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. 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 in Link: http://cdsco.nic.in/cosmetics/G.S.R 426 (E).pdf

Q4. Whether all imported cosmetic products are regulated in India?
Ans: Yes, all imported cosmetic products which come under the definition of Cosmetics as per Drugs & Cosmetic Act 1940 are regulated in India.

Q5. 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 Phone: 91-11-23236965 / 23236975, Fax: 91-11-23236973, E-mail:- dc@nic.in

Q6. Which division of CDSCO (HQ) is responsible for registration certificate in Form 43 for import of Cosmetics 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, is responsible for registration certificate in Form 43 for import of cosmetics in India.

Q7. 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.

Q8. 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.

Q9. To whom shall the application be submitted for Registration for 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.

Q10. What is the procedure to apply in Form 42 for obtaining "Registration certificate" in Form-43 for Cosmetics in India?
Ans: Following steps may be adopted for Registration application

STEP 1. Compilation of Registration dossier as per the guidance documents available at the link: http://cdsco.nic.in/Cosmetics/guidelines on registration of import of cosmetics.htm.

STEP 2. Submit Product Registration application at CDSCO (HQ), New Delhi.

Q11. How the fees shall be paid 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” and the original copy of the treasury challan shall be submitted along with the application for product registration. Provided that in the case of any direct payment of fees by a manufacturer in the country of origin, the fees shall be paid through Electronic Clearance System (ECS) from any bank in the country of origin to the Bank of Baroda, Kasturba Gandhi Marg, New Delhi, through the Electronic Code of the bank in the Head of Account “0210-Medical and Public Health, 04- Public Health, 104-Fee and Fines”, and the original receipt of the said transfer shall be treated as an equivalent to the bank Challan, subject to the approval by the Bank of Baroda that they have received the payment.

Q12. Is there any system of prescreening of applications for issue of grant of Registration Certificate at the time of submission at CDSCO (HQ) New Delhi?
Ans: Yes, application will be prescreened as per checklist available under link: http://cdsco.nic.in/cosmetics/prescreening checklist for registration of cosmetic.htm

Q13. What is the time period for Grant of Registration Certificate in Form 43?

Ans: As per Rule 129C provided that 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

Q14. 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 issue.

Q15. How to register additional product(s) in the 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 needs to be paid. Validity of the endorsement issued for these additional products will be same as of main registration certificate.

Q16. How much fees for issuance of duplicate copy of "Registration certificate" in Form-43 Cosmetics in India?

Ans: A fee of one hundred US dollars or its equivalent shall be paid for a duplicate copy of the Registration Certificate, if the original is defaced, damaged or lost.

Q17. Whether Cosmetic products, having valid registration certificate, can be imported from any notified ports of India?

Ans. Yes.

Q18. 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

Q19. 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.

Q20. 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.

Q21. What are the changes which do not require fresh registration and only notification or amendment may be obtained?

Ans. Change in 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).

Q22. Any changes in name and/or address of Indian agent/ Importer/ legal and/or actual manufacturer or change in constitution after issue of Registration Certificate are 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).

Q23. 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.
Q24. At the time of submitting applications for registration of Cosmetics, original labels are to be submitted to the CDSCO?

Ans. While original labels are required however applicants may submit copy of original label incorporating all details as per Rule 148 of Drugs and Cosmetics Rules 1945 which is authenticated by the manufacturer or his authorized agent.

Q26. 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 License Number on imported Cosmetic products post landing in India at customs warehouse or place approved by the CDSCO prior to release into market.

Q27. 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.

Q28. 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 and Rules, however, it should be reasonable and justifiable.

Q29. Can Third party/Authorized Consultant ask the status of the application?

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

Q30. 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.

Q31. 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.
Q32. Does it is required to get Registration Certificate 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.

Q33. 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)