

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

FDA Bhawan, Kotla Road
New Delhi-110002

Dated: 05 JUN 2014

To,
All State/UTs Drug Controllers


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.

Please refer to this office letter of even no. dated: 15.01.2013 under which you were requested to ask the manufacturers to prove the safety and efficacy of such FDCs which were licensed by the State Licensing Authorities without due approval of DCG(I), within a period of 18 months.

An issue has been raised regarding applicability of above requirements for FDCs licensed by State Licensing Authorities before 21.09.1988, after which all relevant provisions relating to New Drugs were introduced in Drugs and Cosmetics Rules.

The matter has been considered by this office and it is hereby clarified that requirements of proving safety and efficacy as mentioned above is not applicable for such FDCs which are licensed prior to 21st September 1988.

Yours faithfully,


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

Copy to:-

1. PPS to ASDG, Ministry of Health and Family Welfare, Nirman Bhawan, New Delhi.
2. PPS to DGHS, Ministry of Health and Family Welfare, Nirman Bhawan, New Delhi.
3. All Zonal/Sub Zonal offices of CDSCO.