F.No 4-14/97-DC (ADR)

From:

The Drugs Controller General (India)
Directorate General of Health Services,

FDA Bhawan, Kotla Road,
New Delhi-110002.
Dated the 21 JUL 2009

To

M/s. Sipra Labs Limited,
Sanathnagar Industrial Area, Sanathnagar,
Hyderabad-500018.

Sub: Bioavailability/Bioequivalence Study for new drug formulations - Regarding.

Dear Sir,

Please refer to your letter number SLL/MD/05/2009-10 dated 09/4/2009 on the above subject.

As per documentation submitted by you, this Directorate, will accept the protocol and bioavailability / bioequivalence study reports of New drugs from your laboratory subject to following conditions:-

1. Specific Protocol for conducting BE/BA studies with new drug formulations should be cleared by Institutional Ethics Committee and then got approved from this office on case to case basis.

2. After one year there will be assessment of performance of the said study center for continued acceptance of reports.

Yours faithfully,

(A.B.Ramteke)
For Drugs Controller General (India)

Copy to:-

The Dy. Drugs Controller (I),
CDSCO (South Zone),
2nd Floor, Shastri Bhawan Annexe,
26, Haddows Road, Chennai-6