U.S. FOOD & DRUG ADMINISTRATION

5/05/2025

MixLab TX LLC
Attention: Vinh X. Dam, Pharm.D.
Chief Pharmacy Officer
953 Hilltop Dr Ste 100
Weatherford, TX 76086

Ref: Case 706939

Dear Dr. Dam:

The U.S. Food and Drug Administration (FDA) inspected your facility, Mixlab TX LLC, located at 953 Hilltop Dr Ste 100, Weatherford, TX 76086, from July 23, 2024, through August 2, 2024. 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 drugs for food-producing animals, copies of FDA-approved products, and office stock compounded without patient-specific prescriptions. You responded to the inspection in writing on August 23, 2024, and September 23, 2024.[1] We have reviewed your responses to the objectionable practices and conditions related to drug quality described on the Form FDA 483 and regarding the circumstances under which you intend to produce and distribute unapproved new animal drugs from bulk drug substances.

A. Unapproved New Animal Drugs

You compound drugs for animals from bulk drug substances (BDS). From April 23 to July 23, 2024, you filled approximately (b) (4) prescriptions or orders for animal drugs. Most of your products are compounded using BDS.[2]

Animal drugs compounded from BDS are new animal drugs as defined in section 201(v) of the Federal Food, Drug, and Cosmetic Act (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 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-

[1] We acknowledge additional communications with your firm between 9/23/2024-9/30/2024.
[2] 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.

U.S. Food and Drug Administration
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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. Distribution of animal drugs compounded from BDS without an approval or index listing 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 they are not exempt from this requirement by any other statutory provision or regulation.

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 compounded without a patient-specific prescription (i.e., office stock).

Drugs for Food-producing Animals

Use of drugs compounded from BDS to treat food-producing animals and free-ranging wildlife species risks exposing humans to harmful residues in the animals' edible tissues because these drugs have not been reviewed to determine human food safety. According to your product labels, compounding log, and prescriptions, you compound products for use in food-producing animals, for example:

- Rx (b) (6): MKB Kit (Sedation & Reversal) (Medetomidine/Ketamine/Butorphanol 10/50/25 mg/ml 10ml vial + Atipamezole 20mg/ml 30ml vial + Naltrexone 25mg/ml 10ml vial) for a herd of 120 cows at (b) (4)
- Rx (b) (6) MKB Kit (Sedation & Reversal) (Medetomidine/Ketamine/Butorphanol 10/50/25 mg/ml 10ml vial + Atipamezole 20mg/ml 30ml vial + Naltrexone 25mg/ml 10ml vial) a herd of 120 cows at (b) (4)
- Rx (b) (6) Tolazoline HCl injectable for office stock use in cows
- Rx (b) (6) Dexamethasone Sodium Phosphate injectable for a herd of 300 deer at (b) (4)

We acknowledge that your labels for these prescriptions state that they should not be used in food animals. However, your labels also advise the user to consult the veterinarian for any withdrawal times, suggesting that these could be used in food-producing animals. A withdrawal time is intended to ensure that food products from a treated food-producing animal are safe to enter the human food supply by establishing sufficient time from when the animal was last treated with the drug to when meat or other food (e.g., milk, eggs, etc.) are derived from the animal. We also acknowledge that documentation for prescriptions (b) (6) asserts that the cows are not food-producing. However, your records do not contain information regarding the cows' life circumstances or uses that support the conclusion that they are not food-producing. We also note that for Rx (b) (6) (b) (4) offers a

hunting package including meat processing. Additionally, we acknowledge that you stated that you have implemented a new software workflow that requires a veterinarian to check a box certifying that the animal is not food-producing. This workflow does not appear to capture information about the animals' life circumstances or uses that would support the conclusion that they are not food-producing.

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 is 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. You compound copies of approved products, for example:

- Rx (b) (6): Detomidine HCl 20 mg/mL injectable for a horse
  - Your detomidine (injectable ROA) is a copy of detomidine 10 mg/mL injectable solutions FDA-approved for use in horses (b) (4). Your records state that "Patient will be administered this medication, as the needed concentration is not available commercially", but do not describe how the compounded medication will achieve a clinical difference in the patient (i.e., they do not explain why the 20 mg/mL concentration is needed and why the horse cannot be administered twice as much of the FDA-approved 10 mg/mL solution).
- Rx (b) (6) Detomidine HCl/Xylazine HCl 2.5/100 mg/mL injectable for a horse
  - Your detomidine/xylazine (injectable ROA) is a copy of multiple FDA-approved drugs including detomidine HCl 10 mg/mL injectable (b) (4) and xylazine 100 mg/mL injectable (b) (4) Your records state "Combo not available commercially", but do not describe how the compounded medication will achieve a clinical difference in the patient (i.e., they do not explain why the horse requires an injectable containing both active ingredients and why the two FDA-approved injectables cannot be used).
- Rx (b) (6): Omeprazole/Sucralfate 220/100 mg/mL oral paste for a horse
  - Your omeprazole/sucralfate (oral ROA) is a copy of multiple FDA-approved drugs including omeprazole oral pastes FDA-approved for use in horses (b) (4) and oral dosage forms of omeprazole and sucralfate FDA-approved for use in humans. Your records state "The commercial product is difficult to administer". This rationale does not identify which of the commercial product(s) is difficult to administer and it is not clear that all the FDA-approved drugs containing these active ingredients have been considered. Furthermore, the rationale does not explain why the compounded paste containing omeprazole will be less difficult to administer than the approved paste.

