-2023 07:25:17	11/27/2023

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Robert L. West, Animal Nutrition Manager	
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☐You are not following established testing procedures when preparing the sample for analysis.

☐According to the mycotoxin test results you provided from October 17, 2023 to the present, you have collected (b)(4) (b) (4) corn samples and (b) (b) (4) ground corn samples.

-23 of the (b)(4) Vomitoxin results for incoming corn exceeded your written established threshold values.
-Only (b) (4) corn sample and (b) (4) ground corn sample was evaluated for mycotoxins other than Vomitoxin, and one of those (b)(4) loads exceeded your written T2 and Aflatoxin threshold values.
-One of the (b) (4) corn samples on 11/20/23 exceeded your verbal action level for Vomitoxin of (b)(4) ppb.

You stated that you (b) (4), so your corrective action has been to continue to test the farms that exceed your threshold values and (b) (4) s. You did not reject any of the loads.

OBSERVATION 3

You did not take adequate precautions to prevent contamination of animal food and conduct all animal food manufacturing under such conditions and controls to protect against contamination of animal food.

Specifically,

you do not have written procedures to address metal and foreign objects in your facility. There are

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multiple areas in the facility where metal-on-metal contact could cause metal to sheer off into the feed. Magnets were not present anywhere in the Textured Feed/Calf Plant. Additionally, the Magnet Cleaning Log detailed in your Housekeeping Plan is not being completed for the magnets and screeners located in the main mill.

In addition, you do not have current good manufacturing practices in place that ensure that the nutrients you use in manufacturing do not contribute to unsafe toxicities or deficiencies in the animal food. For example, you routinely manufacture mixes containing (b) (4), and (b) (4). You stated that (b) (4) finished feed samples from the main plant and (b) (4) (b) (4) samples from the calf plant are sent to (b) (4) in (b) (4) approximately (b) (4) to be tested for (b) (4), and(b) (4). You said the acceptable ranges for these values were determined by values in generic ingredients. Of the (b) (4) feeds tested for calcium, phosphorous, magnesium, and potassium between March 2020 and August 2022, (b) (4) customer-specific cattle feeds and (b) (4) in-house heifer feeds were out of the acceptable range for (b) (4), and (b) (4) heifer feeds did not meet the minimum value for (b) (4).

***DATES OF INSPECTION**
10/18/2023(Wed), 11/13/2023(Mon), 11/14/2023(Tue), 11/16/2023(Thu), 11/20/2023(Mon), 11/27/2023(Mon)

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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."