MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 29th July, 2025

G.S.R. 513(E).—Whereas a draft of certain rules to amend the Cosmetics Rules, 2020 was published, as required under sub-section (1) of section 12 and sub-section (1) of section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), *vide* notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health and Family Welfare) number G.S.R. 371 (E), dated the 15th May, 2023, published in the Gazette of India, Extraordinary, Part II, Section 3, sub-section (i), dated the 17th May, 2023, 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 the copies of the Official Gazette containing the said notification were made available to the public;

And whereas, copies of the said Official Gazette were made available to the public on the 17th May, 2023;

And whereas, objections and 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 section 12 and section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules to amend the Cosmetics Rules, 2020, namely:—

- 1. Short title and commencement.- (1) These rules may be called the Cosmetics (Amendment) Rules, 2025.
- (2) They shall come into force on the date of their publication in the Official Gazette.
- 2. In the Cosmetics Rules, 2020 (hereinafter referred to as the said rules), in rule 3, in clause (w), the following explanation shall be inserted, namely:-
 - "Explanation:-For the purposes of this clause, the expression "use before" means, use before the first day of a month mentioned on label and the expression "date of expiry" mean the cosmetic expires on the last day of the month."
- 3. In the said rules, in rule 6, for the words "controlling officer" at both the places, where they occur, the words "Controlling Authority" shall be substituted.
- 4. In the said rules, for rule 7, the following rule shall be substituted, namely:-
 - "7. Government Analyst:- The Government Analyst appointed under section 20 of the Act (23 of 1940) shall be the Government Analyst for the purposes of these rules."
- 5. In the said rules, in rule 9, for the words "controlling officer", wherever they occur, the words "Controlling Authority" shall be substituted.
- 6. In the said rules, in rule 11, for the heading and sub-rule (1), the following heading and sub-rule shall respectively be substituted, namely:-
 - "11. *Central Cosmetics Laboratory and its function.* (1) The Central Drugs Laboratory established under the Act shall function as the Central Cosmetics Laboratory for the purposes of,
 - (a) analysing or testing such samples of cosmetics as may be sent to it under sub-section (2) of section 11 or under sub-section (4) of section 25 of the Act; or
 - (b) functioning as an appellate laboratory; or
 - (c) carrying out any other function as may be specifically assigned to it by the Central Government."
- 7. In the said rules, in rule 26,-
 - (i) in clause (c), in sub-clause (ii), for the words 'Central Licensing Authority', the words "State Licensing Authority" shall be substituted;
 - (ii) for clause (f), the following clause shall be substituted, namely:-

- "(f) The licensee shall keep record of the details of each batch of cosmetic manufactured and of the raw materials used therein as per the particulars specified in the Eighth Schedule either as hardcopy or through electronic means and such records shall be retained for a period of three years or six months after expiry of the batch whichever is later.";
- (iii) for clause (h), the following clause shall be substituted, namely:-
 - "(h) The licensee shall test each batch or lot of the raw materials used for manufacturing the cosmetics and also each batch of final product and shall maintain records or registers, showing the particulars in respect of such tests and the records or registers either as hardcopy or through electronic means shall be retained for a period of three years or six months after expiry of the batch whichever is later.";
- (iv) in clause (m), for the proviso, the following proviso shall be substituted, namely:-
 - "Provided that clauses (f) and (h) shall not apply to the manufacture of soap and the procedure for testing of raw materials and the records to be maintained by a manufacturer of soap shall be such as are approved by the Licensing Authority.".
- 8. In the said rules, in rule 31, in sub-rule (2), for the words "Controlling officer", the words "Controlling Authority" shall be substituted.
- 9. In the said rules, after rule 31, the following rule shall be inserted, namely:-
 - "31A. Cancellation or suspension of licence.— (1) If a licensee fails to comply with any of the conditions of license or with any provision of the Act or the rules made thereunder, the State Licensing Authority may, after giving the licensee an opportunity to show cause as to why an order for cancellation or suspension of license should not be passed and after giving an opportunity of being heard, by an order in writing, stating the reasons thereof, cancel a licence issued under these rules or suspend it for such period as he thinks fit, either wholly or in respect of some of the substances to which it relates.
 - (2) A licensee whose licence has been suspended or cancelled, may, within a period of ninety days from the date of the order, appeal to the State Government which shall, after considering the appeal and after giving an opportunity of being heard to the said appellant for hearing, pass such order as it deems fit which shall be final."
- 10. In the said rules, in rule 34, for sub-rule (10), the following sub-rule shall be substituted,

namely:-

"(10) In case, the cosmetic is meant for export, then the label on package or container of cosmetic shall comply with the law of the country to which the cosmetic is to be exported:

Provided that where a cosmetic is required by the consignee to be not labeled with the name and address of the manufacturer, the label on package or container shall bear a code number as approved by the State Licensing Authority.".

- 11. In the said rules, in rule 49, -
 - (i) in sub-rule (1), the words "or by courier" shall be omitted;
 - (ii) in sub-rule (3), the words "or courier" shall be omitted.
- 12. In the said rules, in rule 53, in sub-rule (2), for the words "or adulterated cosmetic", the words

"or spurious cosmetics under section 17D or adulterated cosmetic" shall be substituted.

- 13. In the said rules, in rule 60,-
 - (i) in sub-rule (1), (a) for the words "A licence issued", the words "An approval issued" shall be substituted;
 - (b) for the words "a licence retention", the words "approval retention" shall be substituted;
 - (ii) in sub-rules (2) and (3), for the word "licence", wherever it occurs, the word "approval" shall be substituted.

- 14. In the said rules, in rule 61,-
 - (i) for the words "premises licensed", the words "approved premises" shall be substituted;
 - (ii) for the word "licence", the word "approval" shall be substituted.
- 15. In the said rules, in rule 62, in clause (e), for the words "renewal of approval", the words "end of retention period of approval"shall be substituted.
- 16. In the said rules, in rule 63, for the word "Part", the word "Chapter" shall be substituted.
- 17. In the said rules, in rule 69, in sub-rule (2), for the words "Central Licensing Authority", the words "Licensing Authority"shall be substituted.
- 18. In the said rules, in First Schedule, in paragraph (6), for the words "withdraw of this Power of Attorney", the word "withdrawal of authorisation" shall be substituted.

[F. No. X.11014/16/2021-DR] RAJIV WADHAWAN, Advisor (Cost)

Note: The principal rules were published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) *vide* notification number G.S.R.763 (E), dated the 15th December, 2020.