U.S. FOOD & DRUG ADMINISTRATION

May 1, 2026

Mixlab WI LLC
Attention: Ms. Valerie Klippel
Pharmacist-In-Charge
407 West Silver Spring Drive
Milwaukee, WI 53217
(b) (6), (b) (7)(C)

Re: Case 729008

Dear Ms. Klippel:

The U.S. Food and Drug Administration (FDA) inspected your facility, Mixlab WI LLC, 407 West Silver Spring Drive, Milwaukee, WI 53217, from July 14 through July 24, 2025. During the inspection, the inspection team noted deficiencies in your practices for producing animal drugs and issued Form FDA 483. The inspection team also discussed the circumstances under which you produce animal drugs from bulk drug substances and distribute them, including copies of FDA-approved products. You responded to the inspection in writing on August 13, 2025, September 12, 2025, and September 19, 2025. We have reviewed your responses and discuss them in the relevant parts of this letter.

For the reasons set forth below, you produce and distribute adulterated and misbranded animal drugs in violation of sections 301(a) and 301(k) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

A. Unapproved New Animal Drugs

You compound drugs for animals from bulk drug substances (BDS). From April 1,2025 to June 30, 2025, you filled approximately (b) (4) prescriptions or orders for animal drugs. Most of your products are compounded using BDS.[1]

Animal drugs compounded from BDS are new animal drugs as defined in section 201(v) of the FD&C Act because they are not generally recognized as safe and effective by experts qualified by scientific training and experience to evaluate the safety and effectiveness of animal drugs. Under section 512 of the FD&C Act, to be legally distributed, a new animal drug requires an

[1] The FD&C Act permits the compounding of animal drugs made from FDA-approved animal or human drugs, provided the conditions for legal extralabel use described in the FD&C Act and FDA's extralabel use regulations are met. Sections 512(a)(4) and (5) of the FD&C Act [21 U.S.C. § 360b(a)(4) and (5)] and 21 CFR part 530. FDA's regulations on extralabel use do not permit compounding from BDS. 21 CFR 530.13(a).

approved new animal drug application, conditionally approved new animal drug application, or a listing on the Index of Legally Marketed Unapproved New Animal Drugs for Minor Species. Compounded drugs do not go through any of these pre-market review processes. Although compounded human drugs are, under certain circumstances, exempt from the human drug approval requirement in section 505 of the FD&C Act, no comparable exemption from section 512 exists for animal drugs. As a result, your compounded drugs are unsafe under section 512(a) of the FD&C Act and adulterated under section 501(a)(5) of the FD&C Act. Distribution of adulterated animal drugs violates the FD&C Act.

In addition, the drug products you compound from BDS are intended for conditions not amenable to diagnosis and treatment by individuals who are not veterinarians. Therefore, adequate directions for use cannot be written so that a lay person can use these products safely for their intended uses. Consequently, their labeling fails to bear adequate directions for their intended uses as required under section 502(f)(1) of the FD&C Act, and as they are not exempt from this requirement by any other statutory provision or regulation, they are misbranded. Distribution of misbranded animal drugs violates the FD&C Act.

Although compounded animal drugs lack required approval or index listing, FDA acknowledges there are some situations in which no FDA-approved or indexed drug can treat an animal, and a drug compounded from BDS may be medically appropriate. FDA's Guidance for Industry (GFI) #256, "Compounding Animal Drugs from Bulk Drug Substances" identifies the circumstances under which FDA does not intend to take enforcement action against drugs compounded from BDS. The guidance also generally describes our enforcement priorities with respect to compounded animal drugs. Our priorities for enforcement include animal drugs that are intended for use in food-producing animals; copies of marketed FDA-approved or indexed drugs; or drugs compounded without a patient-specific prescription (i.e., office stock).

Copies of Approved or Indexed Products

FDA considers an animal drug compounded from a bulk drug substance to be a copy of an FDA-approved or indexed product if it has the same active ingredient or active moiety and is given by the same route of administration ("ROA"). In addition, FDA considers a combination drug product to be a copy if any of its active ingredients are approved in the same ROA. Compounded copies of approved or indexed animal drugs are an FDA priority for enforcement because they may expose animals to drugs produced under lesser quality controls compared to the approved/indexed products and reduce incentives for firms to seek approval or indexing of their drugs.

The following examples are representative of your firm's practice of compounding copies of approved products:

Rx (b) (6) : Methimazole 5 mg/mL Oral Suspension (Anhydrous), 40 mL filled (b) (6)

- Your methimazole (oral ROA) is a copy of multiple FDA-approved drugs including 5 mg/mL oral suspension (ANADA 200-771), 2.5 or 5 mg oral tablets (NADA 141-292), and multiple oral dosage forms of methimazole FDA-approved for use in humans.

- Your records did not include the reasons why this prescription was compounded from BDS as opposed to using an FDA-approved product as the source of the active ingredient(s).

- Your records for the prescriber's medical rationale for this prescription reads "patient cannot safely be dosed with the approved dosage form". This does not describe why the approved drug is unacceptable or unsafe and how using the compounded medication is expected to achieve a clinical difference in the identified patient.

- Rx (b) (6) : Benazepril HCl 5 mg oral MICRO Tab filled (b) (6)
    - Your benazepril HCl (oral ROA) is a copy of multiple FDA-approved oral dosage forms of benazepril HCl approved for use in humans (e.g., ANDA 076267 or ANDA 076820, both of which are available in 5 mg tablets). Your records did not include the reason(s) why this prescription was compounded from BDS as opposed to using an FDA-approved product as the source of the active ingredient(s).

