

# ***Guidelines on Registration of Import of Cosmetics***

(AS ON 2.1.2013)

## **A: PURPOSE:**

1. The Government of India has issued a Gazette Notification G.S.R 426(E) dated 19<sup>th</sup> May 2010 for amending the Drugs & Cosmetics Rules, 1945 providing for registration of import of cosmetics into the Country.
2. The above provision was to come into effect from the 1st April, 2011. But in view of the various possible difficulties apprehended by the stakeholders, its implementation has been deferred till the 31st March, 2013.
3. With a view to implementing the provisions of the aforesaid notification and facilitate the registration process for import of cosmetics, the following guidelines / clarifications, including general requirements for grant of Registration Certificate, are being provided hereunder:
4. These guidelines are not exhaustive and may be augmented / modified further through additional guidelines or amendments of these rules, if considered necessary.

## **B. GUIDELINES / CLARIFICATIONS:**

1. All cosmetic products that are imported for sale in India need to be registered with the licensing authority as defined under Rule 21 of Drugs & Cosmetics Rules, 1945.
2. An application for registration in Form-42, along with all requisite documents, shall be submitted to Drugs Controller General (I), CDSCO, FDA Bhavan, Kotla Road, New Delhi 110002.
3. Who can apply for Registration of Import of Cosmetics / who can be an importer:
  - (i) The Manufacturer himself having registered office in India.
  - (ii) The Authorised Agent of the Manufacturer
  - (iii) The Subsidiary of the Manufacturer
  - (iv) Any other importer
4. A "Brand" for the purpose of these rules will mean each category of cosmetic products as mentioned in Column 3 of the list enclosed at Annexure.
5. A "Brand" will include all variants of a product e.g. colour, shades, pack sizes, etc.
6. A "Brand" will not mean the trade name of any product of a manufacturer or the manufacturer himself / itself.
7. A "Manufacturer" means a person or entity in a Country other than India who owns the trade name of the brand of the cosmetic product for which registration has been applied for and who / which manufactures such product at his / its own manufacturing site or at a site owned by another manufacturer in the trade name of his / its brand.
8. An "Authorized Agent" means a person or entity in India authorized by the manufacturer. The authorized agent will be responsible for the business activities of the manufacturer in India including compliance to the provisions of the Act in all respects.
9. "Subsidiary" means an entity in India owned by the manufacturer.
10. "Any other importer" means any person or entity purporting to import cosmetic products other than the manufacturer, its authorised agent and its subsidiary.
11. An application for issue of a registration certificate will be accompanied by the specified fee along with the information and undertaking in Schedule D-III.
12. A single application may be made in Form 42 for any number of brands manufactured at one or more locations by a single manufacturer.
13. A single registration certificate in Form 43 may be issued to a particular applicant in respect of import of any number of

brands manufactured at one or more locations by a single manufacturer.

14. Each application will be accompanied by a fee of USD 250 or its equivalent Indian rupees for each Brand viz. each category of cosmetics as mentioned in Column 3 of the list enclosed at Annexure.
15. If the applicant seeks to import the same brand belonging to different manufacturers, he needs to submit separate application for each manufacturer and has to pay separate fees therefor.
16. In any existing valid Registration Certificate, if the applicant wants to add any further brand or product of already registered category as mentioned in Column 3 of the Annexure for the same manufacturer, separate application will need to be submitted by the importer. But no fee will be charged. In such cases additional product permission will be endorsed to the already approved category in a given Registration Certificate.
17. Power of Attorney – The authorization by a manufacturer to his authorized agent in India will be documented by a Power of Attorney. The power of attorney shall be
  - (a) executed and authenticated either in India before First Class Magistrate, or in the country of origin of the manufacturer before such an equivalent authority.
  - or**
  - (b) attested by the Indian Embassy of the said Country.
  - or**
  - (c) Apostille from Hague convention member countries is also acceptable.

The original of the same will be furnished along with the application for Registration Certificate.

While submitting the Power of Attorney, the following points should be kept in mind: -

