U.S. FOOD & DRUG ADMINISTRATION

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Pharmaceutical Quality
Office of Surveillance
Division of Quality Surveillance Assessment
10903 New Hampshire Avenue
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Silver Spring, MD 20993
TELEPHONE: (301) 796-3254
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06/26/2017

Aurobindo Pharma Ltd
Unit 3, Survey No. 313-314
Bachupally, Quthubulapur Mandal,
Hyderabad, Telangana , IN 500 090

Reference: Inspection Date(s): 04/10/2017 - 04/18/2017

Location: Aurobindo Pharma Ltd
Unit III, Survey No. 313-314, Bachupally
Quthubullapur (M), RR District.
Hyderabad, 500090 , IN

Dear Mr. M. Venkateswar Rao

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 there is any question about the released information, feel free to contact me at above address and number

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

Sincerely,

Digitally signed by Luis A. Carrion -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300185781, cn=Luis A. Carrion -S
Date: 2017.06.26 08:30:02 -04'00'

FEI: 3004021229

Enclosure: Establishment Inspection Report (EIR)