

September 13, 2019

Case # 261209

VIA UPS EXPRESS

Ashley W. Dick, Director of Pharmacy Paradigm Healthcare Solutions, LLC dba Athena Pharmacy 2025 North Mount Juliet Road, Suite 100 Mount Juliet, Tennessee 37122-3934

Ms. Dick:

We are enclosing a copy of the Establishment Inspection Report (EIR) for the inspection conducted at your facility, Paradigm Healthcare Solutions, LLC dba Athena Pharmacy, located at 2025 North Mount Juliet Road Suite 100, Mount Juliet, TN 37122-3934, from February 28, 2019, to March 5, 2019, 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.

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 me at (214) 253-5288 or john.diehl@fda.hhs.gov.

Sincerely,

John W. Diehl -S3 Digitally signed by John W Diehl S3 DN: c=US o=US Government ou=HHS ou=FDA ou=People cn=John W Diehl 33 0 9 2 3 42 19200300 100 1 1=20000099727 Date: 2019 09 13 11:23:24 05'00'

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