

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

Dated: 16 MAR 2017

NOTICE

Subject: Procedure to be followed for subsequent applicant in respect of FDCs declared as rational by Prof. Kokate Committee and approved by DCG(I) -regarding.

This is with reference to this office letter dated 15.01.2013 whereby all the State/UT Drugs Controllers were requested to ask the concerned manufacturers in their State to prove the safety and efficacy of FDCs within 18 months which were permitted by State Licensing Authorities without due approval from the office of DCG(I).

After examination of such applications received, in consultation with Prof. Kokate Committee constituted by Ministry of Health and Family Welfare, concerned manufacturers were issued NOC for continued manufacturing and marketing in case of FDCs held as rational.

The list of such FDCs for which NOCs have been issued so far in respect of the applicants under 18 months policy decision is already available on CDSCO website i.e. www.cdsco.nic.in


Subsequently, this Directorate received representations from various stake holders for issuance of permission to subsequent applicants of such FDCs which have been held to be rational and approved by DCG(I) (i.e. those manufacturers who have license from SLA, but did not obtain NOC from DCG(I) or those manufacturers who intend to manufacture these FDCs henceforth).

The matter was examined by this Directorate in consultation with the Ministry of Health and Family Welfare. Accordingly, the pathway to be followed for clearances of such subsequent applications by CDSCO is as under:

1. The applicants who wish to manufacture such FDCs will apply in Form 44 with a fee of Rs. 15000/- to the CLA through TR (6) challan clearly specifying whether he is already holding product permission from SLA, indicating date of permission or intends to obtain a fresh (new) permission.
2. The period of 4 years to be reckoned from the date of approval of the Kokate Committee recommendation by the Central Government in respect of particular FDC.

3. The NOC from the Central Licensing Authority under Rule 21(b), as per Drugs and Cosmetics Rules, shall be issued within 30 working days, failing which it shall be deemed to have been approved. Copy of NOC will be mailed to concerned SLA also.
4. State Licensing Authority shall permit the manufacturing of such FDCs, if other conditions of license under Drugs and Cosmetics Rules, which need to be verified by SLA, are found to have been fulfilled. The SLAs shall verify the quality of such FDCs of each applicant/manufacturer, before grant of license as per Drugs and Cosmetics Rules, 1945; and
5. Every manufacturer permitted to manufacture these FDCs shall submit the periodic safety update reports (PSURs) as per Schedule Y of the Drugs and Cosmetics Rules to the Licensing Authority under Rule 21(b) i.e. DCG(I). Failure to submit the PSURs shall be considered as contravention of these Rules.

In view of above, all the State Licensing Authorities, manufacturers and concerned stakeholders are requested to follow the above procedure for clearances of the cases w.r.t subsequent applicants in respect of FDCs declared as rational by Prof. Kokate Committee and approved by DCG(I).


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

Copy to:-

1. PPS to Secretary/AS(F&D)/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.