Anuradha Vadupu

From: Harriman Vungal
Sent: 2023-June-15 10:49
To: Anuradha Vadupu; MD Office
Subject: FW: [WARNING: MESSAGE ENCRYPTED]USFDA - FMD 145 EIR - Vimta Labs Limited - 3006587427
Attachments: EIR for Vimta Labs Limited_reviewed.pdf

From: Douglas.Kovacs@FDA.HHS.GOV <Douglas.Kovacs@FDA.HHS.GOV>
Sent: Thursday, June 15, 2023 12:28 AM
To: Harriman Vungal <harriman@vimta.com>
Subject: [WARNING: MESSAGE ENCRYPTED]USFDA - FMD 145 EIR - Vimta Labs Limited - 3006587427

06/08/2023
Vungal Harriman, Executive Director-Operations
Vimta Labs Limited
Facility Plot No. 5 Mn Park Genome Valley, Shameerpet, Medchal-Malkajgiri
Hyderabad, Telangana

Dear Mr. Vungal Harriman, Executive Director-Operations:

The U.S. Food and Drug Administration (FDA) conducted an inspection at Vimta Labs Limited, FEI 3006587427, located at Facility Plot No. 5 Mn Park, Genome Valley, Shameerpet, Medchal-Malkajgiri, Hyderabad, Telangana, from 03/13/2023 to 03/17/2023. FDA has determined that the inspection classification of this facility is "voluntary action indicated" ("VAI"). Based on this inspection, this facility is considered to be in a minimally acceptable state of compliance with regards 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 application referencing this facility. Please note, however, that application approval will depend on a product- and application-specific facility assessment conducted by CDER’s Office of Pharmaceutical Quality. 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 Douglas C Kovacs via telephone at 9733314936 or email at Douglas.Kovacs@FDA.HHS.GOV.

Sincerely,

Douglas C Kovacs
SUPERVISORY CONSUMER SAFETY
OFFICE OF PHARMACEUTICAL QUALITY OPERATIONS