



November 29, 2018

Phanesh Koneru, PhD, LLM  
President and CEO  
Exela Pharma Sciences, LLC  
1245 Blowing Rock Blvd  
Lenoir, NC 28645

Dr. Koneru,

We are enclosing a copy of the Establishment Inspection Report (EIR) for the inspection conducted at your facility, Exela Pharma Sciences LLC, located at 1245 Blowing Rock Blvd, Lenoir, NC 28645, from September 19, 2017, to September 28, 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 you have any questions as to the content of this letter, please contact Rebecca Asente, Compliance Officer, via (504) 846-6104 or [Rebecca.asente@fda.hhs.gov](mailto:Rebecca.asente@fda.hhs.gov).

Sincerely,

John W.  
Diehl -S3

Digitally signed by John W. Diehl -S3  
DN: c=US, o=U.S. Government, ou=HHS,  
ou=FDA, ou=People, cn=John W. Diehl -  
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Date: 2018.11.29 15:28:34 -06'00'

LCDR John W. Diehl, M.S.  
Director, Compliance Branch  
Office of Pharmaceutical Quality Operations,  
Division 2

Enclosure: EIR

U.S. Food & Drug Administration  
Office of Pharmaceutical Quality Operations, Division II  
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