



September 13, 2019

Case # 261209

VIA UPS EXPRESS

Reginald Dilliard, D.Ph
Executive Director
Tennessee State Board of Pharmacy
665 Mainstream Drive
Nashville, Tennessee 37243

Dr. Dilliard:

The purpose of this letter is to notify the Tennessee State Board of Pharmacy (BOP) that the U.S. Food and Drug Administration (FDA) does not intend to take further action with regard to an inspection of a pharmacy licensed by the Tennessee BOP, Paradigm Healthcare Solutions, LLC dba Athena Pharmacy (licensed under the name Athena Pharmacy), located at 2025 North Mount Juliet Road Suite 100, Mount Juliet, Tennessee 37122-3934 (License #: 00003723).

FDA inspected the firm from February 28, 2019, to March 5, 2019. An investigator from the Tennessee BOP accompanied the FDA investigator during the inspection. No Form FDA 483 was issued to the firm.

During the inspection, the FDA investigators reviewed a small sample of records for products compounded by Paradigm Healthcare Solutions, LLC dba Athena 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, which is consistent with traditional pharmacy practice. After review of the records, FDA does not intend to take further action with regard to the findings of this inspection at this time and believes that the firm's pharmacy practice can be appropriately overseen by the State. 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.

Page 2 – Reginald Dilliard, D. Ph, Executive Director
Tennessee State Board of Pharmacy
Paradigm Healthcare Solutions, LLC dba Athena Pharmacy
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We look forward to continuing to work with you on the oversight of compounding pharmacies. If you have additional questions, 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
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ou=FDA, ou=People, cn=John W. Diehl -
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Date: 2019.09.13 11 31:52 -05'00'

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

Cc:
Ashley W. Dick
Director of Pharmacy
Paradigm Healthcare Solutions, LLC dba Athena Pharmacy
2025 North Mount Juliet Road, Suite 100
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