

Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



19 April 2013

FDA Advisory No. 2013 - 010

SUBJECT: CONSUMER eReport FACILITY ON COSMETIC PRODUCTS

The FDA, the DOH agency tasked to look after the interests of the consumers, would like to inform the public that the cosmetic standards for quality and safety of ingredients or products are contained in the "ASEAN Cosmetic Directive" (ACD). The ACD is a product of cooperation, harmonization and agreement among the ASEAN Member States to ensure the safety and quality as well as the claimed benefits of all cosmetic products marketed in ASEAN region.

Cosmetic is defined as any substance or preparation that can be applied on the external parts of the body, such as the skin and its appendages, epidermis and hair system, nails, lips, external genital organs, and teeth, and that have any of the following functions: a) for cleaning, b) promoting health benefits, c) perfuming, d) modifying one's appearance, e) correcting body odour, or f) for protecting and keeping any structure of the body in good condition, among others.

For the safety of all consumers, it is important that all cosmetics pass the FDA evaluation. All cosmetic establishments must first secure a License to Operate and notify the FDA before cosmetic products are offered for use or sale. The notification scheme is an assurance that the product has been manufactured according to the guidelines of current Good Manufacturing Practice (GMP). The consumers have the right to file any complaint against the market authorization holders or outlets in the event of any side effect or reaction after using a product.

Redness or any type of skin irritation after using or putting on lotion, soap, perfume, shampoo, conditioner, make-up, such as blush-on, face foundation, mascara, and lipstick, is not normal. Consumers who have experienced hair loss right after using shampoo or conditioner, or noticeable blotches on the skin after putting on make-up, or any burning sensation of the scalp after receiving hair color treatment and re-bonding or after the application of hair relaxer and hair straightener, are advised to seek professional help. Pruritus or itchy feeling after undergoing a body treatment and massage using oils and other cosmetic products in spa or wellness clinics need to be reported to FDA.

If you have experienced side effects or reaction, even if the directions were not followed, kindly report them to the Food and Drug Administration for appropriate action and to protect other consumers. Consumers may send their complaints at info@fda.gov.ph or through the FDA eReport facility at http://www.fda.gov.ph/ereport, or call telephone no. 857-1900 or 165-332 local 8113. Consumers may also visit us at Civic Drive, Filinvest Corporate City, Alabang, Muntinlupa City. For those in the



Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



province, consumers may get in touch with FDA inspectors in any Center for Health Development (CHD) in the regions.

Consumers are further advised to check if the cosmetic product is allowed in the country by visiting http://www.fda.gov.ph/consumers-corner/cosmetic-product-notification and to buy only from legitimate cosmetic outlets. To facilitate prompt response on all complaints, the consumers are kindly requested to include the following information in their reports:

- The name and contact information of the person who experienced the side effect or reaction;
- The age, gender, and other information, like ethnicity;
- The name of the product and manufacturer;
- The description of the side effect or reaction after using the cosmetic product;
- The healthcare provider's name and contact information, if medical attention was given; and
- The name of the outlet, the date when the product was purchased, and a copy of the Official Receipt, when available.

All consumers are assured that all information given will be treated with strict confidentiality and will be informed immediately on the actions taken and decisions made by the FDA.

KENNETH Y. HARTIGAN-GO, MD

Director General