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

February 19, 2018

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

Dear Mr. Dillard:

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, Diabetes Corporation of America Pharmacy, located at 233 Bedford Way, Franklin, TN 37064-5527 (Pharmacy License #00003440).

FDA inspected the firm from June 5, 2017, to June 15, 2017. The FDA investigator was accompanied by a Tennessee State investigator for two days. 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/ucm568739.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 Diabetes Corporation of America 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:

1. The firm used non-sterile wipes in the ISO 5 areas.

2. The firm's ISO 7 cleanroom contained particle generating equipment. The firm did not certify their cleanroom while this equipment was in operation.

3. An aseptic operator touched equipment outside the ISO 5 area and then proceeded with aseptic manipulations without disinfecting or changing their gloves.

4. The firm's media fill program did not closely simulate the most challenging aseptic production operations, including production volumes of up to 1,000 mL.

5. The firm released drug products despite failing post-production testing.

Diabetes Corporation of America committed to FDA in its written responses, dated June 26, 2017, and November 29, 2017, to correct the deviations in the Form FDA 483 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 Tennessee 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 Mark W. Rivero, Compliance Officer, at (504) 846-6103, or by email at Mark.Rivero@fda.hhs.gov.

Sincerely,

John W. Diehl -S

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, 0.9.2342.19200300.100.1.1=2000099727
Date: 2018.02.19 22:01:11 -06'00'

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

Cc:
Hoy D. Allen, Jr.
President and Chief Executive Officer
Diabetes Corporation of America
233 Bedford Way
Franklin, TN 37064-5527