Note: This draft is only intended as a copy for comments during the stakeholder consultation period of the proposed guidelines. The content of this draft may change and does not prejudge any policy nor decision of the FDA. Citation of any text in this draft, for purposes other than the submission of comments as indicated in the issued announcement, is not recommended.

FDA CIRCULAR
No. _____

SUBJECT: **Updated Guidelines on Product Information File (PIF) for Cosmetic Products Repealing FDA Circular No. 2018-001 "Reiterating the Mandatory Implementation of Article 8 of the ASEAN Cosmetic Directive 'Product Information'"**

I. BACKGROUND

In 2005, the ASEAN Cosmetic Directive (ACD), its annexes and appendices, were adopted and implemented through the issuance of Department of Health (DOH) Administrative Orders (AO) No. 2005-0015 and 2005-0025, respectively, to harmonize the cosmetic regulatory scheme in the ASEAN region. The harmonization scheme aims to eliminate restrictions to trade of cosmetic products and enhance cooperation within the ASEAN Member States (AMS) in ensuring the safety, quality and claimed benefits of cosmetic products. The processes instituted by the Food and Drug Administration (FDA), through the Center for Cosmetics and Household/Urban Hazardous Substances Regulation and Research (CCHUHSRR), pursuant to the adoption of the ACD, therein included pre- and post-marketing regulatory processes, such as the notification of cosmetic products and the audit of Product Information Files (PIF), among others. Under the ACD, ASEAN Member States (AMS), through the National Regulatory Authorities (NRA), shall conduct post-marketing surveillance (PMS) activities, and undertake all necessary measures to ensure that only cosmetic products that conform to the provisions of the ACD, its Annexes and Appendices may be placed in the market.

To further enhance the efficiency of the notification application process and promote transparency of information, in 2015, through FDA Memorandum Circular (FMC) No. 2015-011, CCHUHSRR digitized and implemented the Cosmetic Electronic Notification process using the FDA E-Portal. With the entry of cosmetic products facilitated by the implementation of the electronic notification, the FDA reiterated the responsibilities of the Market Authorization Holder (MAH), pursuant to the ACD, including the maintenance of a Product Information File (PIF). Wherein, the PIF is intended to contain evidence that should be sufficient to review safety, quality and claimed benefits of cosmetic products, it is incumbent upon the MAH to ensure the accessibility and availability of such documents for the review and audit of the FDA. To assist MAHs, the FDA issued FDA Circular No. 2018-001 and FDA Advisory No. 2022-0383 providing guidance on the PIF requirement.

However, in the course of the implementation of the ACD and PIF Audits, findings of the FDA showed that a number of MAHs remain to be non-compliant to the PIF requirement. Violations were found to range from an incomplete PIF to completely without PIF for cosmetic products already placed in the market. There is thus a need to strengthen the

implementation and enforcement of the ACD with the end-view of ensuring the safety and quality of cosmetic products. It is in this light that these updated PIF guidelines are hereby issued, which is intended to form part of the FDA PMS framework complementing the cosmetic electronic notification scheme. Further, wherein the COVID-19 pandemic has introduced mobility restrictions that posed challenges in the conduct of PIF Audits, alternative audit arrangements and other sustainable mechanisms have been considered in the design of the PIF Audit.

II. OBJECTIVES

This Circular aims to:

1. Improve the regulatory compliance to PIF requirements as set forth by the ACD; and
2. Establish an updated PIF guidelines in the context of evolving digital technology and pandemic resiliency.

III. SCOPE

This circular shall cover all cosmetic establishments duly licensed by the CCHUHSRR who are holders of a valid Certificate of Product Notification (CPN).

IV. GENERAL GUIDELINES

A. Only duly notified cosmetic products that conform to the provisions of the ACD, its Annexes and Appendices, shall be placed in the market. Cosmetic products that are duly notified with the FDA shall have a corresponding PIF.

B. The PIF of a Cosmetic Product must be made readily available and accessible to the FDA by the MAH upon the issuance of a Certificate of Product Notification (CPN). The PIF shall be kept, updated and maintained by the MAH in accordance with the language, format, retention period, among others, as provided in these Guidelines.

C. Cosmetic products duly notified with the FDA shall be subjected to a PIF Audit. The FDA may perform PIF audits as part of routine inspections and audits or in an *ad hoc* manner, and may be conducted on-site or off-site. The MAH, through its Qualified Person, shall coordinate with the FDA to ensure the orderly conduct of the PIF Audit.

D. The FDA shall ensure the confidentiality of the data and information submitted or presented during the PIF Audit.

E. Failure to comply with these guidelines, including but not limited to, deficiencies in the PIF content and format, non-submission of documentation necessary to determine the safety, quality, and claimed benefit of a cosmetic product, refusal of the MAH and/or Qualified Person to coordinate with the FDA thereby preventing the orderly conduct of the PIF Audit, shall be subject to appropriate regulatory action.

