

August 2, 2018

Pamala S. Harmon, Director of Operations Care Solutions, Inc. 1838 Elm Hill Pike, Suite 117 Nashville, TN 37210-3726

Dear Ms. Harmon:

We are enclosing a copy of the Establishment Inspection Report (EIR) for the inspection conducted at your facility, Care Solutions, Inc., located at 1838 Elm Hill Pike, Suite 117, Nashville, TN 37210-3726, from June 13, 2017, to June 19, 2017, by the U.S. Food and Drug Administration (FDA).

When the Agency concludes that an inspection is "closed" under 21 C.F.R. 20.64(d)(3), it will release a copy of the EIR to the inspected establishment.

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 Dayna Martinez, Compliance Officer, at 787-729-8608 or dayna.martinez@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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LCDR John W. Diehl, M.S. Director, Compliance Branch Office of Pharmaceutical Quality Operations, Division II

Enclosure: EIR

U.S. Food & Drug Administration
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