

File No. 4-146/2007-DC  
(Govt. of India)  
Directorate General of Health Services  
Central Drugs Standard Control Organization  
(FDC Division)

Dated:

11.2 APR 2019

To,

All State/UT Drugs Controllers

**Subject:** Consideration of directions of Hon'ble Supreme Court of India in the case of 294 FDCs in respect of FDCs which require further generation of data -regarding.

Sir,

This is in continuation to this Directorate letter of even number dated 27.02.2019 on the subject mentioned above. As you are aware that New Drugs and Clinical Trials Rules-2019 have been published vide GSR 227(E) dated 19.03.2019 for regulation of new drugs and clinical trials for human use. As per the said Rules, the applicants for new drugs are required to submit the fees as specified in sixth schedule of these Rules.

You are therefore requested to direct all the applicants to submit their applications alongwith requisite fees as specified in the sixth schedule of New Drugs and Clinical Trials Rules, 2019.

Yours faithfully,

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

**Copy to:-**

1. PS to JS(R), Ministry of Health and Family Welfare, Nirman Bhawan, New Delhi.
2. All Zonal/Sub Zonal offices of CDSCO.
3. Indian Drug/Pharmaceuticals Association Forum.
4. Website of CDSCO.