**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 (AIDAN). 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 AIDAN may submit the information in the prescribed format as per **Annexure 'D'** which is enclosed herewith for further action in compliance to the directions of the Hon'ble Supreme Court.

Accordingly, All India Drugs Action Network is hereby 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.

**(Sanjeev Kumar)**
**Convener**
**Sub-Committee of DTAB**

**Copy to:**

1. Dr. Nilima Kshirsagar, the Chairperson, Sub-Committee of DTAB
2. All India Drugs Action Network
4. Website of CDSCO for information and necessary action of AIDAN for complying the hearing and subsequent report submission process.

## Annexure D

## Format for submission of information on FDC to DTAB Sub-Committee by All India Drug Action Network (AIDAN)

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

| For Office Use: | |
|---|---|
| Identification No. | |

**1. Composition / product details**

**Dosage form:**

| Sr. No. | Ingredient | Quantity |
|---|---|---|
| | | |
| | | |
| | | |
| | | |
| | | |

**2. Is there therapeutic justification for each ingredients and the quantity of each ingredient in FDC ?(Please provide one page summary of justification/ rationale/ basis for your opinion with supporting scientific evidence as maximum five relevant published articles)**

**3. Does the FDC have therapeutic value claimed/ purported to be claimed?**

**(Please provide one page summary of justification/ rationale/ basis for your opinion with supporting scientific evidence as maximum five relevant published articles)**

**4. Is the FDC likely to involve any risk to human beings or animals?**

**(Please provide one page summary of justification/ rationale/ basis for your opinion with supporting scientific evidence as maximum five relevant published articles)**

**5. In AIDAN opinion, in public interest is restriction or regulation sufficient instead of prohibition to control the manufacturer and use of FDC.**

**(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 in separate form if required )**

Name of the AIDAN representative filing the information: _____

Designation: _____

Signature and Date: _____

Seal