



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

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

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Chairman :
P. K. Gupta
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Secretary General :
R.K. Jain
Cell : 09927900920

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: CIPI/2017/313
Date: 18/12/2017

Dear All CIPI Members,

We are pleased to give the extract of judgment given by the Supreme Court in respect of 344 FDC's plus 5 FDC's and 294 FDC's which were pending in the Madras High Court.

The Supreme Court given their judgment for above mention FDC's i.e. 344 plus 5 banned in March 2016 and 294.

Regarding 344 FDC's plus 5 FDC's:

- 15 FDC's which were approved before 1988 can be continue
- Rest 329 plus 5 FDC's sent back to Drug Technical Advisory Board (DTAB) and directed them to form a Sub Committee and all these FDC's shall be verify by the Sub Committee.

The Sub Committee will justify which FDC's is rational or irrational and complete report will be submitted to the Central Government.

Regarding 294 FDC's pending in Madras High Court, now transferred to Supreme Court and Supreme Court have given judgment which is as follows:

A report of expert committee was reviewed by the Supreme Court. It includes:

- 42 FDC's were repeated or duplicate
- 44 FDC's were already banned in the country
- 83 FDC's were considered rational
- 56 FDC's considered not rational



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- 49 FDC's required further generation of data
- 17 FDC's were considered inadequate rationality
- And remaining 3 FDC's were sent for further examinations

Complete judgment of Supreme Court is enclosed.

Regards

For Confederation of Indian Pharmaceutical Industry (CIPI)

P.K.Gupta
Chairman