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

February 8, 2017

Reginald Dilliard
Executive Director
Tennessee Board of Pharmacy
665 Mainstream Drive
Nashville, Tennessee 37243

Dear Mr. Dilliard:

The purpose of this letter is to refer to the Tennessee 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 Tennessee BOP, Green Hills Health and Wellness Pharmacy, Inc., dba Health & Wellness Compounding Pharmacy, located at 329 21st Avenue North, Suite 3, Nashville, Tennessee 37203-1839 (license # 00001436).

FDA inspected the firm from June 14, 2016, to June 30, 2016. FDA investigators were accompanied by a Tennessee State investigator for three days. A redacted copy of a Form FDA 483 that documents our investigators' observations from the inspection can be found at http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/UCM510566.pdf

During the inspection, the FDA investigators reviewed a small sample of records for products compounded by Health & Wellness 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. In the response to the Form FDA 483[1], received July 22, 2016, the firm advised FDA that "To the extent that Health & Wellness engages in sterile and non-sterile compounding, it compounds only patient-specific pharmaceuticals pursuant to a valid prescription issued by a licensed prescriber."

[1] See attached the firm's response to the Form FDA 483, received July 22, 2016, from Mark F. Binkley, D.Ph., to the New Orleans District Office.

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During the inspection, the FDA investigators observed a deviation from appropriate sterile practice standards that, if not corrected, could lead to contamination of drugs, potentially putting patients at risk. Specifically, the firm failed to depyrogenate glassware used during production for mixing drug products that are intended to be sterile.

Health & Wellness Compounding Pharmacy committed to FDA in its response to the Form FDA 483, received July 22, 2016, to correct the deviation in the Form FDA 483. In addition, the deviation identified appears to be readily correctable.

After review of the record, at this time FDA does not intend to take further action with regard to the findings of this inspection. This firm apparently obtains prescriptions for identified individual patients, and FDA believes that the corrective actions can be appropriately overseen by the State. Therefore, FDA is referring this matter to the Tennessee 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 human or animal 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.

For reporting animal adverse drug events, please follow the link to the FORM FDA 1932a found at: http://www.fda.gov/AnimalVeterinary/SafetyHealth/ReportaProblem/ucm055305.htm

We look forward to continuing to work with you on the oversight of compounding pharmacies. If you have additional questions, please contact Rebecca Asente, Compliance Officer, at 504-846-6100, ext. 6104, or by email at Rebecca.Asente@fda.hhs.gov.

Sincerely,

Ruth P. Dixon
District Director
New Orleans District Office