



DRUGS & COSMETICS

Shakun Sl.No.8

-COPY OF-

NOTIFICATION

Dated 9th July, 2008

The following draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945, which the Central Government propose to make rules, in exercise of the powers conferred by Section 33N of the Drugs and Cosmetics Act, 1940 (23 of 1940), is hereby published as required by the said Section for the information of all persons likely to be affected thereby and notice is hereby given that the said draft rules will be taken into consideration after the expiry of a period of forty five days from the date on which copies of the Official Gazette in which this notification is published, are made available to the public;

Objections or suggestion, if any, may be addressed to the Secretary (Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy) (AYUSH), Ministry of Health and Family Welfare, Indian Red Cross Society Building, New Delhi-110001;

Any objection or suggestions, which may be received from any person with respect to the said draft rules within the period specified above will be taken into consideration by the Central Government.

DRAFT RULES

1. (1) These rules may be called the **Drugs and Cosmetics (2nd Amendment) Rules, 2008**.
- (2) They shall come into force after the expiry of forty five days from the date of their publication in the Official Gazette.
2. In the Drugs and Cosmetics Rules, 1945, for rule 169, the following rule shall be substituted, namely:-
“169. Permitted Excipients:- Permitted Excipients along with their standards i.e. additives, preservatives, antioxidants, flavouring, agents, sweeteners, chelating agents etc. permitted in the Indian Pharmacopoeia (IP), Prevention of Food Adulteration Act, 1954 and Bureau of Indian Standard Act, 1986 are permitted for use in Ayurveda, Siddha and Unani drugs with the following conditions, namely:-
 1. The above excipients shall be used in the permissible limits as prescribed in the Indian Pharmacopoeia/Prevention of Food Adulteration Act, 1954/Food Product Order/Bureau of Indian Standard Act, 1986 and they shall comply with the respective quality specification, not exceeding any specified limits of usage therein, and except Hydrogenated vegetable oil.

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2. Only Natural coloring agents as permitted under rule 26 of Prevention of Food Adulteration Rules 1955 will be used for Ayurveda, Siddha and Unani drugs and additionally, colors permitted under rule 127 of Drugs and Cosmetic Rules 1945 shall be used for Proprietary Ayurveda, Siddha and Unani drugs as defined in sub clause (i) of clause (h) of Section 3 of Drugs and Cosmetics Act 1940, not exceeding any specified limits of usage therein.
3. Preservatives and Colouring agents shall be mentioned on the label for the information of the consumer as required under rule 161 of the Drugs and Cosmetics rule, 1945.
4. Additives used in various processes and in formulating dosage forms shall be mentioned clearly with quantities used, in the application for licenses and the record for the same shall be maintained by the manufacturers.
5. Manufacturers shall be responsible to ensure rationality, safety and quantity used of various excipients in the formulation.
6. If any excipients or additive or preservative etc. referred in Indian Pharmacopoeia/Prevention of Food Adulteration Act, 1954/Food Product Order/Bureau of Indian Standard Act, 1986 is deleted at a particular point of time, this will also be deleted simultaneously for the use in Ayurveda, Siddha and Unani drugs.
7. Any previous notification issued by the Department of AYUSH regarding use of excipients/additives or preservatives in Ayurveda, Siddha and Unani medicines stands superseded.”

Sd/-
(Shiv Basant)
Jt. Secy.

G.S.R.513(E)
No.K.11022/47/2006-DCC(AYUSH)
Issued by:
Ministry of Health and Family Welfare
(Department of Ayurveda, Yoga and Naturopathy,
Unani, Siddha and Homeopathy)
New Delhi

Footnote: The Principal rules were published in the Gazette of India *vide* Notification Number F.28-10/45-H(I), dated the 21st December, 1945 and last amended *vide* notification numbers G.S.R. 678(E), dated 31st October, 2006.

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