Health Canada Santé Canada

[redacted]

Subject: GMP Compliance Notification Email - MEGSAN LABS PRIVATE LIMITED, 3-31/33, Plot No. 33, Part Sy Nos: 123, 124, 125 & 142, Kompally, Quthbullapur, Hyderabad, Telangana, 500014, India

Based on the assessment of the Good Manufacturing Practices (GMP) evidence available for the inspection conducted by U.S. Food and Drug Administration (US FDA) at the above named foreign building from 2019-10-29 to 2019-11-01, Health Canada has found the foreign building above compliant with Division 2 of the Food and Drug Regulations in regards to the following:

Category	Activity	Dosage	Sterile (yes or no)
Pharmaceutical	Test	ACTIVE PHARMACEUTICAL INGREDIENT	No
Pharmaceutical	Test	CAPSULE	No
Pharmaceutical	Test	POWDER	No
Pharmaceutical	Test	TABLET	No

This GMP Compliance Notification does not replace an authorization for importation. If the site is currently listed on your Drug Establishment License (DEL) you may continue the activities in accordance with your DEL. Otherwise, you may only import from this foreign building upon issuance of an amended DEL with the foreign building listed. The Establishment Licensing Unit will be informed of this compliant rating.

The evidence submitted will remain valid until 2022-10-29 or until new information is received and assessed. Please note that Health Canada may request foreign building GMP evidence at any time, including during a scheduled or unscheduled inspection of your facility.

You are responsible for ensuring that foreign buildings listed on your DEL remain GMP compliant. If any information changes, or if an event occurs that may affect the quality, safety or efficacy of a drug fabricated, packaged/labelled, tested or stored at a foreign building—contravening the applicable requirements in Divisions 2-4 of the Regulations—you must notify Health Canada in writing within 15 days of the change or event.

If you have questions about GMP evidence or establishment licences, please do not hesitate to contact us at hc.foreign.site-etranger.sc@canada.ca or hc.del.questions-leppp.sc@canada.ca, respectively.

Yours sincerely,

[redacted]