



Republic of the Philippines  
Department of Health  
**FOOD AND DRUG ADMINISTRATION**



24 JAN 2018

FDA CIRCULAR  
No. **2018-001**

**TO: ALL COSMETIC MANUFACTURERS, TRADERS, DISTRIBUTORS AND OTHER CONCERNED PARTIES**

**SUBJECT: Reiterating the Mandatory Implementation of Article 8 of the ASEAN Cosmetic Directive "Product Information"**

## I. BACKGROUND

The ASEAN Harmonized Cosmetic Regulatory Scheme (AHCRC) and its technical documents have been adopted and implemented in 2015 through the issuance of Administrative Order (AO) No. 2005-0015 "*Adoption of the Association of Southeast Asian Nation (ASEAN) Harmonized Cosmetic Regulatory Scheme and ASEAN Common Technical Documents*" and AO No. 2005-0025 "*Implementation of the ASEAN Harmonized Cosmetic Regulatory Scheme and ASEAN Common Technical Documents,*" respectively. The said issuances are primarily directed towards enhancing cooperation amongst the ten (10) ASEAN Member States (AMS) in ensuring the quality and safety of cosmetic products marketed in the ASEAN region and to eliminate barriers to its trade. Part and parcel of the AHCRC is the shift from a pre-approval system to a post-market surveillance (PMS) regulatory scheme, wherein companies intending to distribute and/or market cosmetic products in the country are required to notify the Food and Drug Administration (FDA) of their intentions by securing the appropriate cosmetic product notification (CPN). This regulatory framework transferred the responsibility for the safety, quality and/or efficacy of cosmetic products from FDA to the company responsible for placing the product in the market or the Market Authorization Holder (MAH).

Because the MAHs are the ones responsible for the cosmetic products they market/distribute, they are required to keep and maintain the product's technical and safety information readily accessible to the FDA representatives during audits. This is clearly stated in Article 1 of the ASEAN Cosmetic Directive (ACD) and further elaborated in Article 8 of the same.

However, since the full implementation of ACD in 2008, audit reports show that not all MAHs are compliant with the aforementioned ACD provision, thus, cannot ensure the safety, quality and/or efficacy of the cosmetic products they place in the market. Violations range from incomplete Product Information File (PIF) to completely without PIF.

In order to fulfill its mandate and to provide the MAHs with the needed guidance in preparing PIFs and in line with the FDA's thrust to strengthen its enforcement of existing FDA laws, rules and regulations against violative establishments and health products, there is a need to



provide a cohesive set of guidelines to aid in the regulatory compliance to the PIF requirements as set forth by the ACD.

## II. OBJECTIVES

The objectives of this Circular are the following:

1. To strengthen the implementation of Articles 1 and 8 of ACD
2. To clearly list the documents required to be part of a PIF

## III. SCOPE

This Circular shall apply to all cosmetic establishments who are holders of valid CPNs. Cosmetic establishments may be a cosmetic manufacturer, trader and/or distributor duly licensed by the Center for Cosmetics Regulation and Research (CCRR).

This Circular shall not apply to unlicensed cosmetic establishments and their unnotified cosmetic products which shall be subjected to appropriate regulatory actions such as closure and seizure of violative products upon verification of violations committed.

## IV. GENERAL GUIDELINES

Below are the general guidelines:

1. The MAH who has notified a cosmetic product with FDA shall keep and maintain an **updated** PIF. Every cosmetic product duly notified with FDA shall have a corresponding PIF.
2. The MAH shall be updated on the latest amendments of the ACD, its annexes and appendices. The MAH shall preferably keep a file of all FDA issuances disseminating the new rules, regulations and standards for cosmetic products.
3. The PIF shall be kept and maintained in a per product basis.
4. The PIF shall be readily accessible at the address of the MAH as declared in the CPN in consistence with the address indicated on the immediate or secondary packaging of the cosmetic product as per ACD Appendix II – ASEAN Cosmetic Labeling Requirements.
5. The PIF documents shall be written in English and/or National Language.
6. The PIF shall be arranged according to the format provided by the ACD Guidelines for Product Information File (PIF)
7. The PIF shall be kept in either electronic and/or hard copies. For PIF audits, accessibility and availability of information to FDA shall be ensured by the MAH.
8. The PIF shall be kept for a minimum of three (3) years after the cosmetic product has last been placed in the market (i.e. date when the inventory reaches 0 at retail level) or according to the company's Standard Operating Procedure (SOP), whichever provides for a longer retention period.
9. Routine PIF audits shall be conducted by FDA during the validity of the CPN. The MAH shall be notified through a notice of audit (NOA) to be sent preferably one (1) month before

