

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: 28 APR 2022

To
All State/UT Drugs Controllers,

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

Reference:

1. This Directorate letter no 04-146/2007-DC (Part-I) dated 27.02.2019.
2. This Directorate letter no 04-146/2007-DC (Part-I) dated 19.08.2019.
3. This Directorate letter no 04-146/2007-DC (Part-I) dated 08.09.2020.
4. This Directorate 02 letters no 04-146/2007-DC (Part-I) dated 27.08.2021.

Sir ,

This is with reference to this Directorate's various above letters w.r.t. FDCs falling under 294 category. As per the said letters, manufacturers who are already holding licenses from State Licensing Authorities for such FDCs and did not apply to DCG(I) were required to submit their applications to this Directorate as per the defined pathways. The date for filing such applications of various categories has already expired.

Meanwhile in the wake of Covid 19 pandemic, this Directorate has received various representations requesting for extension of time for submission of such applications. Accordingly, it has been decided that manufacturers/stakeholders who are holding licenses from State Licensing Authorities and have not yet applied to this Directorate may submit their applications w.r.t these FDCs by 31.10.2022.

In view of above, you are requested to direct all the concerned manufacturers/stakeholders who are already holding manufacturing permissions for manufacturing these FDCs to submit their application to this Directorate alongwith requisite fees by 31.10.2022 positively.

Yours faithfully



(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. CDSCO Zonal and Sub-Zonal offices
3. Indian Drug/Pharmaceuticals Association Forum
4. Web site of CDSCO