CENTRAL DRUGS STANDARD CONTROL ORGANIZATION

(Cosmetics Division)

Guidance Document

Guidance Document on Common Submission Format for Import Registration of Cosmetics in India

Note:

The Guidance Document is aimed only for creating public awareness about Cosmetics Regulation by CDSCO and is 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.

PREFACE

As per section 3(aaa) of the Drugs and Cosmetics Act, 1940

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.

As per Rule 129 of Drugs and Cosmetic Rules, 1945

No cosmetic shall be imported into India unless the product is registered under the rules by the licensing authority appointed by the Central Government under rule 21 or by any person to whom such powers may be delegated under rule 22.

Any article falling within the definition of cosmetic (Section 3aaa of D&C Act, 1940) is required to be registered along with pack size and manufacturing premises before import into the country.

An application for issue of a Registration Certificate for cosmetics intended to be imported into India shall be made online in Form 42 on SUGAM Portal of CDSCO either by the manufacturer himself or by his authorised agent or importer in India or by the subsidiary in India authorised by the manufacturer to the Licensing Authority under the Act i.e. Drugs Controller General (I), CDSCO (HQ).

The purpose of this document is to provide guidance for submission of online application in Form 42 to CDSCO for obtaining Registration Certificate for import of cosmetics in India.

Guidance Document for Submission of application for grant of Registration Certificate in Form 43 to import cosmetics

1. Covering Letter

- Purpose (Fresh or Endorsement of Products/Pack Size/Additional Sourcing Location or Re-Registration) should be clearly mentioned along with the details of earlier issued Registration certificate (If any) and product/ product category (whether already registered or not).

Note: Mention the Section no. of checklist where the correlation charts between Serial number of products in Form-42 with Free Sale Certificate/ Power of Attorney is uploaded.

2. Power Of Attorney

- 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.
- Name and full address of the manufacturer & its manufacturing premises as per Form-42.
- Name and full address of the authorised Indian Agent as per Form-42.
- Name of the Cosmetic product, variants (if any) along with name and complete address of manufacturing premises of the product to be registered. The categorization of the product should be as per Column 3 of Guidelines on Registration of Import of Cosmetics
- Duly conjointly signed, stamped, and dated with name & designation of the signatory by both authorised Indian agent & the manufacturer.
- Time period for which POA is valid must be mentioned in power of attorney.
- In case the Brand Owner is located in India and gets its products manufactured from sites located outside India, a Letter of Authorization (LOA) with conditions (Same available in POA pro forma) of the Brand Owner and acceptance by the overseas manufacturer is required. LOA should be 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.

Note: Power of Attorney including product list duly apostilled and authenticated from the country of origin. All the pages of Power of Attorney including product list should be signed by both authorised Indian agent and manufacturer before authentication.

Pro forma for Power of attorney enclosed as Annexure-I

3. Schedule D III

- Duly filled and signed Schedule D III by manufacturer or authorised Indian agent along with undertaking.

Pro forma for Schedule D-III enclosed as Annexure-II

4. List of Ingredients

- Name of the cosmetic and name of Ingredients in the nomenclature of standard reference along with percentage contained in the cosmetic duly signed by competent authorized person with stamp from the manufacturer.

5. Labels of proposed products

Legible Original label for proposed products along with their variants (if any) as per Drugs and Cosmetics Rules, 1945 which includes following:-

- Name of Cosmetic
- Name and address of the manufacturer and name of the country where the product has been manufactured. If the product has not been manufactured in a factory owned by the manufacturer, the name and address of the actual manufacturer or the name of the country where it has actually been manufactured as "Made in ..... (Name of country)" should be there on the label.
- Further, for very small size container where the address of the manufacturer cannot be given, the name of the manufacturer and his principal place of manufacture shall be given along with pin code.
- Use Before
- Direction for safe use/Caution
- Batch no
- Manufacturing License no.(If any)
- Registration Certificate Number and R.C holders name and address.
- Information (if any) as per Part XV of Drugs and Cosmetics Rules, 1945.

6. Specification

- Specification and testing method for testing of cosmetics.

7. Pack insert

If any

8. Manufacturing Licenses

- Authenticated copy of manufacturing licenses/registration/marketing authorization in respect of applied products issued by Regulatory Authority from country of origin.

Note: In case there is no provision of manufacturing licenses/marketing authorization in country of origin, an undertaking for the same from the manufacturer is required to be submitted.

