

टिप्पण: विज्ञापन में अनुमति किसी भी रूप में प्रतिबिंबित या प्रदर्शित नहीं की जाएगी।

नामिका: जार्जिकर्ना अधिकारी की मुहरबंद

(हस्ताक्षर और नाम)

राज्य अनुज्ञापन प्राधिकारी/औषधि नियंत्रक

राज्य या संघ राज्य क्षेत्र का नाम

18481

03/01/16

[फा.सं. के.11024/03/2013-डीसीसी (आयुष)]

पी.एन. रणजीत कुमार, संयुक्त सचिव

पाद टिप्पण:- मूल नियम भारत के राजपत्र में अधिसूचना संख्यांक एफ. 28-10/45-एच(आई) तारीख 21 दिसम्बर, 1945 को प्रकाशित किए गए थे और अंतिम संशोधन सा.क.नि.सं. 1193 (E) तारीख 12 दिसम्बर, 2018 द्वारा किया गया था।

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MINISTRY OF AYURVEDA, YOGA AND NATUROPATHY, UNANI, SIDDHA AND HOMOEOPATHY

NOTIFICATION

New Delhi, the 21st December, 2018

G.S.R 1230(E).—Whereas the draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945 was published as required by sub-section (1) of section 33N of the Drugs and Cosmetics Act, 1940 (23 of 1940) in Part II, Section 3, Sub-section (i) of the Gazette of India, Extraordinary, vide number G.S.R 396 (E), dated the 4th April, 2016 inviting objections and suggestions from persons likely to be affected thereby before the expiry of a period of forty five days from the date on which copies of the Official Gazette containing the said notification were made available to the public;

and whereas, the said Gazette was made available to the public on the 4th April, 2016;

and whereas, objections or suggestions received from the public on the said draft rules have been considered by the Central Government;

now, therefore, in exercise of the powers conferred by sub-section (1) of section 33-N read with clause (e) of sub-section (2) of the said section of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Ayurvedic, Siddha and Unani Drugs Technical Advisory Board, hereby makes the following rules further to amend the Drugs and Cosmetics Rules, 1945, namely:-

RULES

1. (1) These rules may be called the Drugs and Cosmetics (Eleventh Amendment) Rules, 2018.

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

2. In the Drugs and Cosmetics Rules, 1945, -

(i) after rule 169, following rule shall be inserted, namely:-

"170 Prohibition of advertisements of Ayurvedic, Siddha or Unani drugs-

(1) The manufacturer or his agent, of Ayurvedic, Siddha or Unani drugs, shall not participate in the publication of any advertisement relating to any drug for the use of diagnosis, cure, mitigation, treatment or prevention of any disease, disorder, syndrome or condition.

(2) The Ayurvedic, Siddha or Unani drug shall be advertised for the purpose other than specified in sub-rule (1) after the allotment of the Unique Identification Number.

(3) The manufacturer of the Ayurvedic, Siddha or Unani drug shall apply for the Unique Identification Number for the advertisement issued or aired before this notification, within the period of three months from the date of the publication of this notification.

(4) The application for advertisement shall be rejected if,

(i) it is incomplete; or

(ii) the intended advertisement does not contain the contact details of the manufacturer; or

(iii) the contents of the advertisement directly or indirectly tantamount to vulgarity or obscenity; or

