

7-5/2020/Misc/070
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi- 110002.

Dated:- 30/4/2020

Circular

Subject: Extension of validity of BA/BE Study Centres - Regarding

To conduct the Bioavailability and Bioequivalence study in of New Drugs in human in the country, the centre shall be registered under rule 44 of New Drugs and Clinical Trial (NDCT) Rules 2019. Before the implementation of the NDCT Rules, 2019 on 19/03/2019 the permissions were issued to the study centers to conduct the BA-BE studies having the validity of 3 years. However all such centers permitted by CDSCO before implementation of the NDCT Rules, 2019, need to be registered under the NDCT Rules.

This office has received representations from stakeholders requesting to extend validity of BA/BE study Centers registration whose validities are expiring between now and August 2020 in view of COVID-19 outbreak.

The matter has been examined by committee of CDSCO in light of pandemic COVID-19, and it is clarified that, in accordance with NDCT Rules, 2019, if application for the renewal of registration of BA/BE study centre in Form CT-08 is received by CDSCO ninety days prior to the date of expiry, the registration shall continue to be in force until order passed by the said authority on the application.

In view of above, the BA/BE study Centres who has already applied or will apply for renewal of the registration 90 days prior to the date of expiry of its existing registration, in Form CT-08 along with requisite fees and documents, the registration of such centers will remain valid until any order is issued by CDSCO otherwise.



Dr. V. G. Somani
Drugs Controller General (India)

To
All stakeholders through CDSCO website

Copy to
PS to JS (R), MoHWF, GOI, Nirman Bhawan, New Delhi