

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION

(Cosmetics Division)

Frequently Asked Questions on **Registration and Import of Cosmetics in** **India**



CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
DIRECTORATE GENERAL OF HEALTH SERVICES
MINISTRY OF HEALTH AND FAMILY WELFARE
GOVT. OF INDIA

Note:

The replies to the FAQs are aimed only for creating public awareness about Cosmetics Regulation by CDSCO and are not meant to be used for legal or professional purposes. The readers are advised to refer to the statutory provisions of Drugs and Cosmetics Act 1940 & Rules made thereunder, Notifications in the Official Gazette published by Central Government and Guidelines/Clarifications issued by CDSCO time to time for all their professional needs.

FREQUENTLY ASKED QUESTIONS (FAQ'S) - COSMETICS IMPORT REGISTRATION

Q1. What is a Cosmetic in India?

Ans: As per Section 3(aaa) of the Drugs and Cosmetics Act 1940 and Rules 1945, Cosmetic means any article intended to be rubbed, poured, sprinkled or sprayed on, or introduced into, or otherwise applied to, the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance and includes any article intended for use as a component of cosmetic.

Q2. Whether Cosmetics are regulated in India?

Ans: Yes, imports of cosmetic products are regulated in India under the provisions of the Drugs & Cosmetic Act 1940 & Rules 1945 vide [Gazette notification G.S.R 426\(E\)](#).

Q3. What is the purpose of regulating import of cosmetics in India?

Ans: Import of cosmetics in India needs to be regulated to ensure quality and safety of cosmetics being imported in India and safety of consumers using these cosmetics.

Q4. Where can we get a copy of the Gazette notification G.S.R 426 (E)?

Ans: The copy of the Gazette notification G.S.R 426 (E) is available under Cosmetics Section on CDSCO website.

Q5. Where can we get a copy of the Drugs & Cosmetics Act 1940 & Rules, 1945?

Ans: The copy of the Drugs & Cosmetics Act 1940 & Rules 1945 is available on CDSCO website.

Q6. Whether all imported cosmetic products are regulated in India?

Ans: Yes, all imported cosmetic products which come under the definition of Cosmetic as per Drugs & Cosmetic Act 1940 are regulated in India.

Q7. Which is the Regulatory Authority that governs the regulations of Import of Cosmetics in India?

Ans: Drugs Controller General (India), Central Drugs Standard Control Organization (CDSCO)HQ, Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India , FDA Bhawan, ITO, Kotla Road, New Delhi -110002.

Q8. Which division of CDSCO (HQ) is responsible for registration of Cosmetics for import in India?

Ans: Cosmetics Division, Central Drugs Standard Control Organization (CDSCO)HQ, Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India , FDA Bhawan, ITO, Kotla Road, New Delhi -110002.

Q9. What are the requirements for import of Cosmetics in India?

Ans: For the import of Cosmetics in India, the imported cosmetic products are required to be registered with Central Drugs Standards Control Organization by giving application in Form 42 to obtain Registration Certificate in Form 43.

Q10. What is Form-42?

Ans: Form-42 is an application for issue of a Registration Certificate for Import of cosmetics into India under the Drugs and Cosmetics Rules, 1945.

Q11. What is Form-43?

Ans: Form-43 is a Registration Certificate to be issued for Import of cosmetics into India under the Drugs and Cosmetics Rules, 1945.

Q12. Who can import Cosmetics into India?

Ans: The Manufacturer himself/The Authorized Agent of the Manufacturer/The Subsidiary of the Manufacturer/any other importer can be an applicant for issuance of Registration Certificate for import of cosmetics into India.

Q13. To whom shall the application be submitted for Registration of Cosmetics in India?

Ans. Applications for Registration Certificate for import of Cosmetic products shall be submitted to the Drugs Controller General (India), Central Drugs Standard Control Organization (CDSCO), FDA Bhawan, ITO, Kotla Road, Delhi-110002. Phone: 91-11-23236965 /23236975. Fax: 91-11- 23236973.

Q14. What is the procedure to obtain the “Registration Certificate” in Form-43 for import of cosmetics in India?

Ans: Procedure to obtain the “Registration Certificate” in Form-43 is available under Cosmetics Section on CDSCO website.

Q15. What are the documents required for issuance of Registration Certificate in Form-43?

Ans: Documents required for issuance are available under Cosmetics Section on CDSCO website.

Detailed information of documents required is available in the guidance document on CDSCO website.

Q16. What is the fee required for registration of cosmetics for import in India?

