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

FDA Bhawan, Kotla Road,
New Delhi
Dated: 01 JUL 2019

NOTICE

Subject:- Evaluation of Fixed Dose combinations (FDCs) by DTAB Su-Committee which were earlier considered as irrational in the assessment report of the Prof. Kokate Committee reg-

Sir,

This is in continuation to this office notice 4-01/2013-DC (Misc. 13-Part III) dated 29.05.2019 on the subject cited above whereby all the manufacturers/stakeholders were requested to submit the information in the prescribed format as per Annexure A by 30th June 2019 till 5:00 P.M. for further action.

In this regard, various representations have been received requesting for further extending the timeline for submission of the information. The issue was considered and it has been decided that manufacturers/stakeholders may be permitted to submit the information in the prescribed format by 16.08.2019.

In view of above, all the manufacturers/stakeholders may note that the date for submission of information in the prescribed format is extended upto 16.08.2019 till 5:00 p.m.

(Sanjeev Kumar)
Convener
Sub-Committee of DTAB

Encl: As above

To:-

1. Indian Drug/Pharmaceuticals Association Forum
2. Web site of CDSCO for information and necessary action by manufacturers of said FDCs and concerned stakeholders.

Copy to:

1. Dr. Nilima Kshirsagar, the Chairperson, Sub-Committee of DTAB
2. Drugs Controller General (I), Central Drugs Standard Control Organization, FDA Bhawan, Kotla Road, New Delhi-110002

Copy for information to:

Directorate General of Health Services, Ministry of Health and Family Welfare, Nirman Bhawan, New Delhi.

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

FDA Bhawan, Kotla Road
New Delhi-110002
Dated: 29 MAY 2019

NOTICE

Subject: Evaluation of Fixed Dose Combinations (FDCs) by DTAB Sub-committee which were earlier considered as irrational in the assessment report of the Prof. Kokate committee-regarding.

The 82nd meeting of the Drugs Technical Advisory Board (DTAB) was held on 2nd April 2019 under the Chairmanship of the Director General of Health Services. It deliberated on the report of Prof. Kokate Committee with respect to Fixed Dose Combinations (FDCs) considered as irrational in the assessment report of the committee.

Accordingly, a Sub-committee has been constituted under the Chairmanship of Dr. Nilima Kshirsagar, The Chair in Clinical Pharmacology, ICMR, Mumbai, to examine these FDCs declared as irrational in the assessment report of the committee. (Copy enclosed)

In this regard, a meeting of the Sub-committee of DTAB took place and in order to give an opportunity to the manufacturers of said FDCs and the concerned stakeholders for presenting the precise data with respect to these FDCs, the Sub-committee has desired that the manufacturers and other stakeholders submit the information in the prescribed format as per **Annexure 'A'** (along with supporting documents) which is enclosed herewith for further action.

Accordingly, all the manufacturers of said FDCs and the concerned stakeholders are hereby requested to submit the information in the prescribed format and the relevant supporting documents in hard copy as well as soft copy (i.e. in C.D. Form) to this office latest by 30th June 2019 till 5:00 PM.

Sanjeev

(Sanjeev Kumar)
Convener
Sub-Committee of DTAB

Copy to:

1. Dr. Nilima Kshirsagar, the Chairperson, Sub-Committee of DTAB.
2. Indian Drug/Pharmaceuticals Association Forum
3. Website of CDSCO for information and necessary action by manufacturers of said FDCs and concerned stakeholders

Annexure A - May 2019

FDC Identification number as on the website:

Version 1 dated 17.05.2019

Format for submission of information on FDC to DTAB Sub-Committee

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

S. No.	Item	Response	
1a.	(a) Composition of Product (FDC): (Details of all ingredients, strengths /dosage forms)		
	(b) Brand name/s if any:		
	(c) Name and Address of the Applicant Whether the applicant is i. Manufacturer: ii. Marketer : iii. Any other (please specify) : iv. --		
1b.	Licensing authority with year of license and informations, if any submitted to Licensing Authority while obtaining the License	Name and Designation of the licensing Authority	Date &Year of Product License
1c.	Whether the FDC is approved by DCGI, If so details/evidence thereof		
1d.	Whether the FDC is Pre 1988, If so details/evidence thereof		

S. No.	Item	Response
2.	Particulars of the drug: Dosage form, composition of the formulation (including all active ingredients)	
3.	Indication(s)	
4.	Provide a copy of the approved Package insert that is currently provided	
5.	State the category under which FDC approval is claimed as per Drugs and Cosmetics Rules.	
6.	Pharmacological classification	
7.	a) Therapeutic justification / rationale for each ingredient and quantity contained in the FDC	
	b) Therapeutic value claimed or purported to be claimed of the FDC (Postulated advantage/ Therapeutic value of FDC)[Tick (√) appropriate option(s)]	
	i. Increased efficacy	
	ii. Reduced incidence of adverse effects	
	iii. Dose reduction	
	iv. Reduced cost	
	v. Booster for another drug	
	vi. Improved patient adherence/ Convenience	
	vii. Minimization of abuse of other actives	
	viii. Reduced development of microbial resistance	
	ix. Any other (please specify)	
	c) Submit a one-page summary with highest level of evidence, supporting the claim of postulated advantage/rationale. The evidence should be enclosed in the form of maximum of five relevant full text articles in peer-reviewed journals/ relevant information from textbooks	
8.	Pharmacokinetic/ pharmacodynamics rationality with half-life details of individual ingredients, dosage schedule of individual drugs and dosage schedule of FDC (Submit a one-page summary with highest level of evidence, supporting the claim of postulated advantage/rationale. The evidence should be enclosed in the form of maximum of five most relevant full text articles in peer-reviewed journals/ relevant information from textbooks)	

S. No.	Item	Response
9.	Published data regarding safety and efficacy of FDC (Submit a one-page summary with highest level of evidence, supporting the claim of postulated advantage/rationale. The evidence should be enclosed in the form of maximum of five most relevant full text articles in peer-reviewed journals/ relevant information from textbooks)	
10.	Safety & Efficacy data if any, regarding the FDC, generated by the applicant (Submit a one-page summary. Also submit the article based on these data, if published or one-page abstract of each study if unpublished with CTRI number if available)	
11.	Please specify the guidelines National/international/ professional Association/Chapters/bodies) if any, that have recommended the use of the above FDC or use of the ingredients thereof concurrently	
12.	a) Whether marketed in EU, UK, Canada, Australia, Japan and the USA?	
	b) If yes, which country/countries?	
	c) Specify country-wise product brand name, ingredients, dosage form, its strength, amount of usual ingredients per dosage form, indication/s and dosage frequency	
13.	Regulatory status of the FDC in other countries	
13.1	Countries where the drug is:	
	(a) Marketed	
	(b) Approved	
	(c) Approved as IND	
	(d) withdrawn, if any, with reasons	
13.2	Restrictions on use, if any, in countries where marketed/approved	
14.	Specimen of labels and cartons	
15.	Any other relevant information	
16.	Submit one page summary of grounds and reasons in support of FDC with not more than 5 relevant references	
17.	Submit PPT of presentation in hard copy (Maximum 7 slides) which the company will present to the committee	

(Note: Individual Form shall be submitted for each FDC and all above information shall be provided for each strength/ dosage in the same Form of FDC)

Signature of the Authorized representative: _____

Name: _____

Designation: _____

Date: _____

Place: _____

For Office Use:	
Identification No.	