

File No.4-01/2013-DC (Misc. 175)
Directorate General of Health Services
Office of Drugs Controller General (India)
(FDC Division)

FDA Bhawan, Kotla Road
New Delhi-110002

Dated:

Office Memorandum

06 NOV 2013

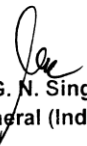
Subject: Exemption of Veterinary products from the purview of DCG(I) letter dated 15.1.2013-regarding.

Reference is invited to the representations received from various manufacturers of the Fixed Dose Combinations for veterinary use on the above subject.

Manufacturers have requested for exemption of requirements of proving safety and efficacy of FDCs as issued by this office letter no. 4-01/2013-DC (Misc. 13-PSC) dated: 15.01.2013 within a period of 18 months before the office of DCG(I), licensed by State Licensing Authorities without prior approval of DCG(I).

With the concurrence of the Ministry of Health and Family Welfare, it is hereby clarified that the letter dated 15.1.2013 issued by this office is with respect to the Fixed Dose Combinations for human use. It does not cover the Fixed Dose Combinations for veterinary use.

However, applications of Fixed Dose Combinations of Veterinary products received by CDSCO would be examined separately on routine basis in consultation with Department of Animal Husbandry, Dairying and Fisheries, Ministry of Agriculture and Cooperation as practiced for any new veterinary product.


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

To,

1. All States/UTs Drugs Controllers
2. All Zonal/Sub Zonal Offices of CDSCO.

Copy to:-

US(D), Ministry of Health and Family Welfare, Nirman Bhawan, New Delhi.