F. No. 04-01/2013-DC (Misc. 13-PSC) (Pt. II)
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(FDC Division)

FDA Bhawan, Kotla Road,
New Delhi

Dated: 7/2/2020

NOTICE

Subject:- Pathway for subsequent manufacture of category 'd' FDCs as per Prof. Kokate Committee Report-extension in time limit for submission of application-reg.

This is in continuation to this Directorate notice of even number dated 22.05.2019. As per this said letter, manufacturers who are already holding licenses from State Licensing Authorities for such FDCs before 01.10.2012 and did not apply to DCG (I) were required to submit their applications to this Directorate. The date for filing such applications expired on 22.11.2019.

Meanwhile, this Directorate received various representations requesting for extension of time for submission of such applications. Accordingly, it has been decided that manufacturers/stakeholders who were holding license prior to 01.10.2012 may submit their applications w.r.t category 'd' FDCs by 30.05.2020.

In view of above, without prejudice to legal validity of such product licenses, all the concerned manufacturers/stakeholders are requested to submit their application alongwith requisite fees as specified in the Sixth Schedule of the New Drugs and Clinical Trial Rules, 2019 by 30.05.2020.

(Dr. V. G. Somani)
Drugs Controller General (India)

Copy to:-

1. PS to JS(R), Ministry of Health and family Welfare, Nirman Bhawan, New Delhi
2. All State/UT Drugs Controllers
3. CDSCO Zonal and Sub-Zonal offices
4. Indian Drug/Pharmaceuticals Association Forum
5. Web site of CDSCO