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: 20-06-13

To,

All State/UTs Drug Controllers

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

Sir,

The State Drug Controllers were requested by this office vide letter of even number dated 15.01.2013 that the manufacturers are required to prove safety and efficacy of such FDCs which are licensed by State Licensing Authorities without the prior approval of DCG(I) before the office of DCG(I) within 18 months. In this connection a subsequent letter was issued on 5.7.2013 that in order to examine safety and efficacy of such FDCs in a timely manner, the manufacturers should submit their applications to the office of DCG(I) by 30.8.2013 in Form 44 alongwith requisite fee and supporting documents.

A drug manufacturers association in its representation has stated that State Licensing Authorities in some States have threatened to cancel the licenses/ renewals if data is not submitted by 30th August 2013. In this connection, it is clarified that 30th August 2013 is the date by which the applicants are required to submit their applications to the office of DCG(I). The question of taking action for not proving safety and efficacy of such FDCs before DCG(I) would be decided by this office in accordance with the directions issued on 15.01.2013.

It is expected that large number of such applications would be submitted to the office of DCG(I). In order to facilitate timely submission of applications by the manufacturers, it has been decided that the applicants may submit their applications in the zonal / sub-zonal offices of CDSCO or at the CDSCO (HQ). The manufacturers may therefore be requested to make their applications for the purpose of proving safety and efficacy of the FDCs at CDSCO (HQ) or respective zonal / sub-zonal offices of CDSCO under whose jurisdiction manufacturers are located.

You are requested to inform manufacturers in your States accordingly.

Yours faithfully,

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

Copy to:-

1. All Zonal/Sub Zonal offices of CDSCO.
2. US(D), Min. of Health and Family Wefare, Nirman Bhawan, New Delhi