9. Free Sale Certificate

Original Free Sale Certificate issued by National Regulatory Authority of Country of origin for the applied products. Product list of free sale certificate should be signed and stamped by issuing authority.

Free sale certificate issued by National Regulatory Authority or other competent associations/organizations from the country of the principal manufacturer or actual manufacturer from country of origin can be considered. 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 needs to be submitted.
Or in case if free sale certificate is authenticated either from chamber of commerce or notary public and apostilled in both cases, then it may be accepted.

Note:

- Free sale certificate should contain the statement that in which country the applied products are freely sold.
- Correlation chart of the products with serial number as per Form-42 is required to be submitted.

10. Non Animal Testing Declaration

Undertaking that the applied cosmetic products to be imported in to the country have not been tested on animals (GSR No.718 (E) 13.10.2014).

11. Declaration for Heavy Metal and Hexachlorophene content.

Test report including result of Pb, As, Hg, other Heavy metals and microbiological test (Wherever applicable) / Undertaking from the manufacturer stating compliance of all raw materials/pigments used, heavy metals (with specified limits) and Hexachlorophene contents in products with Bureau of Indian Standards and Drugs & Cosmetic Rules, 1945.

12. Other documents (If any)

13. Application (Form-42)

- Duly filled, signed & stamped original application by the authorised Indian Agent/Manufacturer.
- Name of the Cosmetic product, variants (if any), pack size (in Indian Metric System) along with manufacturing premises of the product to be registered. The categorization of the product should be as per Column 3 of Guidelines on Registration of Import of Cosmetics.
- Name & full address of Authorized Agent in India [Name and address should correlate with POA and Schedule D(III)].
- Name & full address of Manufacturer & its manufacturing premises. [Name and address should correlate with POA and Schedule D(III)].

14. Fee: (Bharatkosh Online Payment)

- As per G.S.R.1193(E) dated 12 December, 2018, a fee of Two Thousand US dollars or its equivalent in Indian Rupees per category of cosmetic as mentioned in Column 3 of the Guidelines on Registration of Import of Cosmetics and a fee of Fifty US dollars for each variant shall be paid along with application in Form 42.

As per the circular no. CDSCO/IT/2018-(37) dated 09.01.2019 of this directorate and subsequent letter of even number dated 15.02.2019, the fees shall be paid through Bharatkosh only, from 28.02.2019 onwards. The fee shall be paid through Bharatkosh gateway under Head of Account "0210041040000-00-1" Import and Registration and the acknowledgement receipt shall be submitted along with the application for registration of cosmetics.

Annexure-I

Power of Attorney to accompany an application for issue of Registration Certificate for import of Cosmetics into India, under the Drugs and Cosmetic Rules, 1945.

Whereas,

M/s.----------hereinafter to be known as Authorized Agent of us, intends to apply for a Registration Certificate under the Drugs and Cosmetics Rules, 1945, for the import, use and marketing into India, of the Cosmetics Brand/products marketed by us, we,

M/s. ---------- hereinafter to be known as the Principal Manufacturer, having the factory premises at (1)…

Hereby delegate Power of Attorney that for the duration of the said Registration period:-

(1) The said applicant shall be our Authorized Agent for the Registration Certificate of Cosmetics Products imported into India under the brand " ----------" only, under rule 129 C of the Drugs and Cosmetics Rules;

(2) We shall comply with all the conditions imposed on the Registration Certificate, for import of Cosmetics as required under the provisions of Drugs and Cosmetics Rules, 1945

(3) We declare that we are carrying on the manufacture of the Cosmetics Products at the premises of the supporting Manufacturers and we shall from time to time report any change of premises on which manufacture will be carried on and in cases where manufacture is carried on in more than one factory any change in the distribution of functions between the factories.

(4) We shall comply with the provisions of Part XIII of the Drug and Cosmetics Rules, 1945.

(5) Every Cosmetics products got manufactured by us for import under the Registration Certificate into India shall conform to the specifications given in the Drugs & Cosmetics Rules, 1945 as amended from time to time

(6) We shall inform to the licensing Authority within 30 days in the event of any change in variants or in category or in manufacturing location or in labelling or in documentation of any of the Cosmetics pertaining to the certificate to be granted to us.

