U.S. Food and Drug Administration
Office of Human and Animal
Food- West Division II
8050 Marshall Drive - Suite 205
Lenexa, Kansas 66214-1524
913-495-5100

June 11, 2019

Via United Parcel Service
Signature Required

CMS # 573058

Bradly S. Dalke, Director of North American Feed Business
ADM Animal Nutrition, a division of Archer Daniels Midland Company
1000 N. 30th St.
Quincy, IL 62305

Darin W. Sigler, Plant Manager
2174 E. 59th Ave.
Columbus, NE 68601

Dear Messrs. Dalke and Sigler,

The U.S. Food and Drug Administration (FDA) concluded our most recent inspection of your licensed medicated feed mill located at 2174 East 59th Avenue, Columbus, Nebraska on November 28, 2018. This inspection was conducted as a follow-up to a Reportable Food Report (RFR) filed by your company on November 13, 2018 for the deaths of forty-four (44) calves after consumption of feed manufactured by your firm.

During this inspection FDA documented a significant violation of the Current Good Manufacturing Practice (CGMP) Requirements for Medicated Feeds, Title 21, Code of Federal Regulations (CFR), part 225, as well as a violation of the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals regulation, 21 CFR part 507. These violations cause your non-medicated and medicated animal food to be adulterated under the Federal Food, Drug, and

Cosmetic Act (FD&C Act).[1] You may find the FD&C Act and FDA's regulations through links on the FDA's website at www.fda.gov.

At the close of the inspection, you were issued an FDA Form 483, Inspectional Observations. We received your written responses dated December 14, 2018, January 29, 2019, and March 15, 2019. We have reviewed your responses and we discuss your significant violations and your corrective actions below.

The animal food consumed by the deceased calves was your product AG West Start 6 DC G3757AZY Medicated (lot # NE29818), intended to contain the new animal drug decoquinate, but instead found to be contaminated with high levels of the new animal drug monensin, as follows: Your customer's veterinarian necropsied the animals and found indications of ionophore intoxication. You and your customer each submitted samples from this lot of animal food to different veterinary diagnostic or private laboratories for testing and found monensin at levels of 953-1520 g/ton in a product not intended to contain monensin. Ultimately, after your investigation into this event, you found three additional, similar customer complaints that resulted from the deaths of calves belonging to three other customers and you filed three additional RFRs on November 19 and 26, 2018, and January 22, 2019.

Current Good Manufacturing Practice for Medicated Feeds Violation

Your firm failed to properly install and operate equipment to ensure that feeds produced were of uniform quality, as required by 21 CFR 225.30(a).

Specifically, during your investigation of the root cause of the first reportable food event described above, you determined the presence of monensin was due to a problem with the (b) (4) conveyor delivering ingredients from the microingredient system to the mixer.

Your firm began operating new manufacturing equipment, specifically a new automated system that included a mixer and a (b) (4) microingredient system, in August 2018. The equipment appears to have worked properly until about September 20, 2018. On or about September 21, 2018, the (b) (4) conveyor line that delivered ingredients from the micro-bin into the mixer was started (b) (4) , which (b) (4) (b) (4) . No problems were noted at the time, and manufacturing operations continued until the reportable food event described above was discovered and investigated on November 12, 2018. During that period of time (b) (4) batches of animal food were produced (b) (4) of them intended to be non-medicated and (b) (4) intended to be medicated.

Your investigation found that (b) (4) had been installed on the (b) (4) conveyor between the microingredient system and the mixer, instead of (b) (4)

[1]Violation of the CGMP requirements in 21 CFR part 225 results in non-medicated animal food being adulterated under section 402(a)(2)(C)(ii) of the Act [21 U.S.C. § 342(a)(2)(C)(ii)] and medicated feed being adulterated under section 501(a)(2)(B) of the Act [21 U.S.C. § 351(a)(2)(B)]. Violation of the requirements in 21 CFR part 507 results in animal food being adulterated under section 402(a)(4) of the FD&C Act [21 U.S.C. § 342(a)(4)].

