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

February 6, 2019

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

Dear Mr. Dilliard:

The purpose of this letter is to refer to the Tennessee 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 Tennessee BOP, The Wellness Center Pharmacy, Inc., dba Designer Drugs, located at 7304 Jarnigan Road, Chattanooga, TN 37421 (License #00003203).

FDA inspected the firm from December 12, 2017, to December 22, 2017. An FDA investigator was accompanied by a Tennessee state investigator. 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/ucm592010.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 The Wellness Center Pharmacy, Inc., dba Designer Drugs 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 corected, could lead to contamination of drugs, potentially putting patients at risk. Examples of deviations observed during our inspection include:

1. Media fills were not performed under the most challenging or stressful conditions.

2. Non-microbial contamination was observed in the production area.

3. The ISO 5 classified aseptic processing areas contained dust-collecting overhangs without adequate and frequent cleaning.

U.S. Food & Drug Administration
Division of Pharmaceutical Quality Operations 2
4040 N. Central Expressway, Suite 300
Dallas, Texas 75204
www.fda.gov

The Wellness Center Pharmacy, Inc., dba Designer Drug, committed to FDA in its written responses dated December 27, 2017, June 18, 2018, October 18, 2018, and October 24, 2018, to correct the deviations in the Form FDA 483. In addition, the firm provided documentation in support of the corrective actions and 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 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 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 Mark W. Rivero, Compliance Officer, at (504) 846-6103, or by email at mark.rivero@fda.hhs.gov.

Sincerely,

Jose R. Lopez Martinez -S

Digitally signed by Jose R. Lopez Martinez -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2000379053, cn=Jose R. Lopez Martinez -S
Date: 2019.02.06 16:54:22 -04'00'

Jose R. Lopez
Acting Director, Compliance Branch
Office of Pharmaceutical Quality Operations
Division II

Cc: Randal J. Davis, President
The Wellness Center Pharmacy, Inc., dba Designer Drugs
7304 Jarnigan Road
Chattanooga, Tennessee 37421-3042