Online Application checklist for grant of permission for New Cosmetics in Form COS-12 under the provisions of Cosmetics Rules 2020 of Drugs & Cosmetics Act, 1940

1. Covering Letter-

Purpose should be clearly mentioned with page number and Index.

2. Particulars of New Cosmetics: -

- 2.1 Name of the cosmetics
- 2.2 Category of cosmetic/intended use
- 2.3 Composition of product.
- 2.4 Test Protocol/Test method of the raw materials and finished product.
- 2.5 Specification of the raw materials and finished product along with Certificate of Analysis.
- 3. Assessment of the safety for human health of the finished product, its ingredients, their chemical structure and level of exposure.
- 4. Existing data on undesirable effects on human health resulting from use of the cosmetic product.
- 5. Supporting data for the claimed benefits of cosmetic product should be made available to justify the nature of its effect.
- 6. Specimen copy of the product label and carton.
 - 6.1 Package insert and Promotional literature etc.
- 7. Whether the preparation of the proposed cosmetic is approved and marketed in other major countries if yes details of the same
- 8. Any other data generated on safety, effectiveness and quality parameters.

9. Other documents

9.1 Undertaking that the cosmetic products to be imported in to the country have not been tested on animals as per the Cosmetics Rules, 2020.

- 9.2 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.
- 9.3 Any other (if any)
- 9.4 Details of IEC and GSTIN of the firm (enclose copy of documents)
- 10. Fee Bharatkosh e-receipt and challan
- 11. Application (Form COS 12)