(b) (4) Further, when started (b) (4) this (b) (4) conveyor was found to operate at 23% of the intended speed, such that animal drugs (and other microingredients delivered to the mixer by this (b) (4) conveyor) were not being delivered accurately to each batch of feed. In summary, none of the (b) (4) batches of food manufactured during this time could be guaranteed to contain the correct drug, the right amount of the drug, or the right amount of any other microingredient intended to be included in a given batch. As a result, the medicated feeds produced during the time this faulty equipment was in place are considered adulterated because they were not manufactured in accordance with the applicable CGMP requirements in 21 CFR part 225.[2]

We acknowledge your written responses dated December 14, 2018, January 29, 2019, and March 15, 2019 which explain how you have addressed the equipment failure that was identified as a root cause of the contamination events. You recalled all (b) (4) batches of food manufactured during this period and took steps to correct the equipment failure and to prevent the failure from occurring again. In addition, you committed to providing more oversight of equipment vendors to prevent similar situations from happening in the future. We acknowledge in your March 15, 2019 response you discussed the implementation of a new procedure for the operation of your conveyor system and provided your new procedure for monitoring the microbin system to perform testing periodically and when changes to the microbin system are implemented. It is important the system you put in place can ensure the microbin system is accurately delivering micro ingredients to every batch being manufactured in your facility. The adequacy of this procedure and its implementation will be assessed during a future inspection at your firm.

Current Good Manufacturing Practice for Animal Food Violation

Your firm failed to design, construct, and maintain holding, conveying, manufacturing, and processing systems in a way to protect against the contamination of animal food, as required by 21 CFR 507.22(b).

Specifically, your automated microingredient (b) (4) conveyer system did not protect against the contamination of animal food from animal food ingredients that when included at improper levels could contaminate the animal food and result in drug or nutrient toxicity. As described above, the (b) (4) conveyer system was operating at 23% instead of 100%, so that incorrect volumes of microingredients were added to your animal food for approximately seven weeks. As a result, all the animal food produced during the time this system was operating incorrectly is adulterated because it was not manufactured in accordance with the applicable requirements in 21 CFR part 507.[3]

We acknowledge your written responses dated December 14, 2018, January 29, 2019, and March 15, 2019 which explain how you have addressed the equipment failure that was identified as a root cause of the contamination events. However, as noted

[2] See section 402(a)(2)(C)(ii) of the Act [21 U.S.C. 342(a)(2)(C)(ii)], section 501(a)(2)(B) of the Act [21 U.S.C. § 351(a)(2)(B)] and 21 CFR 225.1(b)(1).

[3] See section 402(a)(4) of the Act [21 U.S.C. § 342(a)4)] and 21 CFR 507.1(a)(ii).

previously your proposed corrective actions will be assessed during a future inspection to ensure that you can detect this issue if it were to reoccur.

Conclusion

The violations cited in this letter are not intended to be an all-inclusive statement of violations that exist at your facility. You are responsible preventing the recurrence of these violations and for preventing the occurrence of other violations. It is your responsibility to ensure that your firm complies with all requirements of federal law and FDA regulations.

Comments

In addition to the above violations, we have the following comments:

Hazard Analysis and Preventive Controls for Animal Food Requirements

1. Your firm's hazard analysis did not determine that drug carryover is a hazard requiring a preventive control. While we recognize that a facility may determine that the chemical hazards of drug carryover and nutrient toxicities and deficiencies are not a hazard requiring a preventive control due to the use of practices such pre-requisite programs, such a determination requires prerequisite programs that are able to sufficiently reduce the probability the hazard would occur in the absence of a preventive control. (See 21 CFR 507.33(c).) As your experience has shown, daily drug and microingredient inventory reconciliation is not necessarily adequate to ensure that the proper amount of a given new animal drug or microingredient was added to each specific batch of animal food produced throughout the day.