F. The FDA shall not be precluded from conducting other PMS activities, apart from PIF Audits, to assess the safety, quality, and claimed benefit of cosmetic products and determine compliance with the ACD and other relevant product standards, in order to

ensure consumer protection and public health and safety, pursuant to its mandate following Republic Act (RA) No. 7394, RA 9711, and other laws, rules and regulations.

V. SPECIFIC GUIDELINES

A. **Responsibilities of the MAH.** The MAH shall have the following responsibilities in relation to the PIF requirement:

1. The MAH or the "company responsible for placing the cosmetic product in the market" shall keep and maintain an updated 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 relevant FDA issuances, rules, regulations and standards for cosmetic products.
3. The MAH shall ensure that the complete PIF is readily available and accessible at the address of the MAH as declared in the CPN consistent with the address indicated on the immediate or secondary packaging of the cosmetic product as per ACD Appendix II – ASEAN Cosmetic Labeling Requirements. For Distributors and Micro, Small and Medium Enterprises (MSMEs), considerations shall be given as to the completeness of the PIF, wherein Part I of the PIF shall be required, at the minimum, to be available at the address of the MAH for the purposes of initial PIF Audits.
4. For PIF Audits, accessibility and availability of information to the FDA shall be ensured by the MAH. Further, upon specific request of the FDA, other information required to determine the safety, quality, and claimed benefit of the cosmetic product shall be provided by the MAH within a reasonable timeframe.

B. **Language, Content and Format of PIF.** The PIF shall be in accordance with the following language, content and format:

1. The PIF documents shall be written in English and/or Filipino Language.
2. The PIF shall contain administrative information pertaining to the status of authorizations of the cosmetic product, its manufacturer and MAH, and technical information pertaining to the quality and safety data of the raw materials and finished product, following the content and format of the **ANNEX A**.
3. The PIF shall be kept in any suitable media type (i.e. paper, electronic, etc.) provided that it is easily accessible to the PIF Auditor.

C. **Retention Period and Updating of PIF.** The retention period and updating of the PIF shall be in accordance with the following:

1. The PIF shall be kept and maintained on a per product basis.
2. 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 zero (0) at retail level) or according to the company's Standard Operating Procedure (SOP), whichever provides for a longer retention period.

D. **Conduct of PIF Audits.** PIF Audits shall be performed by the FDA in accordance with the Audit Plan and/or other Notices issued by the FDA in order to determine and ensure the compliance of the products with the ACD, following these guidelines:

1. **Types of PIF Audit.** PIF Audits may be conducted according to the following classifications:

    a. **Routine PIF Audit** - are audits conducted by FDA during the validity of the CPN, which occurs following a Notice of Audit (NOA) sent preferably one (1) month before the date of Audit.

    b. ***Ad hoc* PIF Audit** - audits which are conducted with or without notice, triggered by any of the following events:
        - results from sampling, testing, and verifying products from the market,
        - consumer complaints,
        - adverse event reports from healthcare practitioners and other verifiable sources,
        - evaluation of ingredients, formulation, intended use and/or product claims during notification application,
        - post-licensing inspections, monitoring, and investigations,
        - advertisements and promotional articles monitoring,
        - post-marketing surveillance (PMS) activities,
        - coordination with local enforcement agencies, government agencies, and international partners, and
        - other assessments, reviews, and/or investigations initiated or referred to the FDA which finds that a cosmetic product has issues relating to safety, quality, and/or claimed benefits which necessitate FDA intervention.

2. **Sites of PIF Audit.** PIF Audits, whether routine or *ad hoc*, may be conducted on-site or off-site based on the urgency of the issue being investigated and the best use of resources available.

    a. **On-site audits** - are audits where the PIF Auditors are physically at the address of the MAH, as declared in the CPN.

    b. **Off-site audits** - are audits where the PIF is audited remotely by the PIF Auditor. Off-site audits may occur in any of the following manner as determined by the FDA:

        i. Synchronous remote PIF Audit - are audits performed off-site, where documents are presented by the MAH to the PIF Auditor, and reviewed, through a live audit session assisted by information and communication technology platforms.
        ii. Desktop PIF Audit – are audits performed remotely by reviewing the required documents submitted by the MAH.

    The conduct of off-site audits shall take into consideration the following:
        i. Synchronous remote PIF audits shall utilize secure virtual meeting/conferencing platforms hosted by the FDA. Virtual meetings shall be documented and/or recorded. Recordings shall only be used for the purposes of accurately documenting the conduct of the PIF Audit meeting, including the agreements made therein.

ii. The PIF and the specific documents requested for review shall be transmitted to the PIF Auditor through a secure file-sharing platform, either hosted by the FDA or the MAH, at the preference of the MAH. All documents transmitted to the FDA shall be treated with utmost confidentiality and shall be used for the purposes of the audit and the regulatory actions that follow.
iii. Findings that cannot be verified remotely shall be verified on-site, if necessary.
iv. Collection of samples, if necessary, shall be coordinated with the establishment.

