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PART II

Statutory Notifications (S.R.O.)

GOVERNMENT OF PAKISTAN
Ministry of National Health Services, Regulations and Coordination
Drug Regulatory Authority of Pakistan

NOTIFICATION

Islamabad, the 6th September, 2017

S.R.O. 912(I)/2017. – The following draft of certain further amendments in the Drugs (Licensing, Registering and Advertising) Rules, 1976 proposed to be made in exercise of the powers conferred by section 23 of the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012), read with clause (a) of section 7 thereof and section 43 of the Drugs Act, 1976 (XXXI of 1976), is hereby published, as required by sub-section (3) of section 43, for the information of all persons likely to be affected thereby and notice is hereby given that the draft will be taken into consideration after seven days of its publication in the official Gazette.

Any objection or suggestion which may be received from any person in respect of the said draft, before the expiry of the said period, will be considered by the Drug Regulatory Authority of Pakistan.

DRAFT AMENDMENTS

In the aforesaid Rules, in rule 27.-

- (i) in the first proviso, for the words “*for the renewal of registration shall not be entertained unless it has been*”, the words “*shall be*” shall be substituted; and
- (ii) after the first proviso, the following proviso shall be added, namely:-

“Provided further that one time opportunity shall be given to those firms who have not complied with the first proviso since 1st January, 2010 till the issuance of this notification and those within sixty days after issuance of this

notification shall deposit three times of their applicable renewal fee for their registration to continue to be valid until explicit orders are passed on the request by the Registration Board. After the expiry of sixty days of issuance of this notification, the registration of the product shall be considered as cancelled and any manufacturing shall be penalized under the provision of the Act. Provided also that those firms who do not fulfill the first proviso, an additional fee shall be charged equivalent to applicable renewal fee for each month till one year of the expiry of registration and after one year the registration shall be cancelled.”

[No. F.1-9/2015-RRR/DRAP]

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