



DRUGS & COSMETICS

-COPY OF-

NOTIFICATION

Dated 11th 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 the Drugs 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 copies of the Gazette of India containing these draft rules are made available to the public.

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

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

DRAFT RULES

- (1) These rules may be called the **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 Drugs and Cosmetics Rules, 1945, after rule 84AA, the following rule shall be inserted, namely,-

"84AB. Information to be uploaded by the licensee on online portal SUGAM-

- (1) The licensee licensed under this PART shall register with portal SUGAM (www.cdscoonline.gov.in) and upload information as per the format provided in the portal pertaining to the licences granted for manufacture for sale or distribution of drugs and it shall be updated from time to time.
- (2) The information uploaded by the licensee with SUGAM portal under sub-rule (1), shall be verified by the concerned Licensing Authority."

Sd/-
(Sudhir Kumar)
Jt. Secy.

G.S.R.629(E)

F.No.X.11014/16/2018-DR

Issued by:

Ministry of Health and Family Welfare

(Department of Health and Family Welfare)

New Delhi

Note: The principal rules were published in the Official Gazette *vide* notification No. F.28-10/45-H (1), dated 21st December, 1945.

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