Ans: A fee of Two hundred and fifty US dollars [or its equivalent in Indian rupees] per category of cosmetic shall be paid along with application in Form-42.

Q17: As per which categories cosmetics are required to be classified while applying for Registration Certificate?

Ans: Cosmetics are classified as per Column (3) of Guidelines on Registration of Import of Cosmetics.

Q18. How the fees shall be paid for registration of cosmetics for import in India?

Ans: The fees shall be paid through a Challan in the designated branches of Bank of Baroda either in US dollars or in equivalent rupees under “HEAD OF ACCOUNT 0210-MEDICAL AND PUBLIC HEALTH, 04-PUBLIC HEALTH, 104-FEES AND FINES” or vide online Bharatkosh payment gateway using SUGAM Portal. The original copy of the treasury

Challan or acknowledgement receipt in case of online payment shall be submitted along with the application for product registration.

Q19. What is the time period for Grant of Registration Certificate in Form 43?

Ans: As per Rule 129C of Drugs and Cosmetic Rule 1945, if the application is complete in all respects and the information specified in Schedule (D III) is in order, the licensing authority shall, within six months from the date of receipt of an application, issue such Registration Certificate, and in exceptional circumstances and for reasons to be recorded in writing, the Registration Certificate may be issued within such extended period, not exceeding three months, as the licensing authority may deem fit. However, CDSCO targeted timeline for processing of application is 90 days as per circular dated 30.05.2014.

Q20. What is the Duration/Validity of "Registration Certificate" in Form-43 for Cosmetics in India?

Ans: A Registration Certificate, unless, it is sooner suspended or cancelled, shall be valid for a period of three years from the date of its issuance.

Q21 How to register additional product(s) in an already granted/valid Registration Certificate in Form 43?

Ans. Importer has to apply for endorsement to the existing Registration Certificate along with the requisite documents except fees if the category is already registered and provided that the additional products(s) is being manufactured at the same manufacturing site. If additional category needs to be added, fees of 250USD per category is required to be paid. Validity of the endorsement issued for these additional products will be same as of main Registration Certificate.

Q22. What is the duration/validity of Endorsement issued under Registration Certificate for additional products?

Ans. Duration/validity of Endorsement will be same as of Registration Certificate under which Endorsement has been issued.

Q23. What if my registration certificate is going to expire?

Ans: Provided that if application for a fresh registration Certificate is made within six months before the expiry of the said certificate, the existing Registration Certificate shall be deemed to continue to remain in force until orders are passed on the application.

Q24. What are the documents required for re- registration?

Ans: Documents required are available under the Cosmetics Section on CDSCO website.

Q25. Whether Cosmetic products, having valid Registration Certificate can be imported from any notified ports of India?

Ans. Yes.

Q26. Who can issue free sale certificate for Imported Cosmetic products?

Ans. Free sale certificate can be issued by the National Regulatory Authority which in Original or authenticated (notarized/apostilled/attested by Indian Embassy) from Country of origin is required to be submitted. In case if it is not issued by National Regulatory Authority from the country of origin then from other competent Associations/ organizations duly authenticated from the Indian embassy of country of origin need to be submitted

Q27. Is it required to submit free sale certificate for all variants of the imported Cosmetic products?

Ans. Yes. Free sale certificate for all variants needs to be submitted.

Q28. What are the changes on granted Registration certificate that require an applicant to make a fresh Registration?

Ans. The following changes require a fresh registration –Any change with respect to manufacturer (legal/ actual) like change in constitution, change in name, change in address, etc. Any change with respect to importer/ Indian Agent like change in constitution, change in name, etc.

Q29. What are the changes which do not require fresh registration and only notification or amendment needs to be obtained?

Ans. Change in product composition, change in the method of testing, minor change in manufacturing process not affecting the final product specifications, updating in labels and packaging (provided proper justification should be provided for the above changes).

Q30. Any change in name and/or address of Indian agent/ Importer/ legal and/or actual manufacturer or change in constitution after issue of Registration Certificate is required to be communicated to the Licensing Authority?

Ans., Yes, the manufacturer or his authorized agent in India shall inform the licensing authority immediately in writing in the event of any change in the constitution of the firm and / or address of the registered office / factory premises operating under this Registration Certificate. Where any such change in the constitution of the firm and/or address takes place, the current Registration Certificate shall be deemed to be valid for a maximum period of three months from the date on which the change has taken place unless, in the meantime, a fresh Registration Certificate has been taken from the licensing authority in the name of the firm with the changed constitution of the firm and/or changed address of the registered office or factory premises (as per condition no.4 of Form 43).

