

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

Dated: 05 OCT 2017

NOTICE

Subject: Procedure to be followed for subsequent applicants in respect of FDCs declared as rational by Kokate Committee and approved by DCGI-regarding.

References: 1. This Directorate's letter no. 4-01/2013-DC (Misc. 13-PSC) dated 15.01.2013. 2. This Directorate's notice no. 4-01/2013-DC (Misc. 13-PSC) dated 16.03.2017. 3. This Directorate's notice no. 4-01/2013-DC (Misc. 13-PSC) dated 05.06.2017.

This is in continuation to this Directorate notice of even number dated 05.06.2017 whereby pathway for clearance of cases with respect to subsequent applicants in respect of FDCs declared a rational by Prof. Kokate Committee and approved by DCGI was clarified.

It was also requested that all the manufacturers who are already holding licence from State Licensing Authority for such FDCs and did not obtain NOC from DCGI are required to submit their applications to this Directorate at the earliest but not later than 4 months, failing which their applications will not be considered and their licenses will be considered as without legal validity.

In view of above, it is again requested that such manufacturers who are yet to submit their applications shall submit the same to this Directorate within 2 months as per the procedure laid down under this Directorate's notice of even number dated 05.06.2017.

Yours faithfully,


(Dr. G. N. Singh)

Drugs Controller General (India)

To:-

All State/UT Drugs Controllers/All Zonal/Sub Zonal offices of CDSCO.

Copy to:-

1. PS to JS(R), Ministry of Health and Family Welfare, Nirman Bhawan, New Delhi.
2. Drug Manufacturing Associations: IDMA/OPPI/IPA/CIPI/FOPE etc.