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: 27/8/2024

To,

All State/UT Drugs Controller

Subject:- Procedure to be followed for regularisation of 19 FDCs (Fixed Dose Combinations) out of 294 FDCs which require further generation of data which were licensed to manufacture and market by State Licensing Authority (SLA) without prior approval from DCG(I) -regarding.

Sir,

This is with reference to this office letter of even number dated 12.04.2019 whereby all the State/UT Drugs Controllers were requested to ask the concerned stakeholders to submit the requisite data/information. The data submitted by the stakeholders was evaluated by the expert committee.

As per the report of DTAB dated 13.04.2021 and recommendations of subcommittee of DTAB as approved, there are 19 FDCs which require further generation of data by way of conducting Phase IV trial/ Active Post Marketing surveillance study as the case may be. List of these FDCs along with recommendations of the expert committee is annexed herewith as **Annexure-A**.

Manufacturers are requested to follow the pathway for clearance of such applications as under:-

1. Form CT 21(duly filled, signed and stamped)
2. Requisite Fees through Bharatkosh.
3. Name and composition of the FDC.
4. Copy of Product Permission issued by SLA to any firm prior to 28.11.2007 as available or the documents in supporting strength and dosage form of FDC.
5. Copy of Manufacturing license of the applied product issued by State Licensing Authority in Form 25/28
6. S. No. of FDC as per the "**Annexure-A**" and Stability studies data as per earlier communication in this regard.
7. Test specifications of the FDC along with Method of Analysis.
8. Phase IV trial protocol/commitment for conducting Active Post Marketing Surveillance study as the case may be.

In case of applicants who are not holding manufacturing license of the applied product from the State Licensing Authority and want to apply for these FDCs, they can apply with data generated on Form 29 with above pathway.

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 within 06 months.

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 product license in respect of these 19 FDCs are issued after approval of DCG(I) in favour of the applicant.

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. Drug Manufacturing Associations: IDMA/OPPI/IPA/CIPI/FOPE/Indian Drug/ Pharmaceuticals Association Forum
4. Website of CDSCO

Annexure – A

Sr. no.	Name of the FDC	Recommendations
1.	Aceclofenac+ Paracetamol+ Chlorzoxazone	Phase IV clinical trial is required to be conducted.
2.	Aceclofenac+ Paracetamol+ Serratiopeptidase	Phase IV clinical trial is required to be conducted. A randomized comparative superiority trial comparing FDC containing serratiopeptidase with the FDC without serratiopeptidase (other ingredients being the same) and efficacy should be the primary objective and should be conducted in a statistical significant number of patients.
3.	Aceclofenac+ Paracetamol+ Tizanidine	Phase IV clinical trial is required to be conducted.
4.	Aceclofenac+ Paracetamol+ Tramadol	Phase IV clinical trial is required to be conducted to demonstrate the superiority of this FDC over two drugs approved FDC.
5.	Alprazolam+ Melatonin	Active PMS study on the FDC is required to be conducted.
6.	Alprazolam+ Propranolol	Phase IV clinical trial is required to be conducted.
7.	Calcium dobesilate+ Decusate sodium	Phase IV clinical trial is required to be conducted to demonstrate the safety and efficacy.
8.	Calcium dobesilate+ Lignocaine	Phase IV clinical trial is required to be conducted to demonstrate the safety and efficacy.
9.	Calcium Dobesilate+ Troxerutin	Phase IV clinical trial is required to be conducted to demonstrate the safety and efficacy.
10.	Chlorzoxazone+ Paracetamol + Diclofenac	Phase IV clinical trial is required to be conducted.
11.	Chlorzoxazone+ Paracetamol+ Ibuprofen	Phase IV clinical trial is required to be conducted.
12.	Chlorzoxazone+ Paracetamol+ Nimesulide	Phase IV clinical trial is required to be conducted.
13.	Diclofenac+ Paracetamol+ Serratiopeptidase	Phase IV clinical trial is required to be conducted. A randomized comparative superiority trial comparing FDC containing serratiopeptidase with the FDC without serratiopeptidase (other ingredients being the same) with efficacy as the primary objective should be conducted in a statistical significant number of patients.
14.	Diclofenac+ paracetamol+ Tizanidine	Phase IV clinical trial is required to be conducted.
15.	Dicyclomine+ Diclofenac Sodium+ Paracetamol	Phase IV clinical trial is required to be conducted.
16.	Ibuprofen+ Paracetamol+ Serratiopeptidase	Phase IV clinical trial is required to be conducted. A randomized comparative superiority trial comparing FDC containing serratiopeptidase with the FDC without serratiopeptidase (other ingredients being the same) with efficacy as the primary objective should be conducted in a statistical significant number of patients.
17.	Nimesulide+ Paracetamol+ Serratiopeptidase	Phase IV clinical trial is required to be conducted provided that paracetamol dose is 325mg. A randomized comparative superiority trial comparing FDC containing serratiopeptidase with the FDC without serratiopeptidase (other ingredients being the same) with efficacy as the primary objective should be conducted in a statistical significant number of patients.
18.	Propranolol+ Diazepam	Phase IV clinical trial is required to be conducted.
19.	Tizanidine+ Nimesulide+ Paracetamol	Phase IV clinical trial is required to be conducted provided that paracetamol dose is 325mg.