FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS

**VIA EMAIL CONFIRMED DELIVERY**

June 17, 2022

Viraj Gandhi, Chief Executive Officer
Tailstorm Health Inc. dba Medivant Health
158 S. Kyrene Road
Chandler, AZ 85226
(b) (6)

Dear Mr. Gandhi:

You registered your facility with the U.S. Food and Drug Administration as an outsourcing facility under section 503B of the Federal Food, Drug, and Cosmetic Act (FDCA) [21 U.S.C. § 353b][1] on October 23, 2019, and most recently on January 25, 2022. From July 7, 2021, to July 21, 2021, an FDA investigator inspected your facility, Tailstorm Health Inc. dba Medivant Health, located at 158 S. Kyrene Road, Chandler, AZ 85226. During the inspection, the investigator noted that drug products you produced failed to meet the conditions of section 503B of the FDCA necessary for drugs produced by an outsourcing facility to qualify for exemptions from certain provisions of the FDCA. In addition, the investigator noted deficiencies in your practices for producing drug products intended or expected to be sterile, which put patients at risk.

The FDA issued a Form FDA 483 to your facility on July 21, 2021. The FDA acknowledges receipt of your facility's responses, dated August 10, 2021, and August 11, 2021. Based on this inspection, it appears you produced drugs that violate the FDCA.

## A. Compounded Drug Products under the FDCA

Under section 503B(b) of the FDCA, a compounder can register as an outsourcing facility with the FDA. Drug products compounded by or under the direct supervision of a licensed pharmacist in an outsourcing facility qualify for exemptions from the drug approval requirements in section 505 of the FDCA [21 U.S.C. § 355(a)], the requirement in section 502(f)(1) of the FDCA [21 U.S.C. § 352(f)(1)] that labeling bear adequate directions for use, and the Drug Supply Chain Security Act requirements in section 582

[1] *See* Pub. L. No. 113-54, § 102(a), 127 Stat. 587, 587-588 (2013).

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of the FDCA [21 U.S.C. § 360eee-1] if the conditions in section 503B of the FDCA are met.[2]

An outsourcing facility, as defined in section 503B(d)(4) of the FDCA [21 U.S.C. § 353b(d)(4)], is a facility at one geographic location or address that — (i) is engaged in the compounding of sterile drugs; (ii) has elected to register as an outsourcing facility; and (iii) complies with all requirements of this section. Outsourcing facilities must comply with other applicable provisions of the FDCA, including section 501(a)(2)(B) [21 U.S.C. § 351(a)(2)(B)], regarding current good manufacturing practice (CGMP), and section 501(a)(2)(A) [21 U.S.C. § 351(a)(2)(A)], regarding insanitary conditions. Generally, CGMP requirements for the preparation of drug products are established in Title 21 of the Code of Federal Regulations (CFR) parts 210 and 211.

In addition, for a compounded drug product to qualify for exemptions under section 503B, the labeling of the drug must include certain information (section 503B(a)(10) of the FDCA [21 U.S.C. §353b(a)(10)]).

## B. Failure to Meet the Conditions of Section 503B

During the inspection, the FDA investigator noted that drug products produced by your facility failed to meet the conditions of section 503B. For example, the investigator noted: The container from which individual units of some of your facility's drug products are removed for dispensing or for administration, including Lidocaine 1% Hydrochloride Injection, Lidocaine 2% Hydrochloride Injection, and Lidocaine 4% Hydrochloride Injection, did not include directions for use (section 503B(a)(10)(B)(iii) of the FDCA [21 U.S.C. §353b(a)(10)(B)(iii)]).

Because your compounded drug products have not met all of the conditions of section 503B, they are not eligible for the exemptions in that section from the FDA approval requirements of section 505, the requirement under section 502(f)(1) that labeling bear adequate directions for use, and the Drug Supply Chain Security Act requirements described in section 582 of the FDCA.

