Reminder

F. No. 04-01/2013-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: 01 MAR 2017

NOTICE

Subject: Examination for Safety and Efficacy of Fixed Dose Combinations (FDCs) licensed for manufacture for sale in the country without due approval from office of DCG (I)-regarding.

Reference: 1. This Directorate letter no. 4-01/2013-DC (Misc.-PSC) dated: 15.01.2013.
2. This Directorate Notices dated: 17.06.2016 and 01.09.2016.

This is in continuation to this office earlier letters addressed to individual firms as well as notices dated: 17.06.2016 and 01.09.2016 whereby all concerned stakeholders were requested to submit phase IV trial protocol based on recommendations of Expert Committee. In this regard, it has been observed that most of the companies are yet to submit Phase IV protocol.

It is therefore again requested that all the applicants who have not yet submitted Phase IV trial protocols shall submit the same in accordance with Schedule Y of Drugs and Cosmetics Rules, 1945.

This may be treated as regulatory reminder for further necessary action.

Yours faithfully,

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

Copy 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. Manufacturing Associations: IDMA/OPPI/IPA/CIPI/FOPE etc.