ANNEX A

Product Information File (PIF)

The PIF shall be composed of the following documents:

1. Part I: Administrative Documents and Product Summary

1.1. Administrative Documentation
- 1.1.1. Copy of valid License to Operate (LTO) of the MAH
- 1.1.2. Copy of valid Distribution Agreement
  - 1.1.2.1. In case the MAH is a Cosmetic Distributor (Importer), the documents must be duly authenticated by the Territorial Philippines Consulate or Apostilled:
    - 1.1.2.1.1. In case the Foreign Supplier is the manufacturer of the cosmetic product, Foreign Agency Agreement (FAA) or Letter of Authorization from the Foreign Supplier.
    - 1.1.2.1.2. In case the Foreign Supplier is not the manufacturer of the cosmetic product,
      - 1.1.2.1.2.1. FAA or Letter of Authorization from the Foreign Supplier and a valid Supply Agreement between the Foreign Supplier and the manufacturer; or
      - 1.1.2.1.2.2. Valid tripartite agreement between the MAH, Foreign Supplier, and manufacturer
- 1.1.3. Copy of the valid CPN

1.2. Qualitative and Quantitative Formula of the Cosmetic Product
- 1.2.1. Complete ingredient list with their corresponding function and percentage (%) content. Ingredients shall be named using the nomenclatures from approved references, namely, (1) International Cosmetic Ingredient Dictionary, (2) British Pharmacopoeia, (3) United States Pharmacopeia, and (4) Chemical Abstract Service.
- 1.2.2. In case the cosmetic product contains fragrance materials, the name and code number of the composition, and the identity of the supplier of the fragrance materials shall be indicated.

1.3. Product Presentation
- 1.3.1. Actual commercial sample of the cosmetic product.
  The retention samples for every batch of cosmetic product manufactured/distributed shall be kept in accordance with the ACD Appendix VI – ASEAN Guidelines for Cosmetic Good Manufacturing Practice (GMP). Retention period shall be according to the SOP of the cosmetic establishment.
- 1.3.2. In case when the actual commercial sample is unavailable, facsimile samples of the immediate and/or secondary packaging and other informative materials that are used (i.e. leaflets, hang tags) may be presented provided that the actual commercial sample shall be submitted to FDA as compliance to the audit.
- 1.3.3. For consistency, the actual sample and/or facsimile presented during the audit shall be treated as the actual commercial product.

1.4. Manufacturing Statement

1.4.1. For cosmetic products manufactured in an AMS, a self-declaration of compliance to the ASEAN Cosmetic Good Manufacturing Practice (GMP) by the cosmetic manufacturer is accepted.

1.4.2. For cosmetic products manufactured in countries other than the AMS, certifications of ASEAN Cosmetic GMP compliance or its equivalent issued by the regulatory agency or any accredited business association in the country of origin shall be presented. The following are the accepted equivalents of the ASEAN Cosmetic GMP:

- World Health Organization (WHO) Guide to Good Manufacturing Practices (GPM) for Pharmaceutical Products
- Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S) Guide to GMP for Medicinal Products/ Australian Code of GMP for Therapeutic Goods
- International Standard ISO 22716: 2007 Cosmetics – Good Manufacturing Practices (GMP) – Guidelines on Good Manufacturing Practices

1.4.3. SOP for Batch Coding System/Numbering/key of the cosmetic product

1.5. Summary of the Safety Assessment of the Cosmetic Product as per the ASEAN Guidelines for the Safety Assessment of a Cosmetic Product

1.5.1. Signed summary of the safety assessment

1.5.2. Name and qualifications of the safety assessor of his/her curriculum vitae

1.6. Summary of the Confirmed Undesirable Effects on Human Health

1.6.1. The summary of confirmed undesirable effects on human health shall be updated monthly or according to the SOP of the cosmetic establishment. The summary may be in any format easily understandable by the users.

1.6.2. SOP for Handling of Consumer Complaints and Adverse Event Reports

1.7. On-pack Product Claim Support

Summary of the claim substantiation/ justification may be based on the following:

1.7.1. Literature review of published data on the properties of the ingredients contained in the cosmetic product

1.7.2. Literature review of published data on the benefits of a product with similar formulation

1.7.3. Actual tests performed which can either be *in vitro* or *in vivo*.

2. Part II: Quality Data of Raw Materials

2.1. Specifications and Test Methods of Raw Materials

2.1.1. Technical Specifications of each ingredient including water

2.1.2. Method of Analysis corresponding to the technical specifications for each ingredient, including the identification test for each ingredient

2.1.3. Signed Certificate of Analysis (COA) for each ingredient corresponding to its technical specifications

2.1.4. In case of fragrance materials, the name and code number of the fragrance, name and address of the supplier, certificate of compliance with the latest International Fragrance Association (IFRA) guidelines

