Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 2021-2656

28 OCT 2021

TO: **GENERAL CONSUMING PUBLIC**

SUBJECT: **Public Health Warning Against the Purchase and Use of Unauthorized Cosmetic Product BABY WIPES Containing Banned Ingredient/s**

The Food and Drug Administration (FDA) warns the public from purchasing and using the unauthorized cosmetic product **BABY WIPES** which tested positive for the presence of **METHYLISOTHIAZOLINONE**. Such ingredient is prohibited to be used in leave-on cosmetic products as per ASEAN Cosmetic Directive. The table below indicates the particulars of the adulterated cosmetic product/s:

PRODUCT DETAILS	**PRODUCT IMAGE/S**
Name of Manufacturer/ Local Company Responsible for Placing the Product in the Market: **Not Indicated** Address: **Not Indicated** Country of Manufacture: **China** Lot/Batch Number: **Not Indicated** Mfg. Date: **Not Indicated** Exp. Date: **Not Indicated**	

Methylisothiazolinone has been listed in Annex VI/57 of the ASEAN Cosmetic Directive to be used as a preservative in the finished cosmetic products. However, the use of the said ingredient have been prohibited for leave-on cosmetic products (including 'wet wipes') in the Philippines through the issuance of FDA Circular No. 2017-006 as a product of the 25th ASEAN Cosmetic Committee Meeting and Its Related Events.

The ban of the aforementioned ingredient for leave-on cosmetic products has been ordered due to clinical data which indicates that, no safe concentrations of Methylisothiazolinone for induction of contact allergy or elicitation have been adequately demonstrated.

The aforementioned unauthorized adulterated product is found to be non-compliant with the existing standards, and, thus pose potential hazards to the consuming public. The use of aduleterated cosmetic products may result to adverse reactions, including but not limited to, skin irritation, itchiness, anaphylactic shock and organ failure.

In light of the foregoing, the public is advised not to purchase the aforementioned unauthorized adulterated cosmetic product. Always check if a product is notified with the FDA by using the FDA Verification Portal feature accessible at https://verification.fda.gov.ph which may be used by typing in the name of the product before the purchase and/or using the cosmetic products.

All concerned establishments are warned not to distribute adulterated cosmetic products.

All FDA Regional Field Offices and Regulatory Enforcement Units, in coordination with law enforcement agencies and Local Government Units, are requested to ensure that violative products are not sold or made available in the market or areas of their jurisdiction.

To report any sale, distribution, complaint and/or adverse event on the use of the violative cosmetic product, the online reporting facility, eReport can be accessed at ereport@fda.gov.ph, or call us at the Center for Cosmetics and Household/Urban Hazardous Substances Regulation and Research (CCHUHSRR) hotline **(02) 8857-1900 loc. 8113 or 8107**.

Dissemination of this advisory to all concerned is hereby requested.

ROLANDO ENRIQUE D. DOMINGO, MD
Director General

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