F.No. 12-01/19-DC(PT-195)

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
Office of Drugs Controller General (India)
(New Drugs Division)

FDA Bhawan, Kotla Road,
New Delhi-110002
Date: 21/2/2020

NOTICE

Subject: Pre-submission meeting – reg.

Under the provision of New Drugs and Clinical Trials Rules 2019, any person who intends to make an application for grant of licence or permission for import or manufacture of new drugs or to conduct clinical trial may, request by making an application in writing, for a pre-submission meeting with the Central Licencing Authority or any other officer authorised by the Central Licencing Authority for seeking guidance about the requirements of law and procedure of such licence or permission of manufacturing process, clinical trial and other requirements.

In this regard, it is to mention that as and when application for a pre-submission meeting is received, meetings are conducted and guidance about the requirements of law and procedure for licence or permission of manufacturing process, clinical trial and other requirements are provided by CDSCO in writing to the applicant, in accordance with the New Drugs and Clinical Trials Rules, 2019.

Yours faithfully,

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

To,

1. **All Stakeholders.**