Central Drugs Standard Control Organization
Directorate General of Health Services
Office of Drugs Controller General (India)
Cosmetic Division

Checklist for Pre Screening of Applications for Grant of Registration Certificate in Form 43 under the provisions of Drugs and Cosmetics Rules.

Name of the Firm----------Date:----------

S. No.	Administrative/Legal/Technical Documents.	Status		
		Please Tick(√)	Pg. No.	Annexure
1	Covering Letter-Purpose should be clearly mentioned with page number and Index.			
2	**Application (Form-42)**			
2.1	Duly filled, signed & stamped original application by the Indian Agent/ importer/Manufacturer.			
2.2	Name of the Cosmetic product, variants (if any) alongwith actual manufacturer of the productto be registered. The categorization of the product should be as per Column 3 of guidelines of cosmetics.			
2.3	Name & full address of Authorized Agent/ importer in India.			
2.4	Name & full address of Manufacturer & its Factory Premises.			
3	**Fee: TR-6 Challan (in Original)**			
3.1	Fees paid (250 USD equivalent Indian rupees for each Brand proposed viz. each category of cosmetics as mentioned in Colum 3 of the guidelines of cosmetics.			
3.2	Head of Account "0210 Medical and Public Health, 04-Public Health, 104-Fees and Fines) adjustable to PAO, DGHS, New Delhi			
3.3	Total categories of cosmetics……**TR6 No.. ……..USD……INR……**			
3.4	TR6 Challan Number, date of challan and Realisation Stamp,			
Note:- The categories of applied products and manufacturer's name shall be mentioned in TR-6 Challan.				
4	**Power Of Attorney(in Original)**			
4.1	Executed & authenticated either in India before a First class Magistrate, or in the country of origin before such an equivalent Authority or attested by the Indian Embassy of the said country or Apostilled from Hague convention member countries as per proforma attached.			
4.2	Name and full address of the manufacturer & its manufacturing site as per Form-42.			
4.3	Name and full address of the Indian Agent			
4.4	Name of the Cosmetic product, variants (if any) alongwith actual manufacturer of the product to be registered. The categorization of the product should be as per Column 3 of guidelines of cosmetics.			
4.5	Duly conjointly signed, stamped, and dated with name & designation of the signatory by both Indian agent & the manufacturer.			

Note:-All the pages of power of attorney including product list duly apostilled/notarized and authenticated from the country of origin or It should be tamper proof seal.				
4.7	Time period for which POA is valid must be mentioned in power of attorney.			
5	Duly filled, signed and sealedSchedule D III by manufacturer or Indian agent along with undertaking.			
6	**Labels of proposed products:-**			
6.1	Legible label of the products circulated in the country of origin.			
6.2	Legible Original label for proposed products along with their variants (if any) as per Drugs and Cosmetics Rules, 1945 which includes following:- • Name of Cosmetics:- • Name of Manufacturer and Complete address of premises where the cosmetic is manufactured. • Use Before • Direction for safe use/Caution • Batch no • Manufacturing License no. • Registration Number and Importer name and address • Other Information(if any)			
7	List of Ingredients with details of concentration of each ingredient used in the product composition duly signed by competent QC person from the manufacturer.			
8	**Regulatory Certificates:-**			
8.1	Authenticated copy of manufacturing licenses/registration/marketing authorization **in respect of applied products** issued by regulatory Authority from country of origin			
8.2	Original Free Sale Certificate issued by National Regulatory Authority of Country of origin for the applied products.			
8.3	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.			
9	**Chemical Information of cosmetics:-**			
9.1	Test protocol for testing of cosmetics			
9.2	Specification			
9.3	Test report including result of Pb, As, Hg and microbiological test. (Wherever applicable)			
Note:-Testing protocol, Specification and Test Report duly signed by competent QC person from the manufacturer.				
10	Pack insert, (if any)			
11	Soft copies of the information (MS Word & MS Excel) about product name along with category, pack size and actual manufacturing site.			
12	One sample pack of product shall be submitted after its first import.			
13	List of countries where market authorisation or import permission or registration was granted.			
14	Other documents (if any)			

Mailing Address of the applicant :	**Stamp & Signature of the Authorised Signatory of the applicant** **Mobile No.** :……..…… **E-mail**:……

Office Use Only:

Accepted for review/Not accepted due to incomplete information in respect of point no. (s) …….mentioned above.

Signature: ……..

Name of the Reviewer:…..…….

Date:…….……