We acknowledge that you provided CVM a copy of "SOP MLTX-001-36" on August 26, 2024, and that this SOP states that (b) (4) In most cases, the options provided in the drop-down do

not appear sufficient to explain how the compounded drug will make a clinical difference for the individual patient compared with each FDA-approved drug of which it is a copy.

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.[3] For example, with respect to the copies discussed above:

- Rx (b) (6): Detomidine HCl/Xylazine HCl 2.5/100 mg/mL injectable for a horse
    - You did not document why the FDA-approved detomidine and xylazine products cannot be used as the source of the active ingredients for compounding.
- Rx (b) (6): Omeprazole/Sucralfate 220/100 mg/mL oral paste for a horse
    - You stated the following: "Commercially manufactured sucralfate tablets are not suitable for direct administration to many small animals because they cannot be fractioned into weight appropriate doses, and they are unsuitable for larger animals because dosing would require the administration of an exceedingly high number of large and foul-tasting tablets that are known to be rejected by many animals. Commercially manufactured sucralfate suspension is not suitable for direct administration to many animals because the cherry flavoring it comes in is not amenable to their tastes and many animals are known to reject it. Additionally, the 100mg/ml concentration is too low to allow for dosages in small volumes that are practical and safe for administration for many animals."
        - Nothing in this explanation addresses why the FDA-approved omeprazole drugs could not be used as the source of the active ingredient for compounding.
        - Your statement about cherry-flavoring is not applicable, as the omeprazole drugs FDA-approved for use in horses are available in cinnamon flavor (not cherry).
        - The generic explanation that "many animals" reject cherry flavor does not address horses generally or the specific horse for which this prescription was written.
        - This rationale might explain why the FDA-approved sucralfate drugs may not be suitable for direct administration to an individual animal but does not explain why the FDA-approved drugs could not be used as a source of the active ingredient for compounding. For example, the FDA-approved sucralfate tablets are not cherry flavored.
        - Explanations regarding small animals are not applicable as this is a prescription for a horse.
        - The statement, "…the 100mg/ml concentration is too low" is not relevant because the dosage form you compounded has a concentration of 100 mg/mL.

Drugs Compounded Without Patient-Specific Prescriptions (Office Stock)

"Office stock" refers to compounded drugs ordered by a veterinarian without a patient-specific prescription to keep on hand in the veterinary clinic or office to administer or dispense to patients. When drugs are compounded for use as office stock, and are therefore readily

[3] See 21 CFR 530.13.

available for use, the products potentially expose large numbers of animals to drugs of unproven safety, effectiveness, and quality. You compound drugs for office stock, for example:

- Rx (b) (6): Adrenocorticotropic Hormone (ACTH) 80IU injectable for horses filled on 7/16/2024
- Rx (b) (6) Altrenogest 225 mg/mL injectable for horses filled on 7/11/2024
- Rx (b) (6) (b) (4) 2 mg/mL injectable for horses filled on 7/17/2024
- Rx Diclazuril 500 mg injectable for horses filled on 7/12/2024
- Rx L-Arginine 100mg/mL injectable for horses filled on 7/5/2024
- Rx Fluticasone Propionate/Amikacin Sulfate 2/50 mg/mL injectable for hor n 7/16/2024

We acknowledge you are making changes to your electronic systems and procedures; however, the level of detail provided in your SOP and response does not provide adequate information to determine whether the prescriptions will identify a specific patient.

Additionally, for the time period of our review, we observed prescriptions for herds of animals that we consider to be office stock. Based on the information available, we do not believe these prescriptions were written with the intent to authorize treatment for a defined group of animals, but rather to obtain office stock for use in a veterinary clinic. For example:

- Rx (b) (6): Amikacin 300 mg/mL injectable for a herd of 60 horses filled on 5/20/2024
  - Although your prescription log indicates that this drug is for a herd of 60 horses, the prescription label states that it is for "Office Use, (b) (4)".
- Rx (b) (6): Altrenogest injectable for a herd of 60 horses filled on 6/11/2024.
  - This prescription for 60 horses also lists the patient as (b) (4).
- Rx (b) (6): (b) (4) injectable for use in a herd of 25 horses filled on 5/7/2024
  - Your label for this prescription does not identify the group of animals in which these drugs are intended to be used. Therefore, we consider these prescriptions to be office stock. Among other factors that indicate this is office stock, we note the number of animals, that the herd is at a racetrack, and the herd size radically changed between prescriptions.

