Online checklist for grant of Registration Certificate in Form COS-1 under the provisions of Cosmetics Rules 2020 of Drugs & Cosmetics <u>Act, 1940</u>

1. Covering Letter-

Purpose should be clearly mentioned with page number and Index.

- 1.1 In case of product/manufacturing site/pack size endorsement Copy of approved registration certificate is required to be uploaded
- 2. Authorization By The Manufacturer To His Agent In India Along With Undertaking (In original in format as per First Schedule) [2.1 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 conditions covered in the proforma available on website, 2.2 Name and full address of the manufacturer & its manufacturing site as per Form COS-1, 2.3 Name and full address of the Indian Agent, 2.4 Name of the cosmetic product, pack sizes, variants (if any) along with actual manufacturer of the product to be registered, The categorization of the product should be as per Fourth Schedule of the Cosmetics Rules, 2020, 2.5 Duly co-jointly signed, stamped, and dated with name & designation of the signatory by both Indian agent & the manufacturer, 2.6 Time period for which Authorization is valid must be mentioned in power of attorney]
- 3. Information and undertaking required to be furnished by the manufacturer or his authorised importer or distributor or agent with the application form for import registration certificate as specified in Part I of Second Schedule of the Cosmetics Rules, 2020

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3.1. Product Details

- 3.1.1 Name of Ingredients in the Nomenclature of standard reference, along with percentages contained in the cosmetics.
- 3.1.2 Manner of labelling as per the Cosmetics Rules, 2020 (Proposed Label)
- 3.1.3 Specification and testing method for testing of cosmetics.
- 3.1.4 Package inserts (if any)

4. Regulatory Certificates:

- 4.1 Particulars of the manufacturing licenses or registration or product permission or marketing Authorisations or free sale certificate or (if any) under which the cosmetics are being manufactured in the country of origin along with the copy of the licenses or marketing authorisation or free sale certificate or registration issued by the Regulatory Authority or any other competent authorities or associations of that country. (In case there is no provision of manufacturing licenses/marketing authorization in country of origin, an undertaking or declaration on letterhead of the manufacturer for the same from the manufacturer is required to be submitted)
- 4.2 Original Free Sale Certificate issued by National Regulatory Authority of Country of origin for the applied products. OR 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. (Free Sale Certificate from the country of Legal Manufacturer in addition to the Actual Manufacturer from the country of origin can be considered)

5. Other documents

- 5.1 Undertaking that the cosmetic products to be imported in to the country have not been tested on animals as per the Cosmetics Rules, 2020.
- 5.2 Undertaking from the manufacturer stating compliance of all raw materials or pigments used, heavy metals and hexachlorophene contents in products with Bureau of Indian Standards and the Cosmetics Rules, 2020.
- 5.3 Any other (if any)
- 5.4 Details of IEC and GSTIN of the firm (enclose copy of documents)
- 6. Retention of old Registration Certificate Number (if yes, please mention the Registration Certificate Number and enclose copy of Registration Certificate)
- 7. Fee Bharatkosh e-receipt and challan
- 8. Application (Form COS 1)
