

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

**FDA Bhawan, Kotla Road
New Delhi-110002**

Dated: 21 MAR 2013

To,

The States/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.

Sir,

This has reference to this office letter of even no. dated: 15.01.2013 whereby all the State Drug Controllers were requested to ask the concerned manufacturers in their States to prove the safety and efficacy of the FDCs falling under definition of "New Drug" licensed by the State Licensing Authority without prior approval from DCG (I).

Action taken in this regard may be communicated to this office.

Yours faithfully,


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