- It should be co-jointly signed and stamped by the manufacturer as well as the Authorised agent indicating the name & designation of the authorized signatories.
  - It should clearly list the names of all cosmetic products along with their trade names, Brand as per Column 2 of the Annexure and variants (e.g. colour, shades, pack sizes, etc). Further, the name of the cosmetics should correlate with those mentioned in the Form 42.
  - The names and addresses of the manufacturer as well as the Authorised agent stated in the Power of Attorney should correlate with the Form 42.
  - It should be valid for the period of said Registration Certificate.
18. In case of any change in product specification, ingredients, variant, etc after grant of Registration Certificate, the applicant will inform about those changes to the Licensing Authority by submitting revised Schedule D III at least 30 days before the date of import.
  19. The label of imported cosmetics will bear the registration certificate number of the brand and name and address of the registration certificate holder.
  20. Sticking of labels containing the registration certificate number of the brand and the name and address of the registration certificate holder may be allowed to be carried out after import at a suitable declared place approved by the Licensing Authority on an application made to the Licensing Authority.
  21. The Label should also bear the 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.
  22. The following documents are required to be submitted for grant of registration certificate:
    - i. Covering letter by the applicant
    - ii. Form 42
    - iii. Treasury Challan
    - iv. Power of Attorney
    - v. Schedule D III
    - vi. Original or a copy of the Label.
    - vii. Free Sale Certificate (FSC)/Marketing Authorization letter/Manufacturing License, if any
    - viii. Product specification and testing protocol.
    - ix. List of countries where Market Authorization or import permission or registration was granted.
    - x. Pack insert, if any

xi. Soft copies of the information about the brands, products and manufacturer

23. The applicant will provide the translated English version of any document which is in any other foreign language from qualified translator.
24. In case where there is no provision for license to manufacture cosmetics in the country of origin, the importer will provide a declaration on an affidavit to that effect.
25. Cosmetic products which are imported into India as bulk for repackaging for 100% export to other countries will not require registration certificate. 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.
26. For Import of cosmetics for R&D purposes like packaging trials, consumer studies, shelf life studies and transport studies, registration certificate is 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.

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**ANNEXURE**

Brands of Cosmetic Products		
Column-1	Column-2	Column-3
1. Skin products		
	1. Skin care products	1. Face care products other than face mask
		2. Face mask
		3. Eye contour products
		4. Lip care products
		5. Hand care products
		6. Foot care products
		7. Body care products
		8. External intimate care products
		9. Chemical exfoliation products
		10. Mechanical exfoliation products
		11. Skin lightening products
		12. Other skin care products
	2. Skin cleansing products	1. Soap products
		2. Bath / shower products
		3. Make-up remover products
		4. External Intimate hygiene products
		5. Other skin cleansing products
	3. Body hair removal products	1. Chemical depilatories
		2. Physical epilation products
		3. Other body hair removal products
	4. Bleach for body hair products	1. Bleach for body hair
	5. Correction of body odour and/or perspiration	1. Products with antiperspirant activity
		2. Products without antiperspirant activity
	6. Shaving and pre- / after- shaving products	1. Shaving products
		2. Pre- / after-shaving products
		3. Other shaving and pre- / after- shaving products
	7. Make-up products	1. Foundation
		2. Concealer
		3. Other face make-up products
		4. Mascara
		5. Eye shadow
		6. Eye pencil
		7. Eye liner
		8. Other eye make-up products
		9. Lip stick
		10. Lipstick sealer
		11. Other lip make-up products

		12. Body or face paint, including "carneval make-up"
		13. Other make-up products
	8. Perfumes	1. Hydroalcoholic perfumes
		2. Non hydroalcoholic perfumes
	9. Sun and self-tanning products	1. Before and after sun products Sun protection products
		2. Self-tanning products
		3. Other sun and self-tanning products
	10. Other skin products	1. Other skin products
2. Hair and scalp products	11. Hair and scalp care and cleansing products	1. Hair conditioner
		2. Scalp and hair roots care products
		3. Antihairloss products
		4. Other hair and scalp care and cleansing products
		5. Antidandruff products
	12. Hair colouring products	1. Oxidative hair colour products
		2. Non-oxidative hair colour products
		3. Hair bleaching and dye remover products
		4. Other hair colouring products
	13. Hair styling products	1. Products for temporary hair
		2. styling Permanent wave products
		3. Hair relaxer / straightener products
		4. Other hair styling products
	14. Other hair and scalp products	1. Hair sun protection products
		2. Other hair and scalp products
3. Nail and cuticle products	15. Nail varnish and remover products	1. Nail varnish / Nail make-up
		2. Nail varnish remover
		3. Nail varnish thinner
		4. Nail bleach
		5. Other nail varnish and remover products
	16. Nail care / nail hardener products	1. Nail care products
		2. Nail hardener
		3. Other nail care / nail hardener products
	17. Nail glue remover products	1. Nail glue remover
	18. Other nail and cuticle products	1. Cuticle remover / softener
		2. Nail sculpting products
		3. Other nail and cuticle products
4. Oral hygiene products	19. Tooth care products	1. Toothpaste
		2. Tooth cleansing powder / salt
		3. Other tooth care products
	20. Mouth wash / breath spray	1. Mouth wash
		2. Breath spray
		3. Other mouth wash / breath spray products
	21. Tooth whiteners	1. Tooth whiteners
	22. Other oral hygiene products	1 Other oral hygiene products