

F. No. 14-07/2012-DC  
Government of India  
Directorate General of Health Services  
Central Drugs Standard Control Organization  
(Legal Cell)

FDA Bhawan, Kotla Road  
New Delhi, dated:

**Notice** 14 NOV 2018

Subject: Writ Petition (Civil) No. 33 of 2012 titled as Swasthya Adhikar Manch Vs Union of India & Anr. pending before the Hon'ble Supreme Court at New Delhi- Reg.

The Ministry of Health and Family Welfare, Government of India has issued Draft rules the **New Drugs and Clinical Trials Rules, 2018** vide G.S.R.104(E) dated 1<sup>st</sup> February, 2018. The Draft Rules are available on the website of the Central Drugs Standard Control Organization, (<https://cdsco.gov.in/opencms/opencms/en/Notifications/Gazette-Notifications/>) of the Ministry of Health and Family Welfare. 45 days time was given to file objections and suggestion to the Draft Rules.

As per the Hon'ble Supreme Court order dated 12.09.2018 in the subject matter, a corrigendum will be issued inviting objection and those who are interested may file their objection to the Draft Rules. Accordingly, a meeting was held in FDA Bhawan on 05.11.2018 with stakeholders. However, some of the parties including the petitioners have requested for another date to present their views.

Accordingly, the interested stake holders are hereby invited to submit their views or any objections/ suggestions on the draft New Drugs and Clinical Trials Rules, 2018 and visit this office for personal hearing on 22.11.2018 at 2:00 PM, Conference Hall, 1<sup>st</sup> Floor, FDA Bhawan, Kotla Road, ITO, New Delhi-110002.

This notice may be treated as corrigendum as per the Hon'ble Supreme Court order dated 12.09.2018



(Dr. S. Eswara Reddy)  
Drugs Controller General (India)

Copy to

1. PPS to DGHS, Nirman Bhawan, New Delhi
2. PPS to AS & DG (CGHS), Nirman Bhawan, New Delhi
3. PS to JS(R)
4. PS to Director (Drugs)
5. Dr. K. Bangarurajan, JDC(I) CDSCO HQ.