F. No.12-01/12-DC (Pt.133)
DIRECTORATE GENERAL OF HEALTH SERVICES
OFFICE OF DRUGS CONTROLLER GENERAL (INDIA)
(NEW DRUG DIVISION)

FDA Bhawan, Kotla Road,
New Delhi
Dated: 26 APR 2013

To

All Zonal Offices of CDSCO

Subject: Monitoring of Clinical Trials - regarding.

It has been decided that the zonal offices of CDSCO should keep the records of the details of names, qualification etc. of Investigators, and clinical trial sites falling under their Jurisdiction and also constitute Expert Committees to conduct clinical trial inspections. The Expert Committee along with drug inspectors shall visit the clinical trial sites at least once a year to verify the compliance with Schedule Y, GCP Guidelines and other applicable regulatory requirements.

In view of above, you are requested to maintain the records of the details of names, qualification etc. of Investigators, and clinical trial sites falling under your jurisdiction and also constitute Expert Committees to conduct clinical trial inspections. You are also requested to ensure that the Expert Committee alongwith drug inspector visits the clinical trial sites under the respective jurisdiction at least once a year to verify the compliance of the Investigators, clinical trial sites as per Schedule-Y of D rugs & Cosmetics Rules, GCP Guidelines and other applicable regulatory requirements.

Yours faithfully

(Dr. G.N. Singh)
Drugs Controller General (India)