U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS
CINCINNATI DISTRICT OFFICE (CIN-DO)

Cincinnati District Office
550 Main Street
Cincinnati, OH 45202
Telephone: (513) 322-0700

October 18, 2022

UNITED PARCEL SERVICE
Delivery Signature Requested

Mr. Gregory Brett Douchard, Owner
Brookhaven Milling Company
219 E. Congress Street
Brookhaven, Mississippi 39601-3001

Dear Mr. Douchard,

The U.S. Food and Drug Administration (FDA) conducted an inspection of your non-licensed medicated feed mill located at 219 E. Congress St., Brookhaven, MS, between March 8 and March 25, 2022. During this inspection, FDA documented evidence of violations of the requirements for animal feed containing a veterinary feed directive (VFD) drug, Title 21, *Code of Federal Regulations*, Part 558.6 (21 CFR 558.6). Failure of a facility to comply with the VFD requirements causes the resulting VFD feed to be unsafe within the meaning of the Federal Food, Drug, and Cosmetic Act (FD&C Act).[1] A drug is adulterated if it is an animal feed bearing or containing a new animal drug and the animal feed is unsafe.[2] Furthermore, certain VFD feeds manufactured at your facility are misbranded because their labeling fails to include the cautionary statement required by 21 CFR 558.6(a)(6).[3]

The inspection also revealed evidence of violations of the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals regulation, 21 CFR Part 507, which also causes your products to be adulterated.[4]

The doing of any act to a food after shipment of the food and/or its components in interstate commerce and while the food is held for sale (whether or not the first sale) that results in the food being adulterated or misbranded is prohibited.[5]

You may find the FD&C Act and FDA's regulations through links on the FDA's website at www.fda.gov.

[1] See section 512(a)(2) of the FD&C Act [21 U.S.C. §360b(a)(2)].
[2] See section 501(a)(6) of the FD&C Act [21 U.S.C. § 351(a)(6)]
[3] See section 504(b) of the FD&C Act [21 U.S.C. § 354(b)].
[4] See section 402(a)(4) of the FD&C Act [21 U.S.C. § 342(a)(4] and 21 CFR 507.1(a)(1)(ii).
[5] See section 301(k) of the FD&C Act [21 U.S.C. § 331(k)].

At the close of the inspection, you were issued a Form FDA 483, Inspectional Observations. We have not received a written response to the Form FDA 483 as of the date on this letter.

Veterinary Feed Directive (VFD) Requirements

As a VFD manufacturer and distributor, your facility is subject to the VFD requirements found in 21 CFR 558.6. During the inspection of your facility, FDA observed evidence of the following:

1. You manufactured and distributed VFD feeds – specifically, custom cattle feed containing Chlortetracycline/CTC made from VFDs that were missing information required by 21 CFR 558.6(b)(3) (see also 21 CFR 558.6(c)(1)). Specifically, the VFD orders dated (b) (4) (VFD feed distributed on (b) (4)) and (b) (4) (VFD feed distributed on (b) (4)) were missing the following elements:

    - The client's business or home address and telephone number.
    - The premises at which the animals specified in the VFD are located.
    - The expiration date of the VFD.
    - The approximate number of animals to be fed the VFD feed by the expiration date of the VFD.
    - The indication for which the VFD is issued.
    - The level of VFD drug in the feed and duration of use.
    - The withdrawal time, special instructions, and cautionary statements necessary for use of the drug in conformance with the approval.
    - The number of reorders (refills) authorized, if permitted by the drug approval, conditional approval, or index listing.
    - The statement: "Use of feed containing this veterinary feed directive (VFD) drug in a manner other than as directed on the labeling (extra label use), is not permitted".

    Furthermore, the VFD order dated (b) (4) was also missing the veterinarian's address and telephone number, the name of the VFD drug(s), and the species and production class of animals to be fed the VFD feed.

2. You failed to keep VFD feed manufacturing records for 1 year, as required by 21 CFR 558.6(c)(4).

    Specifically, you did not keep the manufacturing records for the VFD orders dated (b) (4) (VFD feed distributed on (b) (4)) and (b) (4) (VFD feed distributed on (b) (4)) for at least 1 year.[6]

[6] See also the Current Good Manufacturing Practice for Medicated Feeds regulation in 21 CFR 225.202, which requires you to keep these records for 1 year.

Current Good Manufacturing Practice (CGMP) Requirements

During the inspection of your facility, the FDA Investigator noted violations of the Current Good Manufacturing Practice requirements for animal food (21 CFR 507 subpart B), including the following:

> You failed to evaluate and use raw materials and other ingredients 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, as required by 21 CFR 507.25(b)(2).
>
> Grain and grain products which you use in the production of both medicated and non-medicated animal feed products are known to be susceptible to mycotoxin contamination. You do not receive any analysis of testing for the known or reasonably foreseeable hazards of deoxynivalenol (DON / Vomitoxin) and Fumonisins from your grain supplier. You also do not perform any testing of grain and grain by-product ingredients for Vomitoxin and Fumonisins upon receipt or at any point prior to using the grain and grain by-product ingredients in animal food.

Labeling Requirements

During the inspection, the FDA Investigator reviewed your animal food labeling and determined your products are misbranded under section 504(b) of the FD&C Act [21 U.S.C. § 354(b)].

> You do not have the following VFD cautionary statement, "Caution: Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian," printed or listed on any feed labeling that accompanies a VFD feed sold to your customers, which causes your products to be misbranded under section 504(b) of the FD&C Act [21 U.S.C. § 354(b)].[7] Specifically, the above-mentioned VFD feeds you distributed to your customers on (b) (4) and (b) (4) were manufactured and sold without the VFD cautionary statement written or displayed on the labeling.

Conclusion

This letter is not intended to be an all-inclusive statement of violations that may exist at your facility or in connection with your products. You are responsible for investigating and determining the causes of any violations and for preventing their recurrence or the occurrence of other violations. It is your responsibility to ensure your firm complies with all requirements of federal law and FDA regulations.

This letter notifies you of our findings and provides you an opportunity to address them. Within thirty (30) working days of receipt of this letter, please notify this office in writing of the specific steps that you have taken to correct any violation. 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 actions within thirty (30) working days, state the reason for the delay and the time frame within which you will complete the correction. If you believe that your products are not

[7] See 21 CFR 558.6(a)(6).

in violation of the FD&C Act, include your reasoning and any supporting information for our consideration.

Please send your firm's response to Shondra N. Gipson, Compliance Officer, at ORAHAFEAST5FirmResponses@fda.hhs.gov. Alternatively, you may mail your response to Shondra N. Gipson, 404 BNA Drive, Suite 500, Nashville, TN 37217. If you have any questions about this letter, please contact Shondra N. Gipson at 615-366-7867.

Sincerely,

Steven B. Barber
Director, Division V
Office of Human and Animal Foods Operations-East