File No. 4-01/2013-DC (Misc. 13 PSC Part II)
Govt. of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(FDC Division)

FDA Bhawan, Kotla Road
New Delhi-110002
Dated: 19 AUG 2021

NOTICE

Subject: Evaluation of certain pre 1988 permitted Fixed Dose Combinations (FDCs) de novo for manufacture for sale in the country without due approval from Central Licensing Authority -regarding.

This is in continuation to this Directorate notice of even number dated 26.07.2021 on the subject cited above whereby all the concerned stakeholders were requested to submit the information in the prescribed format by 25.08.2021 till 5:00 PM.

In this regard, various representations were received requesting for further extending the timeline for submission of the information. The issue was considered by this office and it has been decided that concerned stakeholders may be permitted to submit the information in the prescribed format by 25.10.2021 till 5:00 PM.

In view of above, all the concerned stakeholders may note that date for submission of information in the prescribed format along with relevant supporting documents in hard copy as well as soft copy (i.e. in C.D. Form) is extended upto 25.10.2021 till 5:00 PM.

(Sanjeev Kumar)
Deputy Drugs Controller (India)

Copy to:

1. Dr. M.S. Bhatia, Prof. & Head, D/o Psychiatry, UCMS, New Delhi, Chairman, Expert Committee.
2. Indian Drug/Pharmaceuticals Association Forum.
3. Website of CDSCO for information and necessary action by concerned stakeholders.