November 18, 2019

Tanja Battle
Executive Director
Georgia State Board of Pharmacy
2 Peachtree Street NW, 6th Floor
Atlanta, GA 30303

Ms. Battle:

The purpose of this letter is to refer to the Georgia State Board of Pharmacy (BOP) for appropriate follow up, the U.S. Food and Drug Administration's (FDA) concern about practices observed during an FDA inspection at a pharmacy licensed by the Georgia BOP, Concord, Inc. dba Carlton's Dunwoody Pharmacy, located at 5484 Chamblee Dunwoody Road, Suite B19 Dunwoody, GA 30338-4133 (Pharmacy License# PHRE006394).

FDA inspected the firm from April 8, 2019, to April 12, 2019. The Georgia BOP was informed of the inspection but did not accompany FDA investigators during the inspection. A copy of a Form FDA 483 that documents our investigators' observation from the inspection can be found at https://www.fda.gov/media/124960/download, 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. 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 investigators reviewed a small sample of records for products compounded by Carlton's Dunwoody 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.

Additionally, during the inspection, the FDA investigators observed deviations from appropriate 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:

1. Your cleaning procedure was inadequate in that it does not include a cleaning agent to deactivate the hormonal drug products produced at your facility.

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

Carlton's Dunwoody Pharmacy committed to FDA in its response to the Form FDA 483 received May 10, 2019, to correct the deviations in the Form FDA 483. 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 regards 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 Georgia State BOP for follow up to ensure appropriate corrective actions were 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 Rivero, Compliance Officer, at 504 846-6103, or by email at Mark.Rivero@fda.hhs.gov.

Sincerely,

John W. Diehl -S3

Digitally signed by John W. Diehl -S3
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=John W. Diehl -S3, 0.9.2342.19200300.100.1.1=2000099727
Date: 2019.11.18 11:57:10 -06'00'

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

Cc: Marvin O. McCord, Owner
Concord, Inc. dba Carlton's Dunwoody Pharmacy
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Dunwoody, GA 30338-4133