CiPi

CONFEDERATION OF INDIAN PHARMACEUTICAL INDUSTRY (SSI) (Regd.)

(Registered Office : A-3/314, First Floor, Paschim Vihar, New Delhi-110063)

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Constituent Members

All India Small Scale Pharmaceutical Mfrs. Association, New Delhi-110054

All India Small Drug Mfrs. Association, Mumbai-400014

Gujarat Pharma Small Scale Industries Association, Vadodara - 390002

Haryana Pharmaceutical Mfrs. Association, Ambala City - 134003

Himachal Drug Mfrs. Association, Baddi -173205

J&K Small Scale Drug Mfrs. Association, Jammu - 180010

Kerala Pharmaceuticals Mfrs. Association, Kerala - 679322

Organisation of Pharmaceutical Mfrs., Hyderabad - 500038 (A.P.)

Ludhiana Drug Mfrs. Association, Ludhiana - 141001

Rajasthan Pharmaceutical Mfrs. Association, Jaipur - 302006

The Pharmaceutical Mfrs. Association of Tamilnadu, Chennai - 600015

Pharmaceutical Mfrs. Association (Kanpur), Kanpur, U.P.

West Bengal Small Scale Pharmaceutical Mfrs. Association, Kolkata - 700033

Baghat Pharmaceutical Mfrs. Association, Solan - 173212

BBN Industries Association, Baddi - 173205

Federation of Pharma Entrepreneurs, Gurgaon - 122015

Association of Pharmaceutical Mfrs., Haridwar - 249403

Devbhoomi Association of Pharmaceutical Mfrs., Dehradun - 248002

Karnataka Drugs & Pharmaceutical Mfrs. Association, Bangalore - 560001

Sirmour Pharma Mfrs. Association, Paonta Sahib - 173025

Ambala Pharmaceutical Mfrs. Association, Ambala City - 134003

Gurgaon Pharmaceuticals Mfrs. Association, Gurgaon - 122001

Bahadurgarh Pharmaceuticals Mfrs. Association, Bahadurgarh-124507

Goa Pharmaceutical Mfrs. Association, Mapusa - 403526

Ref. No.: CIPI/2017/252
08th June, 2017

Dr. G. N. Singh
Drugs Controller General (India)
Central Drugs Standards Control Organization
Ministry of Health & Family Welfare

Respected Sir,

We are in receipt of your Notice dated 05.06.2017. We extend our most cordial gratitude for taking another lenient view.

We will send this notice to all the manufacturers in the country and will request them to do the needful.

Regards

For Confederation of Indian Pharmaceutical Industry

P. K. Gupta
Chairman

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File No.4-01/2013-DC (Misc. 13-PSC)
Directorate General of Health Services
Office of Drugs Controller General (India)
(FDC Division)

Dated: 05 JUN 2017

NOTICE

Subject: **Procedure to be followed for subsequent applicants in respect of FDCs declared as rational by Kokate Committee and approved by DCG(I)-regarding.**

This is in continuation to this Directorate's earlier notice of even number dated 16.03.2017 whereby pathway for clearance of cases with respect to subsequent applicants in respect of FDCs declared as rational by Prof. Kokate Committee and approved by DCG (I) was explained for submission of the applications and in light of the subsequent requests to CDSCO from various stakeholders to specify the minimum documents required to be submitted alongwith applications, it is to clarify that:-

1. The applicant shall submit application in Form 44 by giving relevant information and clearly mentioning "Not applicable" where such information is considered not applicable by the applicant.
2. Documents required in case of manufacturers already holding licenses from State Licensing Authority (SLA) for the proposed FDCs shall at least contain:-
   a. Form 44 (duly filled, signed and stamped)
   b. Treasury Challan of INR 15,000 duly signed by Bank of Baroda
   c. Name and composition of the FDC
   d. (i) Product Permission issued by SLA
      (ii) Copy of Manufacturing license in Form 25/28
   e. FDCs permitted for continued manufacturing & marketing under 18 months Policy Decision.
      (i) Sl No. of the FDC as per the list available on website, and
      (ii) Name of FDC
3. Documents required in case of new manufacturers for the proposed FDCs shall at least contain:-
   a. Form 44 (duly filled, signed and stamped)
   b. Treasury Challan of INR 15,000 duly signed by Bank of Baroda
   c. Name and composition of the FDC
   d. (i) Product Permission issued by SLA
      (ii) Copy of Manufacturing license in Form 25/28
   e. FDCs permitted for continued manufacturing & marketing under 18 months Policy Decision.
      (i) Sl No. of the FDC as per the list available on website, and
      (ii) Name of FDC
   f. Stability studies data (03 months accelerated)
   g. Test Specifications of the FDC alongwith Method of Analysis
4. 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, all concerned stakeholders are required to follow above procedure for clearance of the cases.

(Dr. G. N. Singh)
Drugs Controller General (India)

To:-
All State/UT Drugs Controllers/All Zonal/Sub Zonal offices of CDSCO.

Copy to:-
1. PS to JS(R), Ministry of Health and Family Welfare, Nirman Bhawan, New Delhi.
2. Drug Manufacturing Associations: IDMA/OPPI/IPA/CIPI/FOPE etc.