(7) We shall from time to time report for any administrative action taken due to adverse reaction, viz. market withdrawal regulatory restriction, or cancellation of authorization and/or **"Not of standard quality report"** report of any Cosmetics pertaining to the Registration Certificate declared by any Regulatory Authority of any country where the Product is marketed/sold or distributed. The dispatch and marketing of the Cosmetics in such cases shall be stopped immediately and the licensing authority shall be informed immediately.

(8) We shall comply with such further requirements, if any, as may be specified by the Government of India, under the Act and the rules, made thereunder.

(9) We shall allow the licensing authority or any person authorized by him in that behalf to take samples of the Cosmetics concerned for test, analysis or examination, if considered necessary by the Licensing authority.

Name(s) of the Cosmetic(s)

Signature on behalf of Principal Manufacturer, with name, designation, date and place.

NAME:

DESIGNATION:

DATE:

SIGNATURE & STAMP

Manufacturing Address(s):

Signature on behalf of Authorized Agent in India with name, designation, date and place.

NAME:

DESIGNATION:

DATE:

SIGNATURE & STAMP

Annexure-II

SCHEDULE D (III)
(See rule 129A)

INFORMATION AND UNDERTAKING REQUIRED TO BE SUBMITTED BY THE MANUFACTURER OR HIS AUTHORISED IMPORTER/DISTRIBUTOR/AGENT WITH THE APPLICATION FORM FOR A REGISTRATION CERTIFICATE.

(The format shall be properly filled in for each application in form 42)

1. PARTICULARS OF THE MANUFACTURER AND MANUFACTURING PREMISES.-

(a) Name and address of the manufacturer and manufacturing premises to be registered along with telephone numbers, Fax numbers and e-mail address.
(b) Name(s) and address of the Partners/Directors.
(c) Name and address of the authorised importer/distributor/agent in India, responsible for the business of the manufacturer.
(d) A brief profile of the manufacturer's business activity, in domestic as well as global market.

2. PARTICULARS OF THE COSMETICS TO BE REGISTERED UNDER REGISTRATION CERTIFICATE.-

(a) Names of cosmetics along with their brands name, category, pack sizes and variants to be registered and meant for import into and use in India.
(b) Particulars of the manufacturing licenses/registration/marketing authorizations (if any) under which the cosmetics are being manufactured in the country of origin along with the copy of the licenses/ marketing authorization/registration issued by the Regulatory Authority of that country.
(c) List of countries where marketing authorization or import permission for the said cosmetic has been granted.

3. CHEMICAL INFORMATION OF COSMETICS.-

(a) Name(s) of ingredients in the nomenclature of standard references, along with percentages contained in the cosmetic.
(b) Specification and testing method for testing of the cosmetic(s).
(c) Manner of labelling as per Drugs and Cosmetics Rules, 1945.
(d) Package insert (if any).

4. UNDERTAKING TO DECLARE THAT.-

(a) We shall comply with all the conditions imposed on the Registration Certificate for the import of cosmetics as required under the provisions of Drugs and Cosmetics rules, 1945.

(b) We declare that we are carrying on the manufacture of the cosmetics mentioned in this Schedule, at the premises specified above, and we shall from time to time report any change of premises on which manufacture will be carried on and in cases where manufacture is carried on in more than one factory any change in the distribution of functions between the factories.

(c) We shall comply with the provisions of Part XIII of the Drugs and Cosmetics Rules, 1945.

(d) Every cosmetic manufactured by us for import under the Registration Certificate into India shall conform to the specifications given in the Drugs & Cosmetics Rules, 1945 as amended from time to time.

(e) We shall inform to the licensing authority, within 30 days in the event of any change in variants or in category or in manufacturing location or in labelling or in documentation of any of the cosmetic pertaining to the certificate to be granted to us.

(f) We shall from time to time report for any administrative action taken due to adverse reaction, viz. market withdrawals/regulatory restriction, or cancellation of authorisation and/or "not of standard quality report" of any cosmetic pertaining to the Registration Certificate declared by any Regulatory Authority of any country where the cosmetic is marketed/sold or distributed. The despatch and marketing of the cosmetic in such cases shall be stopped and the licensing authority shall be informed immediately.

(g) We shall comply with such further requirements, if any, as may be specified, by the Government of India, under the Act and the Rules, made thereunder.

(h) We shall allow the licensing authority or any person authorised by him in that behalf to take samples of the cosmetics for testing if considered necessary by the licensing authority.

The information submitted above is true to the best of my/our knowledge and belief.

Place:
Date:

Signature of the manufacturer or his authorized agent
Seal/Stamp