



February 2, 2018

Allison Vordenbaumen Benz, Executive Director
Texas State Board of Pharmacy
William P. Hobby Building, Suite 3-500
333 Guadalupe Street
Austin, Texas 78701

Dear Ms. Benz:

The purpose of this letter is to refer to the Texas State Board of Pharmacy (BOP) for appropriate follow up, the U.S. Food and Drug Administration's (FDA) concerns about poor sterile practices observed during an FDA inspection at a pharmacy licensed by the Texas BOP, Village Compounding Pharmacy, located at 975 Corbindale Road, Suite 100, Houston, Texas 77024-2810 (Active Texas Pharmacy License #4242 expires on June 30, 2018).

FDA inspected the firm from March 20, 2017, to March 31, 2017. Texas BOP was informed of the inspection but did not accompany the FDA investigator during the inspection. A copy of a Form FDA 483 that documents our investigator's observations from the inspection can be found at <https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-afda-orgs/documents/document/ucm554167.pdf>, with any nonpublic information redacted. Because we consider this inspection to be "closed" under 21 CFR 20.64(d)(3), you may request a copy of the Establishment Inspection Report (EIR) that FDA will provide to the firm, which contains additional information about our inspection. If you are a Commissioned Official or if your state agency has entered into a 21 CFR 20.88 information sharing agreement, you may be able to receive a copy of the Form FDA 483 or the EIR that includes certain nonpublic information. Alternatively, you may also choose to request a copy of the EIR directly from the firm.

During the inspection, the FDA investigator reviewed a small sample of records for products compounded by Village Compounding Pharmacy and determined, based on this sample, that this firm appears to obtain valid prescriptions for individually-identified patients for the drug products that it compounds and distributes.

During the inspection, the FDA investigator observed deviations from appropriate sterile practice standards that, if not corrected, could lead to contamination of drugs, potentially putting patients at risk. Examples of deviations observed during our inspection include

U.S. Food & Drug Administration
Office of Pharmaceutical Quality Operations, Division II
~~4040 N. Central Expressway, Suite 300~~
Dallas, Texas 75204
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the use of non-sterile wipes to clean the ISO 5 classified areas and the use of a dehumidifier within a cleanroom.

Village Compounding Pharmacy committed to FDA in its written responses, dated April 3, 2017, May 11, 2017, and July 17, 2017, to correct the deviations and provided documentation in support of those corrective actions. In addition, the deviations identified appear to be readily correctable.

After review of the record, FDA does not intend to take further action at this time with regard to the findings of this inspection. This firm apparently obtains prescriptions for identified individual patients before distributing its compounded drugs, as required by section 503A(a) of the Federal Food, Drug and Cosmetic Act, and FDA believes that the corrective actions can be appropriately overseen by the State. Therefore, FDA is referring this matter to the Texas State BOP for follow up to ensure appropriate corrective action is taken. Please notify us if you become aware of any adverse events or product quality concerns associated with drugs made at this facility, or if you observe any practices at this facility that concern you or that could be violations of Federal law.

We look forward to continuing to work with you on the oversight of compounding pharmacies. If you have additional questions, please contact Thao Ta, Compliance Officer, at 214-253-5217, or by email at thao.ta@fda.hhs.gov.

Sincerely,

John W. Diehl

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Digitally signed by John W. Diehl -S
DN: c=US, o=U.S. Government, ou=HHS,
ou=FDA, ou=People, cn=John W. Diehl -S,
o=D:342.19200300.100.1.1=2000099727
Date: 2018.02.02 15:34:05 -0600

LCDR John W. Diehl, M.S.
Director, Compliance Branch
Office of Pharmaceutical Quality Operations,
Division II

cc:

Mr. Phillip R. Pylant, Chief Executive Officer
Village Compounding Pharmacy
975 Corbindale Road, Suite 100
Houston, Texas 77024-2810
