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

FDA Bhawan, Kotla Road,
New Delhi

Dated: 19/8/2019

NOTICE

Subject:- Procedure to be followed for regularisation of FDCs declared as rational in respect to 294 FDCs by the DTAB which were licensed to manufacture and market by State Licensing Authority without prior approval from DCG(I)-regarding.

In continuation to this Directorate letter 04-146/2007-DC (Part-I) dated 27.02.2019 and various representation received in the matter, it has been decided that manufacturers/stakeholders who are holding license for these FDCs from State Licensing Authority (SLA) may submit their applications by 02.12.2019. Further, all the applicants are requested to submit their applications alongwith requisite fees as specified in the Sixth Schedule of the New Drugs and Clinical Trial Rules, 2019.

(Dr. V. G. Somani)
Drugs Controller General (India)

Copy to:-

1. PS to JS(R), Ministry of Health and family Welfare, Nirman Bhawan, New Delhi
2. All State/UT Drugs Controllers
3. CDSCO Zonal and Sub-Zonal offices
4. Indian Drug/Pharmaceuticals Association Forum
5. Web site of CDSCO

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This is in continuation to this Directorate letter of even no. 04-146/2007-DC (Part-I) dated 27.02.2019 and 12.04.2019. In this regard, it is to further clarify that for the FDCs mentioned in the list of 83 rational FDCs which are already approved by this Directorate in a particular strength and dosage form, the concerned applicants/Stakeholders may directly approach State Licensing Authority for obtaining the manufacturing license as per the defined procedures except for those strengths and dosage form which are approved after the issuance of this Directorate letter dated 27.02.2019.

(Dr. V. G. Somani)
Drugs Controller General (India)

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