3. **Notice of Audit.** Except for cases involving emergency investigations or on issues that require urgent resolution, the FDA shall issue a Notice of Audit (NOA) to the MAH prior the conduct of a PIF Audit. The NOA shall specify the date, type and site of the audit. In case of off-site audits, the pertinent details for the arrangements of the remote or desktop audit shall also be provided. Communication with the establishment shall be done using the contact details provided in the notification application.

4. **Documents and other materials to be presented during PIF Audits.** The following PIF documents and other materials must be made available to the FDA to ensure the orderly and timely conduct of the PIF Audit:

    a. In general, the complete PIF must be made available during PIF Audits, whether routine or *ad hoc*, onsite or offsite. However, the following considerations may be applied by the FDA, as deemed necessary.
        i. In all cases, MAHs scheduled for a PIF Audit shall be required to present Part I "Administrative Documents and Product Summary" of the PIF, aside from the required documents specified in the Notice.
        ii. For distributors and MSMEs, considerations may be applied for Parts II to IV of the PIF, provided that a reasonable and compelling justification is provided for the absent PIF Parts. The MAH may thus 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 and submit the required documents and/or pertinent information.
        iii. Product Information/documents containing confidential materials and/or proprietary information that have been required by the FDA representatives during audit may be directly sent to the agency by the foreign supplier or local manufacturer or source.

    b. For *ad hoc* audits, the MAH may be required to present specific documents to determine the safety, quality, and claimed benefits of the product. This shall be communicated to the MAH through the NOA, if applicable.

    c. MAHs 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 and classification of the deficiency/ies, to provide their corrective action report (CAR) and other documents required by the PIF auditors. Notwithstanding the provided timeline for compliance to

documentary requirements, the FDA may conduct further regulatory actions and direct further compliance pursuant to the succeeding provisions on the resolution of deficiencies.

E. **Deficiencies.** For purposes of transparency, clarity and efficiency, non-conformances found during PIF Audits shall be classified and treated as follows:

1. **Classification of Deficiencies**. The classification of deficiencies shall be as follows. An illustrative, non-exhaustive list of observations is attached as **ANNEX B** classified following the foregoing definitions as provided. The FDA shall endeavour to publish an updated list, based on the review of the implementation of this Circular.

    a. **Critical deficiency** - a deficiency which has produced, or may lead to, a significant risk of producing either a product which is harmful to humans. It also covers findings of the establishment's or its agent's commission of fraud, misrepresentation or falsification of products, records or data, or withhold any relevant data contrary to the provisions of law, rules and regulations or appropriate standards.

    b. **Major deficiency** - a deficiency which indicates a major deviation from the terms of the marketing authorization, ASEAN Cosmetic Directive, its annexes and appendices, and other internationally-accepted standards; or, a combination of several “other” deficiencies, none of which on their own may be major, but which may together represent a major deficiency and should be explained and reported as such; or, repetitive deviation for at least two consecutive audits.

    c. **Other deficiency** - a deficiency which cannot be classified as either critical or major, but which indicates a departure from the ACD, its annexes and appendices, and other internationally-accepted standards. A deficiency may be “other” either because it is judged as minor, or because there is insufficient information to classify it as major or critical.

2. **Resolution of Deficiencies.** Deficiencies shall be treated and resolved as follows:

    a. In case of findings classified as critical deficiency (ies), the PIF auditor is authorized to direct the establishment to initiate outright, any or all of the following:
        i. Temporarily stop production of affected product line/s and further importation and/or distribution;
        ii. Undertake or cause company-initiated recall of affected batches following existing FDA rules and procedure for product recall;
        iii. Address the deficiencies, including submission of CAPA plan and objective evidence of compliance, not later than thirty (30) calendar days reckoned on the day following the receipt of the audit report.

    Critical findings may result in the FDA imposing subsequent regulatory action, including but not limited to issuance of notice of product recall,

disapproval of application, suspension or revocation of the issued authorization.

b. In case of major and other deficiencies, the PIF auditor is authorized to direct the establishment to address the deficiencies, including the submission of CAPA Plan and objective evidence of compliance, not later than sixty (60) calendar days reckoned on the day following the receipt of the audit report.

   Failure to sufficiently comply and address the deficiencies during the provided compliance period may result in the FDA imposing subsequent regulatory action, including but not limited to issuance of notice of product recall, disapproval of application, suspension or revocation of the issued authorization.