## C. Violations of the FDCA

### Adulterated Drug Products

An FDA investigator noted that drug products intended or expected to be sterile were prepared, packed, or held under insanitary conditions, whereby they may have become contaminated with filth or rendered injurious to health, causing your drug products to be adulterated under section 501(a)(2)(A) of the FDCA. For example, the investigator observed that:

[2] We remind you that there are conditions, other than those discussed in this letter, that must be satisfied to qualify for the exemptions in section 503B of the FDCA.

1. Your firm released sterile injectable drug products which failed visual inspection and were found to be contaminated with unidentified visible materials.

An FDA investigator also noted CGMP violations at your facility, that caused your drug products to be adulterated within the meaning of section 501(a)(2)(B) of the FDCA. The violations include, for example:

1. Your firm failed to thoroughly investigate any unexplained discrepancy or failure of a batch or any of its components to meet any of its specifications, whether or not the batch has already been distributed (21 CFR 211.192).

2. Your firm failed to establish adequate written procedures for production and process control designed to assure that the drug products you manufacture have the identity, strength, quality, and purity they purport or are represented to possess, and your firm's quality control unit did not review and approve those procedures, including any changes (21 CFR 211.100(a)).

3. Your firm failed to establish and follow adequate written procedures for cleaning and maintenance of equipment (21 CFR 211.67(b)).

4. Your firm failed to establish laboratory controls that include scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that components, drug product containers, closures, in-process materials, labeling, and drug products conform to appropriate standards of identity, strength, quality, and purity (21 CFR 211.160(b)).

5. Your firm failed to establish and document the accuracy, sensitivity, specificity, and reproducibility of its test methods (21 CFR 211.165(e)).

Outsourcing facilities must comply with CGMP requirements under section 501(a)(2)(B) of the FDCA. The FDA's regulations regarding CGMP requirements for the preparation of drug products have been established in 21 CFR parts 210 and 211. The FDA intends to promulgate more specific CGMP regulations for outsourcing facilities. The FDA has issued a revised draft guidance, *Current Good Manufacturing Practice — Guidance for Human Drug Compounding Outsourcing Facilities under Section 503B of the FD&C Act*. This draft guidance, when finalized, will describe the FDA's expectations regarding outsourcing facilities and the CGMP requirements in 21 CFR parts 210 and 211 until more specific CGMP regulations for outsourcing facilities are promulgated.

Under section 301(a) of the FDCA [21 U.S.C. § 331(a)], the introduction or delivery for introduction into interstate commerce of any drug that is adulterated is a prohibited act. Further, it is a prohibited act under section 301(k) of the FDCA [21 U.S.C. § 331(k)] to do any act with respect to a drug if such act is done while the drug is held for sale after shipment in interstate commerce and results in the drug being adulterated.

## Unapproved New Drug Products

You do not have any FDA-approved applications on file for drug products that you compound.[3] Under sections 505(a) and 301(d) of the FDCA [21 U.S.C. §§ 331(d)] a new drug may not be introduced into or delivered for introduction into interstate commerce unless an application approved by the FDA under section 505 of the FDCA is in effect for the drug. Marketing of these products, or other applicable products, without an approved application violates these provisions of the FDCA.

## Misbranded Drug Products

You compound drug products that are intended for conditions not amenable to self-diagnosis and treatment by individuals who are not medical practitioners; therefore, adequate directions for use cannot be written so that a layman can use these products safely for their intended uses. Consequently, their labeling fails to bear adequate directions for their intended uses causing them to be misbranded under section 502(f)(1) of the FDCA.[4] The introduction or delivery for introduction into interstate commerce of these products therefore violates section 301(a) of the FDCA. Further, it is also a prohibited act under section 301(k) of the FDCA to do any act with respect to a drug if such act is done while the drug is held for sale after shipment in interstate commerce and results in the drug being misbranded.

## D. Corrective Actions

We have reviewed your facility's responses to the Form FDA 483.

