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: 17 JUN 2016

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.

Please refer to this office letter no. 04-01/2013-DC (Misc. 13-PSC) dated: 15.01.2013 whereby State Licensing Authorities were requested to ask the concerned manufacturers to prove safety and efficacy of FDCs within a period of 18 months which were permitted by SLAs without due approval from the office of DCG(I). After examination of such applications received by CDSCO in consultation with Expert Committee, concerned firms were requested to submit Phase IV clinical trial protocol as per usual procedure.

In this regard, a considerable time has already been given to these firms, however, it has been noted that most of these companies are yet to submit Phase IV clinical trial protocol. Therefore, it is again requested that applicants who have not yet submitted Phase IV trial protocol shall submit the same immediately.

The Phase IV clinical trial protocol may be submitted as per appendix X of Schedule Y of Drugs and Cosmetics Rules, 1945.

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.