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: 8.19.2020

To,

All State/UT Drugs Controller

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 (SLA) without prior approval from DCG(I)-regarding.

Sir,

This is in continuation to this Directorate letter of even number dated 27.02.2019 whereby a detailed pathway was issued for obtaining permission from this Directorate in respect of 83 FDCs declared as rational (copy enclosed). Subsequently, the date for submission of such applications was also extended vide this office letter dated 19.08.2019. However, there have been concerns that there is no mention of strength and dosage forms in the said list.

It is pertinent to mention here that as regard to strength and dosage forms of such FDCs mentioned in 83 rational FDCs list, it is to clarify that if the manufacturer submits copy of product license issued by SLA to any firm indicating that the product in specific dosage form and strength was licensed prior to 28.11.2007, the same will be considered for issuance of permission by this office in accordance with the defined pathway.

As per the report of DTAB dated 29.07.2020, there are 3 more FDCs which have been considered as rational under 294 FDCs category. The pathway for obtaining permission w.r.t. these 3 FDCs will also remain same as already defined under this office letter no. 04-146/2007-DC (Part-I) dated 27.02.2019. The details of these FDCs are as under:-

Sr. No.	Name of the FDC
1	Atenolol + Losartan + Hydrochlorothiazide
2	Duloxetine + Mecobalamin
3	Mecobalamin + Vit. B6 + Folic Acid

Further, it has been observed that only a few applicants who are already having manufacturing licenses for such FDCs issued by SLA have applied for obtaining approval from this office. Now, it has been decided that manufacturers/stakeholders who are already holding license for these FDCs from SLA may submit their applications latest by 31.03.2021.

In view of above, you are requested to ask the manufacturers who are already holding licenses of these (83+03) FDCs under your jurisdiction to submit the applications to this Directorate as per defined pathway as no further extension will be considered in such cases.

Yours faithfully,

V.G.S.

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

Copy to:-

1. 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 Associations
5. Website of CDSCO

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

FDA Bhawan, Kotla road,
New Delhi
Dated: 27 FEB 2019

To

All State/UT Drugs Controller

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**

Sir,

The office of Drugs Controller General (India) received complaints from Consumer Associations in year 2007 regarding rationality of certain Fixed Dose Combinations (FDC) 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 States/UTs Drugs Controllers to withdraw these 294 FDCs which were licensed without approval of DCG(I). The manufacturers association got however stay from the Hon'ble High Court of Madras in respect of 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. All Court cases pending in Hon'ble Madras High Court were transferred to Hon'ble Supreme Court. In this regard Hon'ble Supreme Court accepted the report of DTAB as per court order dated 15.12.2017.

As per the report of DTAB, there are 83 FDCs considered as rational. The list of these 83 FDCs is already available in CDSCO website with the following link:

https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTUxNQ==

In order to regularise these 83 FDCs, which were licensed to manufacture and market by State Licensing Authority without prior approval from DCG (I), following procedure is required to be followed:

a. The applicant shall submit Form 44 mentioning dosage form and strength (duly filled, signed and stamped) alongwith treasury challan of INR 15,000 for each FDC
b. Name and Composition of FDC
c. Copy of Product Permission issued by SLA to any firm prior to 28.11.2007 as documentary evidence.
d. Copy of manufacturing license in Form 25/28 and Form 29 for manufacturers who are not holding product permission from SLA and want to apply for these FDCs
e. S.No. of FDC as per the list available on website,
f. Stability studies data (06 months accelerated data of 03 batches),and
g. Test specifications of the FDC along with Method of Analysis

All the manufacturers who are already holding licenses from State Licensing Authorities for such FDCs and did not obtain NOC from DCG (I) are required to submit their applications to this Directorate at the earliest but not later than **4 months**, failing which their applications will not be considered and their licenses will be considered as without legal validity.

In view of above, you are requested to direct all concerned stakeholders to follow above procedure for clearance of the cases. You are also requested to ensure that no product licensed in respect of these 83 FDCs are issued henceforth without the approval of DCG (I) in favour of the applicant.

Yours faithfully,

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

Copy for information and necessary action 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. Website of CDSCO.