

GSR 302 (E) -font size

1 message

'SUDESH KUMAR' via FOPE <fope@googlegroups.com>
Reply-To: SUDESH KUMAR <sk_aries2001@yahoo.co.in>
To: Fope Google <fope@googlegroups.com>

Thu, Dec 14, 2017 at 10:12 AM

Dear All,

Below please find the text of our submission to CDSCO on 12th instant

regards
sudesh Kumar
Executive Secretary (II)

12th December, 2017

The Drugs Controller General (I),
Directorate General of Health Services,
Ministry of Health & Family Welfare,
FDA Bhawan,
Kotla Road,
New Delhi-110 002

**Sub: Gazette Notification No. 302 (E) dated 30.03.2017 –Comments
Regarding**

Sir

This has reference to the above Gazette Notification issued by the Ministry of Health & Family Welfare containing certain draft rules to further amend the D&C Rules, 1945.

We on behalf of our members wish to thank you for inviting our association along with other stake holders for deliberations on the subject notification.

In this regard we have to state that we had submitted our comments relating to aforesaid notification on 15.05.2017, within the time specified for the same. A copy of our aforesaid letter is enclosed for ready reference.

Our further submissions in this matter are as under for your kind consideration:

The legislative intent in the proposed changes although is loud and clear yet the same shall pave way for more harassment and prosecution being impractical, involving unwarranted expenditure, much against the principles of "Ease of doing Business", hence FOPE suggests following changes to meet the intent and purpose.

A) Change rule 96(1)(I) as under :

The Proper Name of the Drug ,with or without Brand/Trade name, and shall be—

B) Delete rule 96(1)(A)

C) Change rule 96(1)(I)(d) as under:

For other drugs including drugs containing more than one vitamin or containing three or more drugs, the international non proprietary name published by world health organization, if any, or name descriptive of true nature/origin/principal indication or use of such drug; and

D) add following sub rule after rule 96(1)(I)(d)

For all drugs, proper name shall be printed or written, may be in the same font, but larger and more conspicuous, above or before brand / trade name, if any.

Sir, FOPE can provide reasons for aforementioned suggestions.

We hope this will meet your approval and the aforesaid Gazette Notification will be modified as suggested above for "ease of doing business"

Thanking you,
(Aprajita Takkiar)

Secretary General

**CC: The Joint Secretary (Regulation), Ministry of Health & Family Welfare, Nirman Bhawan,
New Delhi-110 011**

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