



February 19, 2018

Hoy D. Allen, Jr.
President and Chief Executive Officer
Diabetes Corporation of America
233 Bedford Way
Franklin, Tennessee 37064

Mr. Allen:

We are enclosing a copy of the Establishment Inspection Report (EIR) for the inspection conducted at your facility, Diabetes Corporation of America, located at 233 Bedford Way, Franklin, TN, 37064, from June 5, 2017, to June 15, 2017, by the U.S. Food and Drug Administration (FDA). In addition, we are enclosing the letter sent to the Tennessee State Board of Pharmacy for follow up.

When the Agency considers an inspection to be “closed” under 21 C.F.R. 20.64(d)(3), it will release a copy of the EIR to the inspected establishment and we have enclosed a copy with this letter.

The Agency continually works to make its regulatory process and activities more transparent for regulated industry. Releasing this EIR to you is part of this effort. The copy being provided to you comprises the narrative portion of the report; it may reflect redactions made by the Agency in accordance with the Freedom of Information Act (FOIA) and 21 C.F.R. Part 20. This, however, does not preclude you from requesting and possibly obtaining any additional information under FOIA.

If there is any question about the released information, 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,
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Date: 2018.02.19 21:55:46 -0600

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

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