FOPE
Federation
Of
Pharma
Entrepreneurs

24th May, 2017

The Under Secretary (Drugs)
Ministry of Health & Family Welfare,
Room No. 414 A, D Wing,
Nirman Bhawan,
New Delhi-110 011

Sub: Draft Gazette Notification G.S.R. 429 (E) dated 02.05.2017- amendments in Rules 71, 71 B, 76, 76A and schedule D – comments regarding

Sir,
This has reference to the Gazette Notification No. G.S.R. (E) 429 dated 02.05.2017 of the Ministry of Health & Family Welfare containing certain draft rules so to amend the D&C Rules, 1945. Our comments / objections as desired are being submitted as under:

The draft rules pertain to the amendment in Rule 71, 71-B, 76, 76-A and Schedule D. These rules are conditions for grant/renewal of manufacturing licenses including loan licenses for other than schedule C & C 1 and X and schedule
C & C-1 drugs. At present, the requirement is that in case of patent and proprietary (P & P) medicines, applicant will submit evidence and data in respect of:

i. Constituent ingredient(s) is/are in prophylactic or therapeutic concentration;
ii. Safety in context with vehicles, excipients and other additives;
iii. Stability under recommended storage conditions;
iv. Therapeutic justification of ingredients.

In the draft rules, it has been proposed that words "patent and proprietary medicines" will be substituted with word "drugs".

In our opinion, the present rules are rational. If word "drugs" is substituted for P & P medicines, an applicant for new license(s) will have to give the above mentioned information along with the application for every drug including pharmacopoeia products and the products which are being manufactured in the country for one or two decades or more. Further, since applicant is not having mfg. license, he will have to obtain license for manufacture of drugs for examination, test/analysis. To generate the data it may take nearly one year. It means that he will get products license(s) in about a year incurring huge losses without business. Over the years, this will reduce the numbers of players in the market and market may not be as competitive as it is with present regulation. It will have potential of rise in prices of drugs. To our knowledge, such requirement is not there in any developing and developed country for pharmacopoeia and

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established products.

It will be retroactive step for pharmaceutical industry and will result in negative growth of industry. It will also be against "Govt.'s declared policy of "Ease of Business"

In view of this, the proposed amendment may be dropped.

Thanking you

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CC: Shri K.L. Sharma, Joint Secretary, Ministry of Health & Family Welfare, Nirman Bhawan, New Delhi-110 011

(ii). Dr. G.N. Singh, Drugs Controller General (India), FDA Bhawan, New Delhi-110 002