the audit. However, this provision does not preclude the FDA from doing *ad-hoc* audits when required which may occur with or without notice.

10. The MAH with incomplete PIF shall be given sufficient amount of time ranging from fifteen to sixty (15-60) calendar days, depending on the urgency of the audit, to provide their corrective action report (CAR) and other documents required by the auditors. Product Information/documents containing confidential materials that have been required by the FDA representatives during audit may be directly sent to the agency by the foreign supplier.
11. MAH scheduled for routine PIF audit shall be required to present Part I of the PIF. For ad-hoc audits, however, MAH may be required to present specific documents depending on the reasons for the PIF audit. This shall be communicated to the MAH through the NOA.
12. Apart from the documents listed in the specific guidelines, FDA reserves the right to request for additional product information needed to determine the product's safety, quality and/or efficacy. MAH shall be given a sufficient amount of time ranging from fifteen to sixty (15-60) calendar days, depending on the urgency of the audit, to make the necessary arrangements with their suppliers.
13. Failure of a MAH to present the required PIF Part I or to comply within the agreed timeline may result to the institution of a legal action directed towards the notification of the subject cosmetic product which may lead to its cancellation and the corresponding product recall thereof when circumstances so warrant.

## V. SPECIFIC GUIDELINES

The PIF shall be composed of the following documents:

1. PIF Part I – Administrative Documents and Product Summary
  - 1.1 Administrative Documentation
    - 1.1.1 Copy of the valid License to Operate (LTO) of the MAH
    - 1.1.2 Copy of the valid Distribution Agreement
      - 1.1.2.1 In case the MAH is a Cosmetic Distributor (Importer):
        - 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 the 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 the 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 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 Pharmacopeia; (3) United States Pharmacopeia; (4) Chemical Abstract Service.
- 1.2.2 In cases when the cosmetic product contains fragrance materials, the name, code number of the composition, and the identity of the supplier of the fragrance material shall be indicated.

## 1.3 Product Presentation

- 1.3.1 Actual commercial sample of the cosmetic product.  
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, hangtags) may be presented provided that the actual commercial sample shall be submitted to FDA as compliance to the audit.

## 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 (GMP) 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 Copy of batch coding system / 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 or 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 Receiving and Processing of Consumer Complaints
- 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. PIF Part II – Quality Data of Raw Material
  - 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 (SCCP) of the European Union (EU) or the United States (US) Cosmetic Ingredient Review Board (CIR)
  - 2.3 In cases when the cosmetic products contain placental protein or any other animal extracts, the following shall be part of 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. PIF 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 Pharmacopeia; (3) United States Pharmacopeia; (4) Chemical Abstract Service.
  - 3.2 Manufacturing details
    - 3.2.1 Details of the 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 Method (BMR)
  - 3.3 Technical specifications of the finished cosmetic product and their corresponding test methods
    - 3.3.1 Technical specifications of the finished cosmetic product
    - 3.3.2 Test methods used corresponding to the technical specifications of the finished cosmetic 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 cosmetic 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 cosmetic products 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. PIF Part IV – Safety and Efficacy Data
  - 4.1 Safety Assessment
    - 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)
- 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

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


- 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 Product Complaints
  - 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*.

**VI. SEPARABILITY CLAUSE**

If any part or term of provision of this Circular shall be declared invalid or unenforceable, the validity or enforceability of the remaining portions or provisions shall not be affected and this Circular shall be construed as if it did not contain the particular invalid or unenforceable part, term, or provision.

**VII. EFFECTIVITY DATE**

This Circular shall take effect immediately.

  
**NELA CHARADE G. PUNO, RPh**  
Director General

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