File No. 04-01/2011-DC (Pt. Deanxit)
Govt. of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(FDC Division)

FDA Bhawan, Kotla Road
New Delhi-110002

Dated: 13 FEB 2019

PUBLIC NOTICE

Subject: Consideration of the orders of High Court of Karnataka dated14.08.2013 & 24.07.2017 to examine the issue of safety and efficacy of Fixed Dose Combination of Flupenthixol + Melitracen for human use in light of notifications G.S.R. 377(E) dated 18.6.2013 & G.S.R. 498(E) dated 11.07.2014 and to provide hearing to the petitioners/manufacturers -regarding.

In the 81st meeting of the Drugs Technical Advisory Board(DTAB) held on 29.11.2018 under the Chairmanship of the Director General of Health Services, the DTAB deliberated the directions/orders of the of Hon'ble High Court of Karnataka dated14.08.2013 & 24.07.2017.

Accordingly, a Sub-Committee has been constituted under the Chairmanship of Dr. Nilima Kshirsagar, The Chair in Clinical Pharmacology, Indian Council of Medical Research (ICMR), Mumbai to examine the issue of safety and efficacy of Fixed Dose Combination of Flupenthixol + Melitracen for human use in light of notifications G.S.R. 377(E) dated 18.6.2013 & G.S.R. 498(E) dated 11.07.2014 and orders of High Court of Karnataka dated14.08.2013 & 24.07.2017.

In this regard, a meeting of the Sub-Committee of DTAB took place on 06th Feb. 2019. The Committee has desired and requested that the Petitioner/Manufactures 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 High Court of Karnataka.

Accordingly all the petitioners/manufacturers 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 15.03.2019 till 05:00pm to fulfil the DTAB Sub-Committee proceedings as per Hon'ble High Court of Karnataka.

This is for the information of all stakeholders.

Sanjeev

(Sanjeev Kumar)
Convener, Sub-Committee of DTAB

Encl: Annexure A

Copy to:

1. Dr. Nilima Kshirsagar, The Chair in Clinical Pharmacology, Indian Council of Medical Research (ICMR), Mumbai, (Chairperson)
2. Indian Drugs Manufacturing Associations OPPI/IDMA/FOPE/CIPI/IPA- with the request to communicate it to your members and publicize it widely so that all concerned can avail this opportunity.
3. Website of CDSCO for information and necessary action of all petitioners and stakeholders for complying the hearing and subsequent report submission process.

Annexure A

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

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

<table>
<tr><th>S. No.</th><th>Item</th><th colspan="2">Response</th></tr>
<tr><td rowspan="6">1.</td><td>(a) Composition of Product: (Details of all strengths/dosage forms)</td><td colspan="2"></td></tr>
<tr><td>(b) Brand name/s, if any:</td><td colspan="2"></td></tr>
<tr><td>(c) Name of the Applicant, specify if
i. Manufacturer:
ii. Marketer :
iii. Petitioner/appellant</td><td colspan="2"></td></tr>
<tr><td rowspan="5">(d) Approving authority with year of approval</td><td>Name of the Authority</td><td>Year of Approval</td></tr>
<tr><td></td><td></td></tr>
<tr><td></td><td></td></tr>
<tr><td></td><td></td></tr>
<tr><td></td><td></td></tr>
</table>

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 allactiveingredients, 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 publishedorone-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	Restrictionson 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)