Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

23 FEB 2022

FDA ADVISORY
No. 20220383

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

SUBJECT: **Reiterating the Article 8 of the ASEAN Cosmetic Directive as per FDA Circular No. 2018-001 Mandating the "Product Information File"**

The ASEAN Cosmetic Directive (ACD) aims to primarily ensure the safety, quality, and claimed benefits of cosmetic products among ASEAN Member States (AMS). Secondly, the ACD aims to reduce technical barriers to its trade without compromising public health and safety to the ASEAN population including the Filipino consumers through harmonization of technical requirements among AMS.

The processes instituted by the FDA pursuant to the adoption of the ACD includes the pre- and post-marketing regulatory processes, such as Cosmetic Notification and Cosmetic Product Information File (PIF), among others.

To strengthen the implementation of the ACD, in January 2018, through FDA Circular (FC) No. 2018-001, the FDA reiterated the mandatory implementation of Article 8 of the ACD "Product Information". The FDA reminded Market Authorization Holders (MAHs) that as they are the ones responsible for the cosmetic products they market or distribute, they are required to keep and maintain the product's technical and safety information, which must be readily accessible to the FDA representatives during audits and other post-marketing surveillance (PMS) activities.

The PIF is a document containing the cosmetic product's technical and safety information. In general, the PIF must contain evidence that should be sufficient to review safety, quality and claimed benefits of cosmetic products. FC No. 2018-001, consistent with the ACD Guidelines for PIF, specifies the list of documents which shall be part of the PIF, as outlined below:

Part I: Administrative Documents and Product Summary
Part II: Quality Data of Raw Material
Part III: Quality Data of Finished Product
Part IV: Safety and Efficacy Data

As the FDA conducts its activities amidst the conditions of the COVID-19 pandemic, the FDA further reiterates the following responsibilities of the MAH:

1. **The MAH or the "Company Responsible for Placing the Product in the Market" who has notified a cosmetic product with FDA shall keep and maintain an updated Product Information File (PIF).**

2. **Every cosmetic product duly notified with FDA shall have a corresponding PIF.**
3. **The MAH shall follow the PIF format as stipulated in FC No. 2018-001.**

Furthermore, the FDA reminds MAHs that ad hoc and routine PIF audits are being conducted by FDA during the validity of the Certificate of Product Notification (CPN). MAHs are reminded to ensure compliance to the above-mentioned points.

Lastly, MAHs are reminded that failure to comply with the provisions of FC No. 2018-001, Administrative Order (AO) No. 2005-0015, AO No. 2005-0025, and other applicable laws, rules and regulations may result in the enforcement of other regulatory actions.

Dissemination of this advisory to all concerned is hereby requested.

DR. OSCAR G. GUTIERREZ, JR.
Officer-in-Charge Director General

DTN 20220203075540