कार्यालय
औषधि नियंत्रक (राज.) जयपुर
12 SEP 2013
क्रमांक To,

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

FDA Bhawan, Kotla Road
New Delhi-110002
02 SEP 2013

All State/UTs Drug Controllers

Subject: **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)-Regarding**

Sir,

All the State Drug Controllers were requested by this office vide letter of even number dated 15.1.2013 that the manufacturers are required to prove 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 5.7.2013 that in order to examine safety and efficacy of such FDCs in a timely manner, the manufacturers should submit their applications to the office of DCG(I) by 30.8.2013 in Form 44 along with requisite fee and supporting documents.

However, some of the drug manufacturers associations have represented that they are in a process of preparing and submitting applications. However there is a bottleneck situation happening during obtaining requisite challan from the Bank of Baroda as there are multiple products of each manufacturer. Accordingly, these manufacturers have requested to extend the timeline i.e. 30th August 2013 so that they are able to submit their applications.

The concern raised as mentioned above has been considered by this office. It has been decided that the timeline for submitting such applications may be extended by one month i.e. by 30th Sept. 2013. You are therefore requested to ask manufacturers under your jurisdiction to submit these applications in respect of such FDCs by one month i.e. by 30.09.2013. In case the applications of such FDCs are not submitted by any manufacturer by 30th Sept. 2013, it will be presumed that they are not willing to prove the safety and efficacy of such FDCs before the office of DCG (I).

Yours faithfully,

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

Copy to:-
1. All Zonal/Sub Zonal offices of CDSCO.
2. US(D), Min. of Health and Family Welfare, Nirman Bhawan, New Delhi

GOVERNMENT OF RAJASTHAN
DRUGS CONTROL ORGANISATION, SWASTHYA BHAVAN, TILAK MARG, JAIPUR

No. DC/D-1/FDC/2013/ 411 Dated: 16.09.2013

Copy of above received letter forwarded to following for information & needful action:-

1. Drugs Controller General (I) CDSCO: FDA Bhawan, Kotla Road, New Delhi.
2. Dy. Drugs Controller (I) CDSCO (NZ) Ghaziabad.
3. Dy. Secretary to Government, Medical Health (Gr.II) Department, Jaipur.
4. Members, Formulation Committee, Hqrs/Asst Drug Controllers, Hqrs.
5. All Pharmaceuticals Manufactures (Formulations) Rajasthan State through their E-mail.
6. President, Rajasthan Pharmaceutical Manufacturers Association, SP-2, 22- Godam Industrial Estate, Jaipur.
7. Desk D-I/D-II/A-I/A-II/A-III, Hqrs.
8. Incharge Server Room Hqrs; with request to upload this letter on department website.

13/9/2013
Drugs Controller
Rajasthan, Jaipur