

File No. 4-01/2013-DC (Misc. 13-PSC) (Pt. II)  
Govt. of India  
Directorate General of Health Services  
Central Drugs Standard Control Organization  
(FDC Division)

Dated:

12 APR 2019

To,

All State/UT Drugs Controllers

**Subject: Procedure to be followed for subsequent applicant in respect of FDCs declared as rational by Prof. Kokate Committee and approved by DCG(I) -regarding.**

Sir,

This is in continuation to this Directorate letter of even number dated 12.12.2018 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 ensure that all the applicants shall 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.