U.S. FOOD & DRUG ADMINISTRATION

August 2, 2019

Uppukonduri Himabindu
Deputy Manager of Quality Assurance
Daicel Chiral Technologies Pvt. Ltd.
Laboratory #5A & 5B, Phase-II,
IKP Knowledge Park, Genome Valley,
Turkapally Village, Shameerpet,
Medchal-Malkajgiri District,
Hyderabad, Telangana 500101, India

Dear Ms. Himabindu,

We are enclosing a copy of the Establishment Inspection Report (EIR) for the inspection conducted at your premises, **Daicel Chiral Technologies Pvt. Ltd., Lab No. 7 & 5, Phase II, IKP, Knowledge Park, Genome Valley, Shameerpet, Medchal-Malkajgiri District, Hyderabad, Telangana 500101, India**, by the United States Food and Drug Administration (FDA) from **March 22** to **March 26, 2019**.

The Agency has concluded that this inspection is closed under 21 CFR 20.64(d)(3). We are therefore releasing a copy of the EIR for the inspected establishment to you. The EIR being provided to you comprises the narrative portion of the report; it reflects redactions made by the Agency in accordance with the Freedom of Information Act (FOIA) and Title 21, Code of Federal Regulations, part 20. However, this does not preclude you from requesting, and possibly obtaining, any additional information provided under FOIA.

The documents provided to you under FDA's FMD-145 Program have not been reviewed for public disclosure, and may contain confidential commercial information (e.g., applicant protocol information) and/or patient information (e.g., patient initials) that you already know in your capacity. FDA would normally redact this type of information before allowing the EIR's public disclosure. **If you were to disclose this information to others, you would be responsible for ensuring that sensitive information is adequately protected.**

If you would like a copy of the EIR that has been reviewed by FDA and redacted for public disclosure, you will need to submit a FOIA request specifically asking for a publicly disclosable version.

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