Hima Bindu

Subject: FW: [WARNING: MESSAGE ENCRYPTED]USFDA - FMD 145 EIR - Daicel Chiral Technologies - 3009883135

From: Lolitha.Lett@FDA.HHS.GOV <Lolitha.Lett@FDA.HHS.GOV>
Sent: 15 June 2023 0:28
To: Ch.Lakshmi Narayana <lakshminarayana@chiral.daicel.com>
Subject: [WARNING: MESSAGE ENCRYPTED]USFDA - FMD 145 EIR - Daicel Chiral Technologies - 3009883135

05/16/2023
Dr. Ch. Lakshmi Narayana, Managing Director
Daicel Chiral Technologies
Survey No. 542/2 Koltur Village
Shamirpet Mandal, Medchal-Malkajgiri District
Hyderabad, Telegana, India 500101

Dear Dr. Ch. Lakshmi Narayana, Managing Director

The U.S. Food and Drug Administration (FDA) conducted an inspection at Daicel Chiral Technologies, FEI 3009883135, located at 2 Koltur Village, Survey No 542, Shamirpet, Telangana, from 02/06/2023 to 02/08/2023. FDA has determined that the inspection classification of this facility is "no action indicated" ("NAI"). Based on this inspection, this facility is considered to be in an acceptable state of compliance with regards to current good manufacturing practice (CGMP).

This letter is not intended as an endorsement or certification of the facility. It remains your responsibility to ensure continued compliance with CGMP.

An inspection classification of NAI for CGMP compliance will not directly negatively impact FDA's assessment of any pending marketing application referencing this facility. Please note, however, that application approval will depend on a product- and application-specific facility assessment conducted by the appropriate CDER or CVM review office. This letter does not address or reflect FDA's decision making with respect to any potential non-CGMP compliance issues.

FDA has concluded that this inspection is ''closed'' under 21 CFR 20.64(d)(3), and we are enclosing a copy of the narrative portion of the Establishment Inspection Report (EIR). It may reflect redactions made by FDA 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 Lolithia L Lett via telephone at 4046694566 or email at Lolitha.Lett@FDA.HHS.GOV.

Sincerely,

LaReese Thomas
Supervisory Investigator
Office of Pharmaceutical Quality Operations II (PHRM2-IB)


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ADMINISTRATION