

F.No.PG/298/import/TL/2019-DCGI
Government of India
Directorate General of Health Services.
Central Drugs Standard Control Organization
(Public Grievance Cell)

FDA Bhawan, Kotla Road
New Delhi-110002,

Dated 20/2/2020

NOTICE


Subject: Grant of permission in Form CT-11/ CT-14/ CT-15/ CT-17 under New Drugs and Clinical Trials Rules 2019; - reg.

Under the provision of New Drugs and Clinical Trials Rules 2019, CDSCO receives applications for grant of permission in Form CT-11/ CT-14/ CT-15/ CT-17 for manufacturing/ import of new drugs for test and analysis, CT or BA/BE study.

Concerns have been raised on certain aspects of submission and processing of such applications.

In this regard, recently, a Notice No. 12-01/20-DC (Pt. 51) has been issued on 18.02.2020 giving clarity on submission and processing of such applications for grant of permission to manufacture trial batches of new drug or investigational new drug for test and analysis, CT or BA/BE study.

Further, to streamline the processing, it has been decided that, such applications will be processed by CDSCO (HQ)/ Zonal/Sub-zonal offices, as the case may be, within 07 working days of receipt of the applications.


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

To,

1. All officers of CDSCO (HQ)/ Zonal / Sub-zonal office.
2. All Stakeholders.