F. No. 12-09/BA-BE/2020/Misc-02/DC
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(BA/BE Division for Export)

FDA Bhawan, New Delhi,
Date: 27/11/2020

NOTICE

Subject: Processing of Post Approval Changes to BA/BE permission issued in Form CT- 07 and Import licence issued in Form CT-17 for Export - regarding.

Permission to conduct BA/BE study of New Drug for export purpose is granted by Central Licensing Authority (CLA), as per the New Drugs and Clinical Trials Rules, 2019, in Form CT-07, Import licence in Form CT-17 is also granted for import of study drug for this purpose.

The conditions of permission for conduct of BA-BE study are prescribed under Rules 35 of the said Rules. Detailed requirements and guidelines in this regard are also prescribed under Fourth Schedule of the said Rules.

Subsequent to the permission in Form CT-07, CDSCO receives various application/ notifications for post approval changes which includes changes in protocols, study site, Principal Investigator, etc.

In order to streamline the processing of such applications/notification, it has been decided that, such cases of Post Approval Changes will be processed by CDSCO within 15 working days of receipt of application for approval / acknowledgement or otherwise.

V.G.S.

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

To,
All stakeholders
IT-Cell for posting on website