2.2. Safety data of the ingredients which are taken from any of the following:
   2.2.1. Ingredient safety data provided by the supplier or Safety Data Sheets
   2.2.2. Published literature and databases (i.e., Toxline, Medline) of ingredients
   2.2.3. Reports from Scientific Committees like the ASEAN Cosmetic Scientific Body (ACSB), the Scientific Committee on Consumer Safety (SCCS) of the European Union (EU) or the United States (US) Cosmetic Ingredient Review Board (CIR)

2.3. In cases when the cosmetic product contains placental protein or any other animal extracts, the following shall be part of the PIF Part II:
   2.3.1. Certificate of origin indicating the specie where the connective tissue, embryo and placental protein are extracted
   2.3.2. Technical specifications for physical, chemical and microbiological purity
   2.3.3. Signed COA reflecting the composition of the placental protein
   2.3.4. Certificate issued by the health authority of the country of origin that the animal source is free from Transmissible Spongiform Encephalopathy (TSE)

3. Part III: Quality Data of Finished Product

3.1. Complete ingredient list of the cosmetic product with their corresponding function and percentage (%) content. Ingredients shall be named using the nomenclatures from approved references, namely, (1) International Cosmetic Ingredient Dictionary, (2) British Pharmacopoeia, (3) United States Pharmacopoeia, and (4) Chemical Abstract Service.

3.2. Manufacturing details
   3.2.1. Details of cosmetic manufacturer including the company name, complete address and contact information
   3.2.2. Details of the secondary assembler / repacker of the cosmetic product including the company name, complete address and contact information, if applicable
   3.2.3. Summary of the Manufacturing Process or Batch Manufacturing Record (BMR)

3.3. Technical Specifications of the finished product and their corresponding test methods
   3.3.1. Technical specifications of the finished product
   3.3.2. Test methods used corresponding to the technical specifications of the finished product. The ASEAN Cosmetic Harmonized Testing Methods shall be preferably used in the quality control procedures of the cosmetic product.
   3.3.3. Signed COA of the finished product corresponding to its technical specifications

3.4. Product Stability
   3.4.1. The stability study shall be part of the PIF to support the cosmetic product's claimed shelf-life. The stability study conducted on the cosmetic product may be accelerated or long-term.
      3.4.1.1. Accelerated stability study shall be provided for the cosmetic product less than one (1) year in the market.
      3.4.1.2. Long-term stability study shall be provided for cosmetic products which have been in the market for more than one (1) year. In cases when the long-term stability study has not been concluded, proof of the on-going study shall be provided.

4. Part IV: Safety and Efficacy Data

4.1. Safety Assessment

The ASEAN Guidelines for the Safety Assessment of a Cosmetic Product shall preferably be used as a guidance document when preparing the safety assessment to ensure that all relevant aspects of the cosmetic product are evaluated and assessed.

4.1.1. Signed safety assessment report of the cosmetic product in terms of potential effects to human health. The safety assessor shall determine the safety of the cosmetic product based on the following minimum factors:

4.1.1.1. Ingredients used in the formulation of the cosmetic product and their chemical structures.

4.1.1.2. Potential hazardous by-products of an interaction between ingredients (i.e., nitrosamines) and/or its impurities

4.1.1.3. The specific population who will use the product

4.1.1.4. The area of the body where the product will be used

4.1.1.5. Duration and frequency of exposure to the cosmetic product

4.1.2. Curriculum vitae of the safety assessor. The safety assessor shall possess qualifications in the field of toxicology, medicine (dermatology), pharmacy and other related fields and shall be suitably trained in the safety assessment of cosmetics.

4.1.3. In cases when the safety assessor is deemed to have no sufficient technical background required to assess/evaluate the product safety, FDA reserves the right to request for additional safety assessment of the product.

4.2. Record of Confirmed Adverse Events or Undesirable Effects on Human Health

4.2.1. Compilation of reports of confirmed adverse events or undesirable effects on human health resulting from the use of the cosmetic product which must be duly investigated by the MAH. The compilation shall be updated monthly or according to the SOP of the cosmetic establishment.

4.2.2. SOP for Handling of Consumer Complaints and Adverse Event Reports

4.2.3. Serious adverse effects shall be reported to the FDA using the ASEAN Cosmetic Directive (ACD) Adverse Event Report Form.

4.3. On-pack Product Claim Support:

4.3.1. In cases when cosmetic products have made a claim, the substantiation of the same shall be part of the PIF. The claim substantiation may be from the following sources:

4.3.1.1. Literature review of published data on the properties of the ingredients contained in the cosmetic product

4.3.1.2. Literature review of published data on the benefits of a product with similar formulation

4.3.1.3. Actual tests performed which can either be *in vitro* or *in vivo*.