File no. 4-01/2013-DC (Misc. 13-PSC)
Directorate General of Health Services
Ministry of Health & Family Welfare
O/o Drugs Controller General (I)

FDA Bhawan, New Delhi
Dated: 3 FEB 2014

To

All State/UTs Drugs Controller

Sub: 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) – Reg.

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 the 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 05.07.2013 and 26.08.2013 that inorder to examine the safety and efficacy of such FDCs in timely manner, the manufacturer should submit the application to the officer DCG(I) or respective zonal/sub-zonal offices of CDSCO by 30.08.2013 in Form 44 along with requisite fees and supporting documents.

The CDSCO has received applications of many such FDCs from the manufacturers for the regularization in the country. In order to evaluate these applications, 10 Expert Committees have constituted to examine the rationality as well as safety and efficacy of the FDCs.

In view of the above, you are requested to advise all the concerned manufactures under your jurisdiction to submit additional documents, if any, which they have not submitted earlier in their application so that the same may be included in their application before placed the matter to the Expert Committee.

Yours faithfully,

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

Copy to :

1. PPS to Secretary (Health)/ PPS to AS&DG (CGHS) /PS to JS(R).