U.S. FOOD & DRUG ADMINISTRATION

Pharmaceutical Quality Investigation Branch
19701 Fairchild Road
Irvine, CA 92612

04/26/2019

Mr. H.S. Jagadeesha
General Manager - Operations
Annora Pharma Private Limited
Survey Number 261
Annaram Village, Gummadidal Mandal
Sangareddy District, Telangana 502313, India

Reference: Inspection Date(s):01/29/2019 - 02/01/2019

Location: Annora Pharma Private Limited
Survey 261, Plots 5,7,8,9,13-14, Annaram Village, Gummadidal Mandal, Sangareddy District
Hyderabad, Telangana, 502313, India

Dear Mr. Jagadeesha:

We are enclosing a copy of the establishment inspection report (EIR) for the inspection that the U.S. Food and Drug Administration (FDA) conducted at your premises on the referenced locale and date(s). When the Agency concludes that an inspection is "closed" under 21 CFR 20.64(d)(3), it will release a copy of the EIR to the inspected establishment. This procedure is applicable to EIRs for inspections completed on or after April 1, 1997.

The Agency continually works to make its regulatory process and activities more transparent to the 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 CFR Part 20. This, however, does not preclude you from requesting additional information under FOIA.

If you have any questions regarding this letter, you may contact me at (949) 608-3519 or email at Katherine.Jacobitz@fda.hhs.gov.

For more information on the U.S. FDA, please visit our website at www.fda.gov.

Sincerely,
Katherine E. Jacobitz -S

Digitally signed by Katherine E. Jacobitz -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300153047, cn=Katherine E. Jacobitz -S
Date: 2019.04.26 13:15:13 -07'00'

CAPT Katherine E. Jacobitz
Investigations Branch Director, Division IV
Office of Pharmaceutical Quality Operations

FEI:3013944676
Enclosure: Establishment Inspection Report (EIR)

U.S. Food and Drug Administration
www.fda.gov

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