

X-11026/08/2018-BD
Central Drugs Standard Control Organization
Office of Drugs Controller General India
FDA Bhawan, New Delhi-110002

Dated: 15 JAN 2018

Notice

The central Drugs Standard Control Organization (CDSCO) in pursuance to implementation of E—Governance, has launched an online portal 'SUGAM' (www.cdsconline.gov.in) on 14.11.2015.

A reference is also invited to the stakeholders meeting held on 10.01.2018 wherein it has been agreed upon that, filling of application for Clinical Trial, Marketing Authorization, Registration Certificate and Import License for r-DNA Derived Drugs will be initiated with effect from 01.02.2018 in SUGAM portal.

In view of above, it has been decided that applications pertaining to Clinical Trial, Marketing Authorization, Registration Certificate and Import License for r-DNA Derived Drugs shall be accepted only through online mode from 1st Feb, 2018 and no offline applications will be accepted thereafter.


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

To-

1. All r-DNA Derived Drugs Manufacturers/Importers/CROs.

CC-

1. CRU Section
2. Guard file
3. Website of CDSCO