

NON COMPLIANCES OBSERVED DURING REVIEW PROCESS OF APPLICATIONS FOR REGISTRATION OF IMPORT OF COSMETICS

1. Covering Letter:

- Not clearly mentioning the type of the application either Fresh or Endorsement of Products/Pack Size/Manufacturing site or Retention of already issued Registration Certificate)

2. Form COS-1:

- Incomplete Name and address of the authorized Indian agent, manufacturer & manufacturing Premises.
- If the products are to be imported in bulk, the actual pack size for import in bulk quantity is not mentioned.
- Colored scan copy of original document containing, Signature & Stamp with Name & Designation of Indian agent/Manufacturer not submitted.
- Name and address of authorized Indian agent/Manufacturer along with product name not correlated with Authorisation and Part-I of Second Schedule.

3. Part-I of Second Schedule

- Name & address of the authorized Indian agent, manufacturer & manufacturing premises not correlating with Form COS-1.
- Name of the Cosmetic along with category applied, variant and pack size not correlating with Form COS-1.
- Undertaking not signed and stamped by Indian agent/ Manufacturer.
- Not mentioning list of countries where market authorization or import permission or registration was granted.
- Incomplete information in Second Schedule as some columns is not filled up.
- Colored scan copy of original document is not submitted.

4. Authorisation:

- Name & address of the authorized Indian agent, manufacturer & Manufacturing premises not as per Form COS-1.
- Name of the Cosmetic along with category applied, variant and pack size not correlating with Form COS-1.
- Not signed, stamped and dated with Name & Designation of the signatory by both Indian agent & the manufacturer.
- Authorisation including product list not apostilled/ not authenticated from Indian Embassy of the country of origin.

- Undertaking by the authorized agent duly signed/stamped not submitted.

5. Fee:

- A copy of acknowledgement receipt of fee paid is not submitted.
- Amount of fee paid in USD or its equivalent in Indian Rupees is not correlating with the category of applied.

6. Product Composition data/Ingredient list:

- Product composition data not submitted for all the proposed products.
- List of ingredients for all the products not submitted with exact concentration of each ingredient.
- Nomenclature of each ingredient (INCI) not submitted.
- Product composition data containing ingredients with concentration more than the prescribed limit of BIS.
- Product composition data containing substances which must not form part of the composition of cosmetic products as per Annexure A of IS 4707 (Part 1 & 2) of BIS.
- Product Composition data not duly signed/stamped by competent QC Person/ Person authorised from the manufacturer.

7. Free Sale Certificate:

- Free sale Certificate not issued from country of origin/country of Manufacturer of the proposed products.
- Colored scan copy of Original/authenticated Free Sale Certificate issued by the national regulatory authority/ other competent association organizations from country of origin/country of Manufacturer not submitted for all the applied products and variants.
- Validity of Free sale Certificate not mentioned.
- Free sale certificate does not clearly indicate that the proposed products are freely sold in the country of origin/ country of Manufacturer.
- Name of the Cosmetic along with category applied, variant and pack size not correlating with Form COS-1 & Authorisation.

8. Specifications and Testing Method for Testing Of Cosmetics:

- Test Protocol for testing of cosmetics and specification as per the standards specified in the Cosmetics Rules, 2020 for the applied product not submitted.
- Test report including result of Mercury, Lead, Arsenic and Other Heavy Metals with limits not complying with the Cosmetics Rules, 2020.
- Test report/specification not duly signed by competent person from the Manufacturer.

9. Labels/Pack insert of Proposed Products:

- Submitted Original Label/pack insert of the products which is not legible and not in English Language.
- Name of the Cosmetics, Pack size & Name/address of the Manufacturer not correlating with that of Form COS-1.
- Label of the proposed products without word Batch no., mfg. License no., Use Before date or Exp. Date not complying with the Cosmetics Rules 2020.
- Labels containing phrases that may appear to attract the definition of the drug. E.g. affects the structure or any function of the human body, Treatment of any disease/disorder, Drug Facts, Dermatologist recommended etc.
- Label does not mentions cautions and Instructions for certain ingredients (e.g. p-Phenylenediamine, fluoride content) as per requirement of the Cosmetics Rules 2020.
- Submitted labels are not signed/ stamped by manufacturer or its authorised agent.

10. Undertaking for Heavy Metal and Hexachlorophene content:

- Heavy Metal undertaking/test reports/specifications not complying with the Cosmetics Rules 2020 and also not issued from the manufacturer.
- Declaration is not mentioning clearly that applied products are free from hexachlorophene and complies with the limit of heavy metals as per the Cosmetics Rules 2020.

11. Manufacturing License:

- Comply of manufacturing licence from the country of origin not submitted.
- An undertaking from the manufacturer not submitted in case if there is no provision of issuing of manufacturing licence in the country of origin.
- Notarized Copy of Manufacturing license/Repackaging license issued by the State Licensing Authority not submitted if the proposed products are imported in bulk for repacking/relabeling.

12. Undertaking for Non Animal Testing:

- Non Animal testing Undertaking/Declaration not issued by manufacturer
- Non Animal testing declaration not duly signed/stamped by competent person/authority from the manufacturer

13. Others: English translated copy of any of the above said documents not signed by the qualified translator.