F.No.4-01/2013-DC(PSC-13PSC)
Directorate of General of Health Services
Central Drugs Standard Control Organization
(FDC Division)

Dated: 17 OCT 2013

NOTICE

Subject: Examination of safety and efficacy of FDCs licensed for manufacture for sale in the country without due approval from DCG(I)-regarding

This has reference to this Directorate letter of even number dated 15.1.2013 on the subject cited above. In this regard, various applications filed by the manufacturers have been examined by the Expert Committee constituted for the purpose and accordingly the reports were published on the website of this office. The FDCs recommended by Kokate Committee are indicated in category 'c' whereas FDCs for which Phase IV clinical trial is required, are indicated in category 'd'.

It is stated that those applicants, who have paid fees and applied to CDSCO and who are having their products licensed by SLAs prior to 1.10.2012 and till date have not received any communication or letter from this office are required to bring to the notice of this office preferably on mail at fdcdivision@gmail.com along with the proof of application with Treasury challan copy and SLA product permission issued prior to 1.10.2012 so that necessary action can be taken in such cases.

This is issued to facilitate the disposal.

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