F. No- 4-01/2013-DC(Misc 13-Part1)
Directorate General of Health Services
Office of Drugs Controller General (India)
(FDC Division)

FDA Bhawan Kotla Road,
New Delhi

Dated: 12 MAR 2018

NOTICE

Subject: Consideration of the directions of the Hon'ble Supreme Court of India in the case of 344 FDCs + 05 FDCs prohibited vide S.O. No. 705(E) to 1048 (E) dated 10.03.2016 and S.O. No. 1851(E) to 1855(E) dated 08.06.2017 and constitution of a sub-committee for having a relook in these cases- Regarding.

In the 78th meeting of the Drugs Technical Advisory Board (DTAB) held on 12th February, 2018 under the Chairmanship of the Director General of Health Services, the DTAB deliberated the directions of the Hon'ble Supreme Court of India dated 15.12.2017 in regard to the notifications issued by the Govt. of India prohibiting 344 FDCs +05 FDCs vide S.O. No. 705(E) to 1048 (E) dated 10.03.2016 and S.O. No. 1851(E) to 1855(E) dated 08.06.2017 respectively.

The Hon'ble Supreme Court in its order dated 15.12.2017 had inter alia directed that these cases should go to the DTAB and/or its sub-committee formed by the DTAB for the purpose of having a relook into these cases. The committee will not only hear the petitioners/appellants before but they also hear submissions from All India Drugs Action Network. The DTAB/sub-committee set up for the purpose will deliberate on the parameters set out in section 26A of the Drugs & Cosmetics Act.

Accordingly, a sub-committee has been constituted under the Chairmanship of Dr. Nilima Kshirsagar, The Chair in Clinical Pharmacology, ICMR, Mumbai, to examine the banned 344 FDCs + 5 FDCs vide S.O. No. 705(E) to 1048 (E) dated 10.03.2016 and S.O. No. 1851(E) to 1855(E) dated 08.06.2017 respectively.

In this regard, a meeting of the sub-committee of DTAB took place on 1st March 2018. The committee has desired and requested that the appellants/petitioner may submit the information in the prescribed format as per **Annexure 'A'** which is enclosed herewith for further action in compliance to the directions of the Hon'ble Supreme Court.

Accordingly all the appellants/petitioners are requested to submit the information in the prescribed format in hard copy as well as in soft copy (i.e. in C.D. form) to this office latest by the 7th April 2018 till 5:00 P.M. to fulfil the DTAB Sub-Committee proceedings as per Hon'ble Supreme Court order.

This is for the information of all stakeholders.

(Sanjeev Kumar)
Convener
Sub-Committee of DTAB

Copy to:

1. Dr. Nilima Kshirsagar, the Chairperson, Sub-Committee of DTAB
2. Drug Manufacturing Associations: IDMA/FOPE/OPPI/IPA/CIPI
3. Website of CDSCO for information and necessary action of all petitioners/appellants and stakeholders involved in the case for complying the hearing and subsequent report submission process.

Annexure A

Format for submission of information by appellant/petitioner on FDC to DTAB Sub-Committee

(Submit information as hard copy as well as soft copy)

S. No.	Item	Response	
1.	(a) Composition of Product: (Details of all strengths/ dosage forms)		
	(b) Brand name/s, if any:		
	(c) Name of the Applicant, specify if i. Manufacturer: ii. Marketer : iii. Petitioner/appellant		
	(d) Approving authority with year of approval	Name of the Authority	Year of Approval

Signature of the Authorized representative: _____

Name: _____

Designation: _____

Date: _____

Place: _____

Communication (Address, Telephone, Email) Details:

Company Seal:

For Office Use:	
Identification No. Company	

Identification No. (Office Use)	

S. No.	Item	Response
2.	Particulars of the drug: Dosage form, composition of the formulation (including all active ingredients, pharmacological classification)	
3.	Indication(s)	
4.	Provide a copy of Package insert as per Schedule Y of Drugs & Cosmetics Rules.	
5.	State the category (as per Appendix VI) under which FDC approval is claimed	
6.	a) Therapeutic justification / rationale for each ingredient and quantity in the FDC	
	b) Therapeutic value claimed or purported to be claimed of the FDC (Postulated advantage/ value 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 relevant full text articles in peer-reviewed journals/ relevant pages from textbooks) [Tick (√) appropriate option(s)]	
	i. Increased efficacy	
	ii. Reduced incidence and/or severity 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. Simpler logistics of procurement and/ or distribution	
	ix. Reduced development of microbial resistance	
	x. Any other (please specify)	

Identification No. (Office Use)	

S. No.	Item	Response
7.	Pharmacokinetic/ pharmacodynamics rationality with half-life details of individual ingredients, dosage schedule of individual drugs (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 pages from textbooks)	
8.	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 relevant full text articles in peer-reviewed journals/ relevant pages from textbooks)	
9.	Original 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)	
10.	Regulatory status of the FDC in other countries	
10.1	Countries where the drug is:	
	(a) Marketed	
	(b) Approved	
	(c) Approved as IND	
	(d) withdrawn, if any, with reasons	
10.2	Restrictions on use, if any, in countries where marketed/ approved	
11	Specimen of labels and cartons	
12	Any other relevant information	
13	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 form for an FDC in the same form or separate form if required)