

09/14/2017 Teena Biolabs Pvt Ltd 41 Sv Co - Op Ind Estate Bachupally, Telangana, IN

Reference: Inspection Date(s):03/15/2017 - 03/16/2017

Location: Teena Biolabs Pvt Ltd

Plot no 41, SV COOP Ind. Estate

Hyderabad, Ranga Reddy Dist., 500 090, IN

Dear Mr. Anjaiah,

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 301-796-1287.

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

Sincerely,

Merideth K. Rose -A Digitally signed by Merideth K. Rose -A DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=130041955 1, cn=Merideth K. Rose -A Date: 2017.09.14 11:37:48 -04'00'

Center for Drug Evaluation and

Office of Pharmaceutical Quality

Division of Quality Surveillance

10903 New Hampshire Avenue

TELEPHONE: (301) 796-3254

Office of Surveillance

Building 51, Room 4316 Silver Spring, MD 20993

FAX: (301) 847-8742

Research

Assessment

FEI: 3008569405

Enclosure: Establishment Inspection Report (EIR)

U.S. Food and Drug Administration

www.fda.gov