

**File No.: COS-11011(11)/28/2024-eoffice
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(Cosmetics Division)**


FDA Bhawan, Kotla Road,
New Delhi-110002

Dated:

12 1 AUG 2025

Corrigendum

In continuation to this office letter dated 20.05.2025 vide File No.: COS-11011(11)/28/2024-eoffice, at the Page No. 1 & 2, the serial no. of the products shall be read as 51, 63, 64, 66 and 67 in place of 7, 3, 5, 63, 64, 66 and 67.


(Dr. Rajeev Singh Raghuvanshi),
Drugs Controller General (India) & Central Licensing Authority

To,

M/s. Spectra Medical India Pvt. Ltd.,
Plot No. 43, 1st and 2nd Floor Developed Plots
Industrial Estate, Perungudi, Kanchipuram, Tamil Nadu (India) – 600096
E-mail: rama@spectramedicals.com

Copy To:

- 1) All Zonal, Sub-Zonal and Port Offices of CDSCO
- 2) All State Drugs Controller

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**Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(Cosmetics Division)**

FDA Bhawan, Kotla Road,
New Delhi-110002

Dated: 20 MAY 2025

Subject: Cancellation of products under RC/COS-003211, for import of Cosmetics under Cosmetics Rules, 2020- Regarding

Whereas, the firm M/s. Spectra Medical India Pvt. Ltd., Plot No. 43, 1st and 2nd Floor, Developed Plots Industrial Estate, Perungudi, Kanchipuram, Tamil Nadu (India) – 60009 had registered cosmetics products for import in India vide Registration Certificate no. RC/COS-003211, Endorsement No. 1 dated 17.07.2023, which is valid upto 31.05.2027.

And whereas, as per the Rule 39 of the Cosmetics Rules, 2020, no cosmetic shall be imported or manufactured unless it complies with the specifications prescribed under the Ninth Schedule or any other standards of quality and safety, applicable to it and other provisions under the rules.

And whereas, as per the condition number 03 of the Registration Certificate issued to you, registered cosmetics will be required to be withdrawn from sale in the events of non-compliance of Standards.

And whereas, according to the provision of the Rule 39 of the Cosmetics Rules, 2020 read with Serial Number 98 of Annex B (list of substances which cosmetic products must not contain except subject to restrictions and condition laid down) of IS 4707 (Part 2): 2017, Salicylic acid (CAS No. 69-72-7) is allowed as Cosmetics ingredients at 3 % and 2 % concentration for Rinse-off hair products and other products respectively.

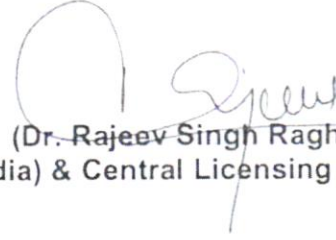
And whereas, after scrutiny of the above application submitted by the firm, the cosmetic products named Mesoestetic- Meso Peel Periocular(64), Mesoestetic- Salicylic; variant 10%(66), Mesoestetic- Salicylic; variant 20%(51), Mesoestetic- Salicylic; variant 30%(67), Dermamelan Intimate Gel(7), Dermamelan Mask(31), and MESOPEEL MODIFIED JESSNER(63) were found to contain salicylic acid in concentration of 7%, 10%, 20%, 30%, 15%, 15%, and 14% respectively.

And whereas, a show cause notice was issued by the Licensing Authority vide even no. dated 07.04.2025 to the firm M/s. Spectra Medical India Pvt. Ltd., for violation of Rule 39 of the Cosmetics Rules, 2020 and condition number 03 of the Registration Certificate.

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And whereas, you have responded and expressed willingness to surrender the products containing salicylic acid beyond the prescribed limit.

AND THEREFORE, the undersigned being the Licensing Authority empowered under Rule 21(b) of the Drugs and Cosmetics Act, 1940, keeping in view of the violation of Rule 39 of the Cosmetics Rules, 2020 and condition number 03 of the Registration Certificate, hereby order to cancel the registration of the products containing salicylic acid, registered under RC/COS-003211 mentioned at serial Nos.7, 3, 5, 63, 64, 66 and 67 from the date of issue of this order.



(Dr. Rajeev Singh Raghuvanshi),
Drugs Controller General (India) & Central Licensing Authority

To,

M/s. Spectra Medical India Pvt. Ltd.,
Plot No. 43, 1st and 2nd Floor Developed Plots
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