We are unable to fully evaluate some of your corrective actions due to lack of adequate supporting documentation:

1. Your response included performing analysis for particulates found in vials going forward and revision of current SOP for Investigating OOS Test Results to ensure language which may be interpreted to allow for retesting of preparations has been removed and staff trained. However, you failed to perform a risk assessment of the potential harm particulates within their sterile products may have on patients, and you did not expand on what steps were taken in the interim to prevent particulates within sterile products while the investigation into these incidences were reevaluated.

2. You initiated a new protocol to address gaps in the original validation of your (b) (4) system identified during the inspection. Your response was inadequate as it did not consider long-term impact on using the (b) (4) system during this validation

[3] The specific products made by your firm are drugs within the meaning of section 201(g) of the Act, [21 U.S.C. § 321(g)] because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of diseases and/or because they are intended to affect the structure or any function of the body. Further, they are "new drugs" within the meaning of section 201(p) of the FDCA [21 U.S.C. § 321(p)] because they are not generally recognized as safe and effective for their labeled uses.

[4] Your compounded drug products are not exempted from the requirements of section 502(f)(1) of the FDCA by regulations issued by the FDA (see, e.g., 21 CFR 201.115).

period and sterile products produced prior to this validation process on product quality.

3. You contracted with (b) (4) to conduct Container Closure Integrity Test for Lidocaine and Calcium Chloride products; results are still pending. However, you failed to provide details regarding how studies for other products will be conducted and when these will be completed. In addition, you failed to address how container closure studies for novel products produced at your facility will be developed.

4. You committed to validating the (b) (4) by (b) (4), and to evaluate and develop a method suitability for sterility for each drug product produced at the firm. Your response is inadequate because your completed report will be finished at (b) (4), and you did not address interim steps on how you plan to address product release during the validation process.

5. Your firm scheduled to perform swab recovery studies for bupivacaine hydrochloride, calcium chloride, ketamine, lidocaine hydrochloride, and sodium bicarbonate; however, you failed to address interim steps on how the firm plans to prevent cross contamination of products while the firm completes the validation of recovery studies.

In addition to the issues discussed above, you should note that CGMP requires the implementation of quality oversight and controls over the manufacture of drugs, including the safety of raw materials, materials used in drug manufacturing, and finished drug products. *See* section 501 of the FDCA. If you choose to contract with a laboratory to perform some functions required by CGMP, it is essential that you select a qualified contractor and that you maintain sufficient oversight of the contractor's operations to ensure that it is fully CGMP compliant. Regardless of whether you rely on a contract facility, you are responsible for assuring that drugs you produce are neither adulterated nor misbranded. [*See* 21 CFR 210.1(b), 21 CFR 200.10(b).]

Regarding issues related to the conditions of section 503B of the FDCA, your corrective actions appear adequate: The revised container labels you submitted include directions for use.

Should you continue to compound and distribute drug products that do not meet the conditions of section 503B, the compounding and distribution of your drugs would be subject to the new drug approval requirement, the requirement to label drug products with adequate directions for use, and the Drug Supply Chain Security Act requirements.

## E. Conclusion

The violations cited in this letter are not intended to be an all-inclusive statement of violations at your facility. 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 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 that you have taken to address any violations. Please include an explanation of each step being taken to prevent the recurrence of any 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 that your products are not in violation of the FDCA, 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 identify your notification with unique identifier: **CMS # 635717.**

Send your electronic response to ORAPHARM4_Responses@FDA.HHS.GOV with ATTN: CDR Steven E. Porter, Jr. or mail your written response to:

CDR Steven E. Porter, Jr.
Director, Division of Pharmaceutical Quality Operations IV
U.S. Food & Drug Administration
19701 Fairchild Road
Irvine, California 92612-2506

If you have questions regarding the contents of this letter, please contact LCDR Rumany Penn, Compliance Officer, at (949) 608-4409, or by email at Rumany.Penn@fda.hhs.gov.

Sincerely,

CDR Steven E. Porter, Jr.
Director, Division of Pharmaceutical Quality Operations IV

SP:rp