U.S. FOOD & DRUG ADMINISTRATION

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Via UPS
Return Receipt Requested

December16, 2022

Mr. Madireddy Jayapal Reddy
Managing Director/CEO
Megsan Labs Private Limited
#3-31/33, Plot No. 33, Part Sy Nos 123, 124, 125 & 142
Kompally, Quthbullapur, Ranga Reddy District
Hyderabad, Telangana 500014
India

Dear Mr. Reddy:

The U.S. Food and Drug Administration (FDA) conducted an inspection at Megsan Labs Private Limited, FEI 3010960741, at #3-31/33, Plot No. 33, Part Sy Nos 123, 124, 125 & 142, Kompally, Quthbullapur, Ranga Reddy District, Hyderabad, Telangana, 500014, India, from September 19 to September 23, 2022. FDA has determined that the inspection classification of this facility is "voluntary action indicated" (VAI).[1] Based on this inspection, this facility is considered to be in a minimally acceptable state of compliance with regard to current good manufacturing practice (CGMP).

A VAI inspection classification indicates that, although investigators found and documented objectionable conditions during the inspection, FDA will not take or recommend regulatory or enforcement action because the objectionable conditions do not meet the threshold for action at this time. Despite this facility inspection classification, FDA recommends that you address any observations noted on the Form FDA 483 issued at the conclusion of the inspection or otherwise conveyed to you following the inspection. If not corrected, the same or similar conditions could lead to a future inspection being classified as "official action indicated" (OAI).

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 VAI for CGMP compliance will not directly negatively impact FDA's assessment of any pending marketing applications 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

[1] See Inspection Classification Definitions, at https://www.fda.gov/ICECI/Inspections/ucm223231.htm.

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 questions or concerns regarding this letter, send an electronic reply to CDER-OC-OMQ-Communications@fda.hhs.gov. Identify your response with FEI-3010960741 and ATTN: Tamara Rosbury, Compliance Officer.

Sincerely,

Milind Ganjawala -S

Digitally signed by Milind Ganjawala -S
Date: 2022.12.16 08:13:46 -05'00'

Milind Ganjawala
Director
Division of Drug Quality II
Office of Manufacturing Quality
Office of Compliance
Center for Drug Evaluation and Research

Enclosure: Establishment Inspection Report