Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 2020-800

08 MAY 2020

TO: **THE GENERAL PUBLIC**

SUBJECT: **Understanding Postmarketing Surveillance (PMS) of Cosmetic Products**

Republic Act No. 9711, otherwise known as the "Food and Drug Administration Act of 2009" provides for the relevant functions, powers and duties of the Food and Drug Administration (FDA), including conduct of postmarketing surveillance system in monitoring health products, and development of policies, standards, regulations and guidelines that would cover establishments, facilities and health products.

Postmarketing Surveillance (PMS) activities for cosmetic products include product verification (PV) of collected market samples, post-evaluation of notified cosmetics, handling of consumer complaints, monitoring of promotion and advertisements, disposition on products tested as out-of-specification (OOS), product recall, verification of product authenticity, Product Information File (PIF) audit, filing of Report of Violation (ROV) and issuance of FDA Advisories.

In the conduct of PMS, several parameters are checked including but not limited to validity of the License to Operate (LTO) and Certificate of Product Notification (CPN), consistency of the list of declared ingredients in the CPN compared with that reflected in the product label, absence of banned ingredients, restricted ingredients not exceeding the maximum allowable limit, claims within the scope and intended use of a cosmetic, and compliance to labeling requirements. Non-compliance or inconsistency to any of these parameters renders the currently notified cosmetic product as an unnotified.

After pre-market approval or notification of a cosmetic product, the FDA conducts product verification through collection of actual products sold in the market to check if the submitted information during notification such as the ingredient listing is consistent with the label of the collected product. When the ingredient list of the product approved for notification by the FDA is entirely different from the collected product in the market, this inconsistency in formulation renders the product as unnotified. The ingredient may be intentionally or inadvertently not declared in its notification documents submitted to the FDA, or may be banned if not restricted under the ASEAN Cosmetic Directive. This is the most common violation of companies included in the FDA Advisories. It is explicitly indicated in the issued CPN that any subsequent changes to the information submitted in the notification, which have been verified by the FDA through PMS activities, will render the notification invalid and a new notification will have to be submitted. The FDA considers this as a major violation of the marketing authorization in the form of a CPN issued to the Marketing Authorization Holder (MAH) or company responsible for placing the product in the market.

Products being rendered as unnotified through these PMS activities are deemed non-compliant to existing rules and regulations. Through the notification process, the FDA accepts the declaration submitted by the companies as true and faithful disclosures, however, the FDA is still duty-bound to validate these submissions at any given time, post-market during the validity of its authorization. FDA Advisories are issued to warn the general public against the purchase and use of unnotified or non-compliant cosmetic products which may pose danger to the

consuming public. Thus, the responsibility of the MAH does not end in the notification process but is prevailing for the duration of the validity of the product notification.

PMS are conducted by the FDA at any given time during the validity of authorization to ensure that the responsible MAH complies with the terms and conditions vested upon them, once the product is produced, distributed, and eventually sold to consumers. Non-compliance therefore is a violation of the existing rules and regulations imposed by the FDA. We wish to reiterate that the issuance of these advisories is part of the FDA's mandate to ensure the safety, efficacy and quality of health products with utmost regard to protect public health.

With this, we enjoin our industry stakeholders, specifically regulatory officers and product owners to be mindful, thorough and exercise due diligence in their submissions to the FDA as these are checked post-market for compliance and consistency. The MAH, as part of their obligation in the issued CPN, shall respond and cooperate fully with the FDA with regard to any postmarketing activity initiated by the FDA. Likewise, we encourage them to check with the FDA through ccrr_prsdd@fda.gov.ph on the advisories issued on their products for better understanding on how to fully comply with the FDA Directives to avoid any further regulatory action.

Dissemination of this advisory to all concerned is hereby requested.

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