CiPi

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

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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/2017/251
08th June, 2017

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

Respected Sir,

Greetings of the Day!

Please permit me to avail the opportunity to compliment you for resolving partially the issue of FDCs within seconds through your Notice dated 05.06.2017. This way of your working has been appreciated by the whole industry. Issue of FDC has started to resolve. When we saw another letter of the same date i.e. 05.06.2017 and noted that on the pending FDCs, you have taken a very lenient view. I am confident that all our issues can be settled with mutual discussions.

Sir, there are more than 70% small scale industry are in favour to manufacture drugs maintaining GMP standards and also want to improve further day by day. Remaining manufacturers either have to close their shutters or have to improve infrastructure, documents and Quality Control. The only need is to asses them, tell them the clear picture, whether their facilities can be further improved or not.

Sir, during your tenure in the Health department, approximately for the last 4 years, you worked so graciously, magnificently and above all without any blemish or interruption. It is a noted fact that you are a custodian of Health for the people of the country. You have put every nerve and muscle to prove yourself.

I once again extend my sincere and warm greetings to you and your colleagues for this commendable job done.

Regards
For Confederation of Indian Pharmaceutical Industry

P. K. Gupta
Chairman

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F. No. 04-01/2013-DC (Misc. 13-PSC)
Directorate General of Health Services
Office of Drugs Controller General (India)
(FDC Division)

FDA Bhawan, Kotla Road,
New Delhi-110002

Dated: 05 JUN 2017

NOTICE

Subject: Examination for Safety and Efficacy of Fixed Dose Combinations (FDCs) licensed for manufacture for sale in the country without due approval from office of DCG (I)-regarding.

Reference: **1. This Directorate letter no. 4-01/2013-DC (Misc.-PSC) dated: 15.01.2013.**
2. This Directorate Notices dated: 17.06.2016 and 01.09.2016 and 01.03.2017.

This is in continuation to this office earlier letters addressed to individual firms as well as notices dated: 17.06.2016, 01.09.2016 and 01.03.2017 whereby all concerned stakeholders were requested to submit phase IV trial protocol based on recommendations of Expert Committee. In this regard, it has been observed that most of the companies are yet to submit Phase IV trial protocols. In order to facilitate the stakeholders for submission of these protocols, the matter was also taken up with the Expert Committee.

The Committee opined that the FDCs for which the post marketing trials have been asked are those FDCs which appear to be rational, however safety in such FDCs is yet to be further ascertained, therefore the Committee recommended that:-

1. Main focus and primary objective for conducting such trials in these FDCs could be safety and efficacy could be secondary objective.
2. The study could be Open label /Double Blind/Comparative/Single arm/Crossover multi-centric trial depending upon the concerned FDC and its therapeutic indication and the number of subjects should be statistically significant.
3. Scientific evaluation by validated parameters/methods should be included for assessing the safety and efficacy.
4. During the study, anticipated safety parameter should be defined clearly alongwith its monitoring mechanism.
5. The study sites should be geographically distributed.

It is therefore again requested that all the applicants who have not yet submitted post marketing Phase IV trial protocols shall submit the same in line with Schedule Y of Drugs and Cosmetics Rules, 1945 taking into consideration all the points as mentioned above.

This may be treated as regulatory reminder for further necessary action.

Yours faithfully,

(Dr. G. N. Singh)
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. All Zonal/Sub Zonal offices of CDSCO
4. Manufacturing Associations: IDMA/OPPI/IPA/CIPI/FOPE etc.