



DRUGS & COSMETICS

-COPY OF-
NOTIFICATION
Dated 3rd July, 2018

The following draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945, which the Central Government proposes to make, in exercise of the powers conferred by Section 12 and section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), after consultation with drug technical advisory board is hereby published for information of all persons likely to be affected thereby, and notice is hereby given that said draft rules will be taken into consideration on or after the expiry of a period of thirty days from the date on which the copies of the Gazette of India containing these draft rules are made available to the public.

Objections and suggestions, if any, may be addressed to the Under Secretary (Drugs), Ministry of Health and Family Welfare, Government of India, Room No. 414A, D-Wing, Nirman Bhavan, New Delhi-110011 or emailed at rq.singh72@nic.in.

Objections and suggestions which may be received from any person within the period of specified above will be considered by the Central Government.

Draft rules

1. (1) These rules may be called **Drugs and Cosmetics (___Amendment) Rules, 2018.**

(2) They shall come into force on the date of their final publication in the Official Gazette.

2. In the said rules, after rule 76A, the following new rule shall be inserted, namely:-

"77. Duration of licence.- (1) A licence issued in Form 28, Form 28B and Form 28D shall remain valid if the licensee deposits a licence retention fee referred to in sub-rule (2) before the expiry of period of every succeeding five years from the date of its issue, unless, it is suspended or cancelled by the licensing authority.

(2) The licence retention fee referred to in sub-rule (1) shall be equivalent to the respective fee required for the grant of such licence excluding inspection fee paid for grant of licence.

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(3) If the licence holder fails to pay licence retention fee on or before the due date as referred to in sub-rule (1), he shall be liable to pay licence retention fee along with a late fee calculated at the rate of two per cent, of the licence fee for every month or part thereof up to six months, and in the event of non-payment of such fee, the licence shall be deemed to have been cancelled.”.

3. In the said rules, after rule 82, the following new rule shall be inserted, namely:-

“83.Duration of loan licence.- (1) A loan licence issued in Form 28A and Form 28DA shall remain valid if the licensee deposits a licence retention fee referred to in sub-rule (2) before the expiry of period of every succeeding five years from the date of its issue, unless, it is suspended or cancelled by the licensing authority.

(2) The licence retention fee referred to in sub-rule (1) shall be equivalent to the respective fee required for the grant of such licence excluding inspection fee paid for grant of licence.

(3) If the licence holder fails to pay licence retention fee on or before the due date as referred to in sub-rule (1), he shall be liable to pay licence retention fee along with a late fee calculated at the rate of two per cent, of the licence fee for every month or part thereof up to six months, and in the event of non-payment of such fee, the licence shall be deemed to have been cancelled.”.

4. In the said rules, in rule 140, sub-rule (1), the words and figures “and Form 33” shall be omitted.

5. In the said rules, in rule 143A, sub-rule (1), the words and figures “or Form 33” shall be omitted.

6. In the said rules, in Schedule A, in Form 24C-

(a) In the heading, after the words ‘GRANT’, the words “OR RENEWAL” shall be inserted;

(b) In paragraph 1, for the words “grant”, the words “grant or renewal” shall be substituted;

Sd/-
(Sudhir Kumar)
Jt. Secy.

G.S.R.608(E)
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Note : The principal rules were published in the Official Gazette vide notification number F. 28-10/45-H(1), dated 21st December, 1945.

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