

File No: COS/MISC/40/21
Government of India
Central Drugs Standard Control Organization (HQ)
Directorate General of Health Services
Ministry of Health and Family Welfare
(Cosmetic Division)

FDA Bhawan, Kotla Road,
New Delhi-110002

Dated:- 6/18/2021

NOTICE

Subject: - Additional clarification on Frequently Asked Questions for grant/retention of registration certificate/license for import or manufacture of cosmetics in India under the Cosmetics Rules, 2020-reg

The Cosmetics Rules, 2020 have been published vide GSR No. 763(E) dated 15.12.2020 with effect from 15.12.2020. On commencement of these new cosmetic rules, this office has received various concerns and challenges faced by the stakeholders regarding application for grant of import registration certificates and subsequent endorsements. Therefore, in order to streamline the process of import registration of cosmetics and to address these issues, it has been decided to provide detailed clarification on these issues. Accordingly, additional set of FAQs (annexed) have been prepared in light of the Cosmetics Rules, 2020 for information of all the stakeholders.



(Dr. V. G. Somani)
Drugs Controller General (India)

To,

All Stakeholders and CDSCO Website

Q.1. What will be the validity of product endorsements granted under existing Registration Certificate in Form 43 as per Drugs and Cosmetics Rules, 1945?

Ans: The validity of product endorsement granted under existing Registration certificate in Form 43 as per Drugs and Cosmetics Rules 1945 will be effective from its date of issuance till the validity of parent RC in Form 43.

(Note- Currently option for endorsement in Form 43 (Old RC as per Drugs and Cosmetic Rules, 1945 have been disabled for streamlining the process of implementation of Cosmetic Rules 2020 and further IT issues as informed by the CDAC Team)

Q.2. What are the documents required for issuance of Registration Certificate/Endorsement in Form COS-2 for products which are already registered in Form 43 as per the provisions of Drugs and Cosmetics Rules 1945?

Ans: “No Change Declaration statement ” with respect to composition, Product label, specifications and test methods is required to be submitted. Further, an authorization from manufacturer in specified format, Information as per Second Schedule (Part-I) and requisite fees for category, manufacturing sites and variants, as applicable is required to be submitted.

Q.3. What are the documents required for issuance of additional Pack Size endorsement for already registered cosmetics products?

Ans: In case of pack size endorsement, “No Change Declaration statement ” with respect to composition, Product label, specifications and test methods is required to be submitted. Further, Information as per Second Schedule (Part-I) and requisite fees for manufacturing sites and variants, as applicable is also required to be submitted.

Q.4. What are the documents required for issuance of additional manufacturing site endorsement for already registered cosmetics products?

Ans: In case of additional manufacturing site endorsement, “No Change Declaration statement ” with respect to composition, Product label, specifications and test methods is required to be submitted. Further, an authorization from manufacturer for newly added manufacturing site, Information as per Second Schedule (Part-I) and requisite fees for category, manufacturing sites and variants, as applicable is also required to be submitted.

***Note:-** It is to be informed that, this office is already processing the product/additional pack size/additional site endorsement applications for previously registered products having valid RC under Rule 72 of Cosmetics Rules, 2020 on the basis of documents mentioned against each FAQ.