We acknowledge that you stated that you are advancing your software capabilities to include the specification of sub-herds within your documentation system and that your SOP MLTX-001-36 states that, (b) (4) (e.g., horse in stall X)". Additionally, your SOP appears to (b) (4) Moreover, it appears to allow (b) (4)

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 sells office stock which potentially exposes large numbers of animals to drugs which do not meet the CGMP quality standard set by the FD&C Act. We further 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 example, unlike FDA-approved products, you fail to test the strength/potency and sterility of each batch before release,[4] perform stability testing,[5] and establish, follow and validate all (b) (4) and sterilization processes to prevent microbial contamination.[6]

You did not conduct media fills that closely simulate (b) (4) production operations under the worst-case, most-challenging, and stressful conditions.[7] Media fills that represent actual, worst-case conditions are critical because they demonstrate whether your operators, environment, and process are capable of consistently producing sterile drugs. Your use of a kit containing (b)((non-control) (b) (4) mL (b) (4) vials to be filled via (b) (4) does not simulate your routine process of filling up to approximately (b) (4) units using (b) (4) mL vials (which you must (b) (4) yourself) and (b) (4) mL serum bottles and then filling them using (b) (4) tubing.

Your routine environmental monitoring in the classified areas is not adequate to ensure your sterile drugs are free from microorganisms.[8] Your frequency of viable surface sampling in the ISO5/7 area, viable active air sampling, non-viable particulate monitoring in the ISO 5, and personnel monitoring is inadequate and your action level for surface sampling of (b) (4) CFU for the ISO 5 area is not appropriate.

The drug contact surfaces used for drug product intended to be sterile may not have been (b) (4) in sterile drugs can result in adverse reactions. Specifically, you were asked to provide documentation that direct product contact tubing that you purchase non-sterile was (b) (4), and you did not do so during the inspection or in your written response.

Use of Components/BDS that Violate the FD&C Act

You compounded drugs from bulk drug substances manufactured by establishments that are not registered with FDA as required under section 510 of the FD&C Act. All manufacturers of BDS must register with FDA to ensure they are inspected. Use of BDS from non-registered establishments presents a risk to patients because the BDS may not have been originally manufactured for use as a drug (i.e., for medical use in or on an animal) or in accordance with CGMP. Drugs manufactured by unregistered establishments are misbranded under section 502(o) of the FD&C Act. These BDS remain misbranded when incorporated into your compounded drugs.

- Lot # (b) (4) of Reserpine USP was used to make lot #A22791. You purchased the product from (b) (4), a drug re-packager, and the manufacturer is (b) (4) as stated on the Certificate of Analysis (COA). This BDS manufacturer is not currently registered with FDA.

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[4] *See* 21 CFR 211.165(a).
[5] *See* 21 CFR 211.137 and 211.166.
[6] *See* 21 CFR 211.113(b) and FD&C Act section 501(a)(2)(A).
[7] *See* 21 CFR 211.113(b) and FD&C Act section 501(a)(2)(A).
[8] *See* 21 CFR 211.42(c)(10)(iv) and FD&C Act section 501(a)(2)(A).

- Lot (b) (4) of Pitcher Plant Extract (10:1) was used to make lot #3216EC. The name of the original manufacturer as listed on the CoA is (b) (4) This establishment is not registered with FDA. We note that the COA indicates it "complies with specifications" but the COA does not indicate what the specifications are or who created them.

Drug establishment registrations are public information and can be viewed on FDA.gov.[9]

In your written response, you indicated that your facility is a dedicated, purpose-built facility designed to meet United States Pharmacopeia (USP) Chapter <797>, USP <795> and USP <800> requirements. As described above, unlike human drugs compounded in accordance with section 503A, the FD&C Act does not exempt pharmacies that produce animal drugs from bulk drug substances from CGMP. The FD&C Act's CGMP requirement in section 501(a)(2)(B) applies to anyone who manufactures or processes animal drugs.

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.[10] 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.

We offer the following additional comment:

> You compound sterile drugs with (b) (4). The USP monograph for (b) (4) for use in injectable dosage forms requires endotoxin testing for the API (BDS), but that testing was not included on the COA. It is important to ensure all the BDS you use was produced in a matter suitable for your intended use, including checking the COA for the appropriate specifications.

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 address any violations. Please include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. This letter notifies you of our concerns and provides you an opportunity to address them. If you believe your products are not in violation of the FD&C Act, include your reasoning and any supporting information for our consideration.

If you cannot completely address this matter within thirty (30) working days, state the reason for the delay and the time within which you will do so. Please direct your response to CVMCompounding@fda.hhs.gov and include "Reference Case: 706939 in the subject line of

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[9] See FDA's "Drug Establishments Current Registration Site" page at https://www.fda.gov/drugs/drug-approvals-and-databases/drug-establishments-current-registration-site.

[10] 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.)

your email. If you have questions regarding the contents of this letter, please contact CVMCompounding@fda.hhs.gov.

Sincerely,

CINDY L. BURNSTEEL -S

Digitally signed by CINDY L. BURNSTEEL -S
Date: 2025.05.05 11:08:41 -04'00'

Cindy L. Burnsteel, DVM
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