

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

## 1. Covering Letter

- Not clearly mentioning the purpose e.g. Fresh RC, Endorsement, Pack size, Amendment, constitution change, change in address of Indian agent/importer/manufacturer, Additional documents etc.

## 2. Form 42

- Incomplete Name and address of the Indian agent, Legal manufacturer & Actual Manufacturing Premises.
- Category of the Product not mentioned as per Column 3 of the Cosmetic guidelines.
- Full name of the of the Cosmetics with Brand name & Variant with Pack size is not clear.
- If the products are to be imported in bulk, the actual pack size for import in bulk quantity is not mentioned.
- Signature & Stamp with Name & Designation of Indian agent/Manufacturer not in original.

## 3. Schedule D (III)

- Name & address of the Indian agent, Legal manufacturer & Actual manufacturing site not correlating with Form 42.
- Name of the Cosmetic with Brand Name & Variant with Pack size not correlating with Form 42.
- 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 Schedule DIII as some columns is not filled up.

## 4. Power of Attorney

- Validity of Power of Attorney not mentioned.
- Name & address of the Indian agent, Legal manufacturer & Actual Manufacturing site not as per Form 42.
- Name of the Cosmetic with Brand Name & Variant with Pack size not correlating with Form 42.
- Not co-jointly signed, stamped and dated with Name & Designation of the signatory by both Indian agent & the manufacturer.
- All the pages of Power of Attorney including product list not apostilled/notarized and not authenticated from country of origin.
- Power of Attorney is found to be not intact.

## 5. TR-6 Challan

- TR-6 challan without challan no. date and Bank realisation stamp.

- TR-6 challan not submitted in original.
- Fees paid in INR are not mentioned in terms of USD.
- Amount of USD paid not correlating with the category of products proposed as per column 3 of the guidelines.
- TR-6 challan not mentioning Head of Account “0210 Medical and Public Health, 04-Public Health, 104-Fees and Fines” adjustable to PAO, DGHS, New Delhi.
- Fees paid other than Bank of Baroda.
- TR 6 challan without complete information of applicant name/ address, categories for which fees paid etc.

## **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.
- 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): 2009 of BIS.
- Product Composition data not duly signed/stamped by competent QC Person from the manufacturer.
- Product composition data not from the actual manufacturer.

## **7. Free Sale Certificate**

- Free sale Certificate not issued from country of origin of the proposed products.
- Original/authenticated copy of Free Sale Certificate issued by the national regulatory authority/ other competent association organizations from country of origin not submitted for all the applied products.
- 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.
- Name of the cosmetics along with Brand name and variants not correlating with Form 42 & Power of Attorney.
- Free sale certificate found to be tampered.

## **8. Chemical Information of Cosmetics**

- Test Protocol for testing of Cosmetics and specification of the product not submitted.
- Test report including result of Mercury, Lead, Arsenic & Other Heavy metals with limits not complying BIS.
- Test report not duly signed by competent QC 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 42.
- Label of the proposed products without word Batch no., mfg.License no., Use Before date not complying Rule 148 of Drugs & Cosmetics Rules 1945.
- 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, Drug Facts, Dermatologist recommended etc.
- Label does not mentions cautions and Instructions for certain ingredients (e.g. p-Phenylenediamine, fluoridecontent) as per requirement of Drugs & Cosmetic Rules 1945.
- Submitted labels are not signed/ stamped by manufacturer or its authorized agent.

#### **10. Heavy Metal Undertaking**

- Heavy Metal undertaking not complying with BIS and Indian regulation and also not issued from the legal/actual manufacturer.

#### **11. Soft Copies**

- Soft copies of the information about Product name along with Category, Pack size and actual manufacturing site in MS Word / MS Excel not submitted.

#### **12. Manufacturing License**

- 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.

#### **13. English translated copy of any of the above saiddocuments not signed by the qualified translator.**

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