

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

FDA Bhawan, Kotla Road
New Delhi-110002
Dated:

21 DEC 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.

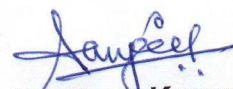
This is in continuation to this office notice dated 26.07.2021 and 19.08.2021 on the subject above, wherein all concerned were requested to submit the requisite information in the prescribed format in hard as well as in soft copy.

Accordingly, the expert committee invites the concerned stakeholders for hearing through WebEx (Video Conference) on 29th and 30th DEC 2021 w.r.t FDCs mentioned under Annexure A. Date and time of hearing is also mentioned under Annexure A.

It is requested that the concerned stakeholders may kindly make it convenient to give a presentation through WebEX (Video Conference) before the Expert Committee on these FDCs. In the event that the Stakeholder does not attend the hearing, the Committee reserves the right to make its decision on the basis of information available before it.

You are requested to kindly confirm your participation through e-mail at fdc@cdsco.nic.in by 27.12.2021 and also submit Power point presentation (PPT) along with the presenter details, Mobile number, email ID, S.No of the FDC as per Annexure-A.

This is for information of all the concerned.



(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. To all the expert committee members.
3. Indian Drug/Pharmaceuticals Association (IDMA/FOPE/CIPI/IPA/OPPI, etc.,) with the request to communicate it to your members and publicize it widely so that all concerned can avail this opportunity.
4. Website of CDSO for information and necessary action by concerned stakeholders.

Annexure-A

| S.No. | FDC Name | Date and Time of Hearing |
|-------|--|---------------------------------------|
| 1 | Nimesulide +Paracetamol dispersible tablets | 29.12.2021 11:30 AM to 06:00 PM |
| 2 | Paracetamol + Phenylephrine + Caffeine | |
| 3 | Amoxicillin + Bromhexine | |
| 4 | Pholcodine + Promethazine | |
| 5 | Imipramine + Diazepam | |
| 6 | Chlorpheniramine maleate+ Dextromethorphan+ Dextromethorphan + Guaifenesin + Ammonium chloride + Menthol | |
| 7 | Chlorpheniramine Maleate +Codeine syrup | |
| 8 | Ammonium Chloride + Bromhexine + Dextromethorphan | |
| 9 | Bromhexine +Dextromethorphan +Ammonium Chloride +Menthol | |
| 10 | Dextromethorphan +Chlorpheniramine + Guaifenesin +Ammonium Chloride | |
| 11 | Caffeine +Paracetamol +Phenylephrine + Chlorpheniramine | 30.12.2021 11:30 AM to 06:00 PM |
| 12 | Paracetamol + Bromhexine +Phenylephrine +Chlorpheniramine + Guaifenesin | |
| 13 | Salbutamol + Bromhexine | |
| 14 | Chlorpheniramine +Codeine phosphate +Menthol syrup | |
| 15 | Phenytoin + Phenobarbitone sodium | |
| 16 | Paracetamol + Propyphenazone + Caffeine | |
| 17 | Ammonium Chloride + Sodium Citrate + Chlorpheniramine Maleate + Menthol | |
| 18 | Salbutamol + Hydroxyethyltheophylline (Etofylline) + Bromhexine | |
| 19 | Chlorpheniramine Maleate + Ammonium Chloride + Sodium Citrate | |