- (iv) it refers to any Ayurvedic, Siddha or Unani drug in terms which suggest or calculated to lead to the use of that drug or medicine for the enhancement of height and dimensions or capacity of performance of male or female sexual organs; or
 - (v) it depicts photographs or testimonials of celebrities or government officials; or
 - (vi) it refers to any Government or Autonomous organization of the Government; or
 - (vii) it gives a false impression about the true character of Ayurvedic, Siddha or Unani drug; or
 - (viii) it makes a misleading or exaggerated claim about the effectiveness of the said drug.
- (5) The application for allotment of the Unique Identification Number for an advertisement shall be submitted in Form 26 E-4 to the State Licensing Authority or Drug Controller specifying therein the claims such as textual references, rationale from the authoritative books, indication(s) or use(s), evidence regarding safety, effectiveness and quality of the drug.
- (6) The application fee of rupees one thousand per advertisement shall be deposited along with Form 26E-4 and other supporting documents.
- (7) The application for the advertisement shall be submitted to the Licensing Authority of the State where the corporate office of the manufacturer is located, in case the Ayurvedic, Siddha or Unani drug is licensed for manufacturing in more than one State.
- (8) The State Licensing Authority shall process the application (if required, in consultation with the concerned technical experts) for disposal within thirty days from the date of receipt of application along with complete information and shall allot Unique Identification Number for the advertisement.
- (9) The manufacturer of Ayurvedic, Siddha or Unani drug may appeal to the State AYUSH or Health Secretary for the direction in case the application for allotment of Unique Identification Number under sub-rule (8) is not disposed off within the period of 30 days.
- (10) The applicant shall furnish the required information to the Licensing Authority or Drugs Controller as and when called for, failing which the application shall be rejected and the application fee shall stand forfeited.
- (11) The State Licensing Authority or Drugs Controller on being satisfied with the application or otherwise, shall record and convey in Form 26 E-5 the recorded contents of advertisement, reasons for rejection of application or any clarification required from the applicant.
- (12) The advertisement recorded by the Licensing Authority or Drugs Controller in Form 26 E-5 shall be valid till the date of validity of license to manufacture for sale of that drug and can be renewed thereafter.
- (13) An appeal may be filed before the Central Government against the decision of the State Licensing Authority under sub-rule (11) and the order of Central Government shall be final and binding on the appellant and the State Licensing Authority.
- (14) The State Government may notify in the Official Gazette the officers of Ayurvedic, Siddha or Unani system to undertake the monitoring of the advertisements of Ayurvedic, Siddha or Unani drugs in the print, electronic, internet and audio-visual media and maintain printed register as well as online register of the advertisements with appropriate entries including those found inappropriate or invalid and action taken against such faulty advertisements and the State Government shall provide information of the advertisements to the Central Government on quarterly basis and also as and when sought by the Central Government.
- (15) The State Licensing Authority may suspend or cancel the license of the manufacturer of the Ayurvedic, Siddha or Unani drug as per the provisions of Rule 159, in case the directions given by the said authority is not complied.
- (16) The Central Government shall, in the public interest, prohibit any advertisement of the Ayurvedic, Siddha or Unani drugs, by notification in the Official Gazette.
- (ii) in Schedule A, after Form 26 E3, the following Forms shall be inserted, namely:-

"FORM 26 E4

[See rule 170]

Application Form for Advertisement of Ayurvedic, Siddha and Unani drugs*(Note: Application may be made only for one advertisement)*

1. I(name of the applicant with designation) am the authorised signatory of(name and full address of the manufacturing company) License number valid up-to hereby apply for consideration of following contents of the intended advertisement:

Name of the Ayurvedic/Siddha/Unani drug	Contents of the advertisement including picture/audio/ video (s) (Enclose copy)	Reference of indication(s)	Language of advertisement	Medium of advertisement (print/electronic/ internet/ audio-visual)

2. The prescribed fee of rupees one thousand has been deposited to the Government under the head of account and the relevant Treasury Challan is enclosed herewith.
3. Copies of the following documents are attached-
- Valid license
 - References of indications/claims
 - Proof of safety
 - Proof of efficacy
 - Quality standards
 - Any other (please specify)
 - ...
 - ...
 - ...

Date

Signature

(Applicant)

Address and contact details

FORM 26 E5

[See rule 170]

State Licensing Authority for Ayurvedic, Siddha or Unani Drugs

Name of the State or Union territory

[Note: Out of (a), (b) and (c) paras, only one shall be ticked and filled]

It is recorded that M/s..... (Name of the manufacturer / company) situated at (Address), is holding Ayurvedic / Siddha / Unani drug manufacturing License Number valid upto and it is conveyed that-

- (a) Following contents of the intended advertisement for the (name of the drug) are noted in the register vide Unique Identification Number (Name of the State/ number/ year):-

"....."

The advertisement contents as above are valid till the validity of the current license. Invalid advertisement or any distortion in the contents of advertisement shall be liable for legal action as per rules.

- (b) Following clarification with relevant supporting information is needed within thirty days of issue of this communication, failing which application shall be declined and application fee forfeited.-

- (c) Application dated is hereby declined due to following reason(s)-

Note: The permission shall not be reflected or shown in the advertisement in any form.

Date: Seal of issuing Officer

(Signature and Name)

State Licensing Authority/Drug Controller

Name of State or Union Territory".

[F.No.K.11024/03/2013-DCC (AYUSH)]

P. N. RANJIT KUMAR, Jr. Secy.

Foot Note.—The Principal Rules were published in Official Gazette of India *vide* Notification No. F.28-10/45-H(I), dated 21st December, 1945 and was last amended *vide* notification G.S.R. No.1193(E) dated 12th December, 2018.