4-14/97-DC (SLL)
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. Sipra Labs Ltd.,
7-2-1813/5/A, Adjacent to post office,
Industrial estate, Sanathnagar,
Hyderabad-500 018.

Sub:- Renewal of Approval of Bioavailability/Bioequivalence Study Centre of M/s. Sipra Labs Ltd., 7-2-1813/5/A, Adjacent to post office, Industrial estate, Sanathnagar, Hyderabad-500 018.

Sir,

Please refer to your letter no. SLL/BE/01/2016 dated 24/03/2016 received by this directorate vide diary no. 18367 dated 31/03/2016 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 80 beds and Bio analytical facility at M/s. Sipra Labs Ltd., 7-2-1813/5/A, Adjacent to post office, Industrial estate, Sanathnagar, Hyderabad-500 018 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 cases basis.
3. After three years there will be assessment of performance of said study centre for continued acceptance of protocol & reports in this regard.

Yours faithfully,

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

Copy to:-

The Deputy Drugs Controller (India), CDSCO, Zonal office, Hyderabad, CDSCO BHAVAN, Beside AP T.B. & Demonstration Centre, S.R. Nagar, Hyderabad – 500038.