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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 28th September, 2017

S.R.O. 1005(I)/2017. – 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), the Drug Regulatory Authority of Pakistan, with the approval of the Federal Government, is pleased to direct that in the Drugs (Licensing, Registering and Advertising) Rules, 1976, the following further amendments shall be made, the same having been previously published as required by subsection (3) of the said section 43, namely:--

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]

AAMAR LATIFDeputy Director (Legal Affairs)