F.No.4-14/97-DC (VLL)
Directorate General of Health Services
Office of Drug Controller General (India)
(Drugs Control Section)

FDA Bhawan, Kotla Road,
New Delhi- 110002.
Dated: 13 DEC 2016

To

M/s. Vimta Labs Limited,
141/2 &142, IDA, Phase -2,
Cherlapally, Hyderabad-500051

Sub: - Renewal of Approval of Bioavailability/Bioequivalence Study Centre of M/s. Vimta Labs Limited, 141/2 &142, IDA, Phase -2, Cherlapally, Hyderabad-500051– Reg.

Sir,

Please refer to your letter no. VLL/CR/CRO Renewal/15-16 dated 17.08.2015 received by this Directorate vide diary no. 44084 dated 20.08.2015 on the subject matter.

As per documentation submitted by you, this Directorate will accept the protocol and bioavailability / bioequivalence study reports of New Drugs from your laboratory having a Clinical facility of 180 Beds at "1st & 2nd Floor" and Bio-analytical facility on Ground Floor at "Ground floor, 141/2 &142, IDA, Phase -2, Cherlapally, Hyderabad-500051 and M/s Vimta Labs Limited, Life Science Campus, # 5, Alexnedria Knowledge Park, Genome Valley, Shameerpet Hyderabad 500078" subject to following conditions:-

1. The study centre should ensure that the whole Informed Consent Process should be documented through Audio-Video means maintaining the principle of confidentiality.
2. Specific protocol for conducting BE/ BA studies with new drug formulation should be cleared by Institutional Ethics Committee and then got approved from this office on case to case basis.
3. After three year there will be assessment of performance of said study centre for continued acceptance of protocol & reports in this regard.
4. Regular training to be imparted to the IEC Members on Schedule Y and GCP Guidelines.

Yours faithfully,

(Dr. S. Eswara Reddy)
Joint Drugs Controller (India)

Copy to:-

Dy. Drugs Controller (I), Central Drugs Standard Control Organisation, Zonal Office, Hyderabad, Beside AP T.B Demonstration and training centre, S.R Nagar, Hyderabad 500038 A.P