

**F. No. 04-146/2007-DC
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(FDC Division)**

FDA Bhawan, Kotla road,
New Delhi

Dated: **12 DEC 2018**

To
All State/UT Drugs Controllers

Subject:- Consideration of the directions of Hon'ble Supreme Court of India in the case of 294 FDCs in respect of FDCs which require further generation of data -reg.

Sir,

The office of Drugs Controller General (India) received complaints from Consumer Associations in year 2007 regarding Fixed Dose Combinations (FDC) not approved by DCG(I) but marketed in the country. As a part of follow up action of complaints, the office of DCG(I) prepared a list of 294 FDCs and directions were issued to all State/UT Drugs Controllers to withdraw these 294 FDCs which were licensed without approval of DCG(I). The manufacturers association, however, got stay from the Hon'ble High Court of Madras on the directions issued in the matter.

The matter was then placed in DTAB in the 56th meeting dated 16.01.2008. A Sub-Committee was constituted by DTAB to examine these FDCs. Accordingly, the Sub-Committee examined these FDCs and submitted its report to the DTAB. DTAB in its meeting held on 16.02.2015 agreed with the recommendations of Sub-Committee of DTAB. The Hon'ble Supreme Court as per its judgement dated 15.12.2017 has accepted the recommendations of DTAB.

As per the recommendations of DTAB, there are 17 FDCs for which data provided by the manufacturer was considered inadequate to prove its rationality, safety & efficacy. List of these FDCs is annexed herewith as **Annexure-A**.

You are requested to direct all concerned manufacturers of the above mentioned 17 FDCs under your jurisdiction to submit the information/data in the prescribed format in hard copy as well as soft copy(i.e. in CD form) as per **Annexure-B latest by 28.02.2019** so that further action can be taken in these FDCs.

It may also be communicated that in case of non-submission of data, this Directorate reserves the right to make its decision on the basis of information available before it in light of the judgement of the Hon'ble Supreme Court.

Yours faithfully,



(Dr. S. Eswara Reddy)
Drugs Controller General (India)

Copy for information and necessary action to:-

1. Web site of CDSCO.
2. CDSCO Zonal and Sub-Zonal offices.
3. All Drugs manufacturer association with the request to publicise it widely amongst their members for submitting the data.

Annexure A

Sr. no.	Name of FDC
1	Acetyl salicylic acid+Ethoheptazine
2	Allantoin+Dimethicone+Methylparaben+Propylparaben
3	Aloe extract+allantocin+Alfa tocoferal acetate+D-panthemol+VitA
4	Aloe extract+Vit-E+Dimethicone+Glycerine
5	Aloe vera+Jojoba oil+Vit-E
6	Aloe vera+Orange oil
7	Aloe vera+Vit-e acetate
8	Aloe+tocopherol
9	Aloevera+Glycerine+PEG 100 stearate+Vit E
10	Aloevera+Jojoba oil+Wheat germ oil+Tea tree oil
11	Aloevera+Vit-E+Herbal
12	Ampicillin+Flucloxacillin Sodium Salt
13	Ampicillin+Flucloxacillin Sodium Salt+Lactobacillus Acidophilus
14	Dicyclomine+Paracetamol+Clidinium Bromide
15	Dicyclomine+Paracetamol+Clidinium bromide+Chlordiazepoxide
16	Gliclazide+Chromium picolinate
17	Paracetamol+Lignocaine

Annexure B

Format for submission of information on FDC

(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:

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)		

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	

(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)