

File No. ECR/Misc/Indt EC/007/2013

Directorate General of Health Services
O/o Drugs Controller General (India)

FDA Bhawan, Kotla Road,
New Delhi – 110 002

Dated: **30 JUL 2013**

NOTICE

Sub: Independent Ethics Committees in respect of periodic review of the ongoing clinical trials.

This office has registered the Independent Ethics Committees subject to the condition that "The Ethics Committees shall review and approve only the study protocols and relate documents of Bioavailability/Bioequivalence studies of the approved drug molecules and also carry ongoing review of such studies".

It has been decided that Independent Ethics Committees which have been registered for conducting Bioavailability(BA)/Bioequivalence (BE) studies only can conduct periodic review of the ongoing clinical trials already approved by them. However, no new clinical trial shall be reviewed and approved by such independent Ethics Committees.


(Dr. G. N. Singh)

Drugs Controller General (I)

To,

1. All zonal and Subzonal offices of CDSCO
2. Web site of CDSCO