    - Your records for the prescriber's medical rationale for this prescription read "patient is unable to tolerate commercial medication – compound required". This rationale does not describe why the patient would tolerate the compounded tablet but not any of the multiple FDA-approved tablets available at the same strength (i.e., the prescription does not specify any changes compared to the approved product(s) and it does not explain how the compounded medication will achieve a clinical difference in the identified patient).

- Rx (b) (6) : Clomipramine HCl 25 mg MINImix Chew Treat filled (b) (6)

    - Your clomipramine HCl (Oral ROA) is a copy of multiple oral dosage forms of clomipramine which are FDA-approved for use in animals and are available in both 5mg or 20mg oral tablets (ANADA 200-635 and NADA 141-120). It is also a copy of multiple oral dosage forms that are FDA approved for use in humans (e.g., ANDA 211822).

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- Your record for the prescriber's medical rationale for this prescription is for medication availability and reads "medication is not readily available commercially." We do not consider a belief that a marketed drug is not available to constitute a *medical rationale* explaining the clinical difference between a compounded drug and an approved drug. Even if a drug is in shortage, FDA uses a variety of mechanisms to address shortages, but we do not generally consider compounding animal drugs without a valid medical rationale (i.e., one unrelated to availability) to be an acceptable means of mitigating a shortage.

When using a compounded drug that will make a clinical difference in the identified patient, it may be possible to legally compound by modifying an approved product (i.e., use an approved product as the source of active ingredients) rather than illegally compound by starting from BDS.[2] As described above, in addition to compounding copies of approved drugs, you did not have acceptable reasons for compounding them from BDS instead of using approved products as your source of active ingredients.

We acknowledge that, in response to our inspection, you committed to retrain prescription intake pharmacists to evaluate whether an FDA-approved product is available and clinically appropriate before compounding from BDS. This includes updating the prescription intake process to require justification from the prescriber when an FDA-approved drug cannot be used as the source of the active ingredient. However, these "Prescriber Documentation Controls" are not appropriate because your pharmacy should be determining why you cannot compound from FDA-approved drugs. Although the prescribing veterinarian can provide a medical rationale explaining the clinical difference a compounded prescription would make for the patient, it is not reasonable to expect a veterinarian to provide reasons why a drug needs to be compounded from BDS and why an approved drug cannot be used as the source of the active ingredients. Compounders select the source of active ingredients for their drugs and should provide their justification for selecting a BDS. You also committed to performing (b) (4) prescription intake audits ensure prescription rationale, documentation, and justification are consistent with GFI #256 and provided a log of these audits in your September 18 update. Additionally, you committed to do a comprehensive review of your currently offered formulations and update all master formulation templates to ensure a clear BDS justification is documented whenever bulk substances are used. We acknowledge these changes but are unable to fully evaluate their impact with the documents provided. (b) (5) .

B. Drug Quality Violations

Current Good Manufacturing Practice Violations

All animal drugs produced from bulk drug substances are subject to the FD&C Act's Current Good Manufacturing Practice (CGMP) requirement, section 501(a)(2)(B), and our inspection determined that you are not in compliance with that requirement.

We noted that your firm produces copies of FDA-approved products from bulk drug substances but does so without the same CGMP controls which ensure their quality. For

[2] *See* 21 CFR 530.13.

example, unlike FDA-approved products, you fail to test the strength/potency of each active ingredient of each batch[3] and do not use a validated production process to ensure each individual unit meets strength, quality, and purity requirements[4].

Your response indicated you intend to follow the United States Pharmacopeia (USP) requirements for compounded drugs, but these do not meet the applicable CGMP requirements for the issues cited above. As you have not adequately addressed our concerns in the section(s) above related to your inappropriate use of bulk drug substances in compounding, we do not consider these CGMP issues to be resolved. We acknowledge you made other corrections related to drug quality and (b) (5) .

C. Other Comments –

During our review, we noted multiple prescriptions filled April 14, 2025, to June 30, 2025, from the same prescriber at a county humane society for two different animals, which we suspect may be office stock use given the volumes prescribed, length of use, and lack of patient-specific dosing instructions despite specific owner names being listed for both patients (e.g., Rx (b) (6) for Metronidazole (as Benzoate) 50 mg/mL Oral Suspension (Aqueous), 250 mL filled (b) (6) for a cat). We recommend you ensure you consider the totality of the circumstances before compounding a purportedly patient specific prescription from BDS.

Conclusion

All of the animal drugs you produce from BDS violate the FD&C Act's requirements for approval/indexing, adequate directions for use, and CGMP.[5] We do not consider you a low priority for enforcement action as described in GFI #256. The specific drugs identified above are examples that represent general practices at your firm. This letter is not intended to be an all-inclusive statement of violations that may exist 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 that your firm complies with all the requirements of federal law, including FDA regulations.

Within thirty (30) working days of receipt of this letter, please notify this office in writing of the specific steps you have taken to address any 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 within which you will complete the correction. If you believe that your product is not in violation of the FD&C Act, include your reasoning and any supporting information for our consideration.

Please direct your response to CVMCompounding@fda.hhs.gov and include "Reference Case: 729008 in the subject line of your email. If you have questions regarding the contents of this letter, please contact CVMCompounding@fda.hhs.gov.

[3] *See* 21 CFR 211.165(a).

[4] *See* 21 CFR 211.100(a).

[5] Section 512 of the FD&C Act [21 U.S.C. § 360b], 502(f)(1) of the FD&C Act [21 U.S.C. § 352(f)(1), and section 501(a)(2)(B) of the FD&C Act [21 U.S.C. § 351(a)(2)(B)] (See also, 21 CFR parts 210 and 211.)

Sincerely,

DILLARD WOODY -S

Digitally signed by DILLARD WOODY -S
Date: 2026.05.01 07:23:06 -04'00'

Dillard Woody
Acting Division Director
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CC:
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