VI. PENALTY CLAUSE

Any establishment found to be in violation of the provisions of this issuance shall be deemed in violation of Republic Act No. 3720 as amended by Republic Act No. 9711 and shall be penalized accordingly following the Uniform Rules of Procedures laid down under Book III of the Implementing Rules and Regulations of Republic Act No. 9711.

VII. SEPARABILITY CLAUSE

The provisions of this Circular are hereby declared separable and in the event that any such provision is/are declared invalid or unenforceable, the validity or enforceability of the remaining portions or provisions including other provisions of the ACD which are not affected by this update, shall remain in full force and in effect.

VIII. REPEALING CLAUSE

FDA Circular No. 2018-001, FDA Advisory No. 2022-0383 and other previous issuances inconsistent with this Circular are hereby repealed, rescinded and modified accordingly.

IX. EFFECTIVITY

This Circular shall take effect after fifteen (15) days after its publication in a newspaper of general circulation and filing with the University of the Philippines, Office of the National Administrative Register.

MARIA ROSARIO D. SINGH-VERGEIRE, MD, MPH, CESO II
Officer-In-Charge
Department of Health

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*.

ANNEX B

List of Product Information File (PIF) Audit Deficiencies

The classification of deficiencies are as follows. The list is non-exhaustive and other observations may be added, removed, or re-classified as appropriate.

Non-inclusion of a non-conformance against the ASEAN Cosmetic Directive, any standard, rule and regulation, shall not preclude the PIF Auditor to assign a classification in this list. In the assignment of classifications for such observations/findings, the PIF Auditor shall be guided by the definitions provided for Critical, Major, and Other Deficiencies in this Circular. The FDA shall endeavour to publish an updated list, based on the review of the implementation of this Circular.

1. Critical

- Lack of or incomplete PIF Document (i.e. technical documents which may affect the product quality and safety).
- The MAH and/or the manufacturer has no valid License to Operate.
- Deviation from the approved LTO authorization for manufacturer (e.g. product line).
- The product contains a banned ingredient based on ACD.
- The restricted ingredient declared on the CPN and/or qualitative and quantitative formula of the product has exceeded the maximum allowable concentration based on ACD Annexes.
- The use of the ingredient is not allowed for its product type.
- Lack of or incomplete Technical Specifications for each ingredient.
- Lack of or incomplete COA for each ingredient.
- Unsigned Certificate of Analysis (COA) for each ingredient.
- The ingredients indicated on the actual commercial sample are inconsistent with the CPN and/or the qualitative and quantitative formula of the product.
- Lack of Technical Specifications for finished product.
- Lack of Test Method for finished product.
- Lack of COA for finished product.
- Unsigned Certificate of Analysis (COA) of finished product.
- Out-of-specification test results not properly investigated and documented according to SOP.
- Evidence of falsification or misrepresentation of analytical results.
- The manufacturer from non-ASEAN Member States (non-AMS) has no GMP Certificate or its equivalent.
- No Batch Manufacturing/Packaging Records.
- Evidence of falsification or misrepresentation of Batch Manufacturing Record.
- There is no Summary of Safety Assessment for the product.
- No data available to establish the shelf-life of the product.

2. Major

- Incomplete PIF Document (i.e. administrative documents)
- Deviation from the approved LTO authorization for Market Authorization Holder (e.g. LTO activity).
- Lack of or incomplete tests/substantiation/justification for ingredients with specific requirements as laid down in the ACD Annexes and/or FDA issuances (e.g. Petrolatum, Triethanolamine, Talc).

- The required labelling information as per ACD Appendix II is not declared on the label.[1]
- The conditions of use and warnings and other limitations and requirements laid down in the ACD Annexes are not printed on the label.[1]
- Lack of SOP for Batch Coding/Numbering.
- Deviations from batch manufacturing instructions during production.
- Unsigned Summary of Safety Assessment.
- Insufficient data to establish the shelf-life of the product
- Lack of SOP for Handling of Consumer Complaints and Adverse Event Reports.
- The intended and/or direction for use/ target area/ product claim is not appropriate for a cosmetic product.[1]
- Lack of or incomplete tests/substantiation/justification for on-pack claims.

3. Others

- The PIF is not written in English or Filipino Language.
- Lack of or incomplete safety data for each ingredient.
- The ingredients are not specified using the nomenclature from the latest edition of standard references, the botanical ingredients and extracts of botanicals are not identified by its genus and species.
- There is no actual commercial sample presented.
- The address of the MAH reflected on the label is inconsistent with the LTO and/or CPN.
- The country of manufacture reflected on the label is inconsistent with the information declared in the CPN.
- The qualifications/curriculum vitae of the safety assessor is not provided.
- Lack of certificate of compliance to latest IFRA guidelines (for fragrance materials)

[1] For these findings, the PIF Auditor may impose additional regulatory actions (i.e. Issuance of Notice of Product Recall) if circumstances require.