2. When an unanticipated food safety event occurs, a facility is required to conduct a corrective action as outlined in 21 CFR 507.42 and reanalyze its Food Safety Plan under 21 CFR 507.50. In your December 14, 2018 written response, you committed to reassessing and revising your Food Safety Plan in response to this incident. We acknowledge in your March 15, 2019 response you reported you have completed the reanalysis of your food safety plan. The adequacy of your Food Safety Plan will be assessed during a future inspection at your firm.

3. For more information on FDA's current thinking regarding 21 CFR part 507, Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals, please refer to the following documents:

- Draft Guidance for Industry #245, Hazard Analysis and Risk-Based Preventive Controls for Food for Animals at: https://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM592870.pdf.
- Guidance for Industry #235, Current Good Manufacturing Practice Requirements for Food for Animals, at:

https://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM499200.pdf.

Consumer Complaint Investigation

4. From September 21, 2018 to November 8, 2018, you received eleven complaints on eight different batches of feed manufactured at your Columbus, NE facility for "lack of consumption". Lack of consumption (or other unexpected consumption pattern) of food by animals can indicate that there may be a quality or a food safety issue with the animal food, which may further result in animals not receiving appropriate nutrition or medication, which may affect the animals' health. Notably, animal feed refusal is a known side effect of monensin toxicity and the labels for the Type A medicated article and the Type B and Type C medicated feeds containing monensin for use in cattle and goats are required to bear a caution statement alerting users to watch for feed refusal as a sign of potential overdosing. (See 21 CFR 558.355(d)(7), (9), and (10).) You may want to make your customer service team aware of this information, as well.

5. When your facility received complaints of food refusal, you could have performed an evaluation that included all relevant food safety hazards that may have been introduced into your animal food to ensure that your firm was not manufacturing and distributing adulterated animal food. Your complaint investigation was limited to sending retain samples for mycotoxin analysis only and reviewing your daily drug reconciliation, neither of which identified any problems. You also could have taken into consideration the potential for cross-contamination of drugs between lots of animal food as part of your complaint investigation to determine whether lack of consumption was due to a food safety issue, such as monensin toxicity. Had you performed a more thorough investigation into the initial complaints you received that considered a wider range of food safety hazards that could have occurred in the manufacture of the food, you may have identified the manufacturing and distribution of adulterated animal food earlier and been able to more promptly resolve the issue.

Response and Reinspection

Within thirty (30) working days of receipt of this letter, please notify this office in writing of the specific steps you have taken to correct violations. Include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. If you cannot complete corrective action within thirty (30) working days, state the reason for the delay and the time frame within which you will complete the correction. If you do not believe that your products are in violation of the FD&C Act, include your reasoning and any supporting information for our consideration.

Section 743 of the FD&C Act [21 U.S.C. 379j-31] authorizes FDA to assess and collect fees to cover FDA's costs for certain activities, including reinspection-related costs. A reinspection is one or more inspections conducted subsequent to an inspection that identified noncompliance materially related to a food safety requirement of the Act, specifically to determine whether compliance has been achieved. Reinspection-related

costs means all expenses, including administrative expenses incurred in connection with FDA's arranging, conducting, and evaluating the results of the reinspection and assessing and collecting the reinspection fees [21 U.S.C. 379j-31(a)(2)(B)]. For a domestic facility, FDA will assess and collect fees for reinspection-related costs from the responsible party for the domestic facility. The inspection noted in this letter identified noncompliance materially related to a food safety requirement of the Act. Accordingly, FDA may assess fees to cover any reinspection-related costs.

Please send your written response to Victoria A. Wagoner, Compliance Officer, U.S. Food and Drug Administration, 8050 Marshall Dr., Suite 205, Lenexa, KS 66214. If you have any questions about this letter, please contact Ms. Wagoner at 913-495-5150.

Sincerely,

Warren J. Lopicka -S

Digitally signed by Warren J Lopicka S
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For: Cheryl A. Bigham
Program Division Director
Office of Human and Animal Foods
Division II West