

File No. 4-01/2013-DC (Misc. 13-PSC)
Directorate General of Health Services
Office of Drugs Controller General (India)
(FDC Division)

26 OCT 2016

OFFICE MEMORANDUM

Subject: Approval of the safety and efficacy of Fixed Dose Combinations (FDCs) permitted for manufacture for sale in the country without due approval from office of DCG (I) - regarding.

The State Drugs Controllers vide letter of even no. dated: 15.01.2013 were requested to ask the concerned manufacturers to prove the safety and efficacy of such FDCs before CDSCO within a period of 18 months, failing which such FDCs will be considered for being prohibited for manufacture and marketing in the country.

Accordingly, various applications for such FDCs were received by this office which were examined by Prof. Kokate Committee.

Further, processing of applications is being done as per the recommendations of Kokate Committee. In pursuance of report of the Committee dated 27.5.2016, show cause Notice were issued to the applicants for submitting the reply within 30 days for the FDCs categorized as irrational under Category 'a'.

The matter was further examined by the Ministry of Health & Family Welfare and it has been decided that reply to these show cause notices may be submitted within 90 days from the date of issue of such letter instead of 30 days.



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

Copy for necessary action to:-

1. JS (R), Ministry of Health and Family Welfare, Nirman Bhawan, New Delhi.
2. All State/UT Drugs Controllers
3. All Zonal/Sub Zonal offices of CDSCO
4. CDSCO, Website