F. No.BA-BE/Misc/01/2016
Directorate General of Health Services
Office of Drugs Controller General (India)

Date: 05 SEP 2016

NOTICE

Subject: Extension of validity of approval of BA/BE Centre from 01 (one) year to 03 (three) years.

Bioavailability and Bioequivalence studies are conducted in healthy human volunteer in study centre. Study centres requires Clinical Pharmacology Unit (CPU) and Bio analytical laboratory, which is being approved by CDSCO as per Schedule Y, L1 of Drugs and Cosmetics Rules, Indian GCP and Bioavailability/ Bioequivalence study guidelines issued by this office. Currently approval of the Bioavailability/Bioequivalence study centre along with Bioanalytical laboratory to conduct Bioavailability/ Bioequivalence studies is given by CDSCO after inspection of the centre for one year. Renewal of the approval is being issued again after assessment of performance by an inspection of the site after one year.

In order to facilitate ease of business, it was decided in consultation with the stakeholders and with the concurrence of the Ministry of Health and Family Welfare (MoHFW) that validity period of approval of Bioavailability, Bioequivalence study centre and Bioanalytical laboratory will be extended from one year to three years subject to the following conditions:

(i) Periodic surveillance audit shall be carried out.
(ii) Any major/critical changes with respect to site and systems during the validity shall be submitted to CDSCO immediately.
(iii) Audit report of international regulatory authority/WHO shall be submitted to the CDSCO after receiving the observations/reports.
(iv) BA/BE study centre shall submit renewal application at least 4 month before the expiry of the present approval.

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

To:

1. Concerned associations e.g. ACRO, CIPI, FICCI, IDMA, ISCR, OPPI
2. All stakeholders.

Copy to:

1. PS to JS(KLS).
2. All JDC(I), DDC(I), CDSCO Headquarters.
3. All DDC(I), Zonal and subzonal offices CDSCO.
4. Guard File.