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: 26 JUL 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.

Hon'ble Supreme Court of India in its judgements dated 15.12.2017 and 14.02.2019 passed an order that the Central Government may, if it so chooses, de novo carry out an inquiry as to whether fixed dose combinations licensed prior to 1988 should be the subject matter of a notification under Section 26A of the Drugs and Cosmetics Act, 1940 (23 of 1940).

In pursuance of above observations, the matter has been duly considered by the Central Government. Accordingly, an Expert Committee has been constituted under the Chairmanship of Dr. M.S. Bhatia, Professor & Head, D/o Psychiatry, University College of Medical Sciences, New Delhi to examine these FDCs.

In this regard, a meeting of the expert committee was held and the Committee has desired that the concerned stakeholders shall submit the information on the rationality, safety and efficacy w.r.t. these FDCs as per the prescribed format which is enclosed herewith along with the list of these FDCs.

Accordingly, all the concerned stakeholders are hereby requested to submit the information in the prescribed format along with relevant supporting documents in hard copy as well as soft copy (i.e. in C.D. Form) to this office latest by 25th Aug 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.

Format for submission of information on FDC to Expert Committee

(Submit all the information including full text of references as hard copy as well as soft copy)

S. No.	Item	Response
1	Name and Address of the Applicant	
2	Name of the FDC	
3	Copy of Product manufacturing license	
4	Composition of the FDC	
5	Indication	
6	International Status	
7	Rationality (to be submitted w.r.t. FDC only, not on individual ingredients)	
8	Brief on Safety and Efficacy Data (along with published data published in peer reviewed journal w.r.t FDC only, not on Individual ingredients)	
9	Presentation Copy (PPT maximum 10 slides)	

List of pre-1988 permitted Fixed Dose Combinations (FDCs)

S.No.	FDC Name
1	Nimesulide +Paracetamol dispersible tablets
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
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