Q31. Whether acquisition/merger of one company by another company is considered as change in constitution of the company?

Ans. Yes and Indian agent/ Importer shall inform the licensing authority immediately in writing and shall submit fresh application as per Rules.

Q32. Whether original labels are required to be submitted to CDSCO at the time of application for registration of Cosmetics?

Ans. While original labels are required however applicants may submit copy of original label incorporating all details as per Part XV of Drugs and Cosmetics Rules 1945.

Q33. What are the labelling requirements to be complied for importing cosmetics into India?

Ans: Label should be in conformity with Rule 129-H read with Part XV of Drugs and Cosmetics Rules, 1945.

Q34. Can the importers of registered Cosmetic products incorporate India-specific requirements on labels after/post landing in India at customs warehouse or place approved by the Licensing Authority?

Ans. Yes, importers of registered Cosmetic products are currently allowed to incorporate India specific requirements like name and address of importer, import Registration Certificate Number on imported Cosmetic products post landing in India at customs warehouse or place approved by the CDSCO prior to release into market.

Q35. If applicant has applied for Registration Certificate and still not issued but in between there is the change has happened in the constitution of either Manufacturer or Indian Agent, address of manufacturer whether fresh fees is required product registration?

Ans. No. The applicant has to submit the Fresh application excluding fee.

Q36. What is the time limit for submission of Query Response?

Ans. There is no time limit for submission of Query Response as per the provision of Drugs and Cosmetics Act 1940 and Rules, however, it should be reasonable and justifiable.

Q37. Can Third party/Authorized Consultant ask the status of the application?

Ans. No. Only either applicant or his authorized employee may ask the status of his application if it is beyond the time limit prescribed under Drugs and Cosmetics Act 1940 and Rules, 1945.

Q38. Who is authorized to make a Technical Presentation, on behalf of applicant, when asked by the CDSCO?

Ans. Only Subject Expert or Technical Person of the company who is competent to make technical presentation.

Q39. Is registration certificate required for importing small quantities of Cosmetic products for R&D purposes like packaging trials, consumer studies, shelf life studies and transport studies?

Ans: No, Registration Certificate is not required.

Q40. Where do we approach to get No objection certificate for import of Cosmetic products for R&D purposes like packaging trials, consumer studies, shelf life studies and transport studies?

Ans. Concerned Port offices of CDSCO are required to be approached for above mentioned purposes.

Q41. Whether Registration Certificate is required for import of Cosmetic products in bulk for repackaging for 100% export to other countries?

Ans. No, Registration Certificate not required. In such cases the importer has to obtain necessary permission from CDSCO HQ. Importer must give written undertaking that these products are not released for domestic sale.

Q42. What supporting documents do I need to submit to comply Rule 135 B with respect to ban on animal testing on imported cosmetics?

Ans. At the time of clearance of the consignment at the port office, an undertaking issued from the manufacturer stating that the cosmetic has not been tested on animals on 12.11.2014 or after the date is required to be submitted to the concerned port office.(as per circular, file no. 18- 12/2013-DC/part file dated 03.02.2015)

Q43. Whether cosmetic with any Drug claim can be considered for registration as cosmetic?

Ans. No. Cosmetic and Drugs are defined separately under Section 3 in Drugs and Cosmetics Act, 1940. Products having drug claim does not come under the definition of cosmetic as per the Act and therefore cannot be considered for registration as cosmetic.

Q44. Whether cosmetics tested on animals in country of origin are allowed for import in India?

Ans. No, cosmetics that are tested on animals are not allowed for import in India.

Q45. Which standards to comply for cosmetic products?

Ans: No cosmetic shall be imported unless it complies with the specifications prescribed under Schedule S and Schedule Q or any other standards of quality and safety, applicable to it, and other provisions under the Drugs and Cosmetics Rules, 1945. In case the cosmetic is not included under Schedule S, it shall meet with specifications under the rules and standards applicable to it in the country of origin.

Q46. Is Certificate of Analysis necessary for grant of registration certificate?

Ans: No, it is not necessary. However, manufacturer may submit this document in place of product specification.

Q47. Does CDSCO grants license to manufacture cosmetics in India?

Ans: No, CDSCO does not grant license to manufacture cosmetics in India.

Q48. Who issues the manufacturing license for cosmetics in India?

Ans: Manufacturing license for cosmetics are issued by respective State Licensing Authorities appointed by State Governments.