



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



FDA ADVISORY
No: **2019-084**

122 MAR 2019

TO: GENERAL CONSUMING PUBLIC

SUBJECT: Dissemination of ASEAN Post-Marketing Alert System (PMAS) Report on Cosmetic Product Containing Banned Ingredient With Reference No. FDA 1008.5/327 (8 February 2019) & FDA 1004.03/746 (4 March 2019)

The Food and Drug Administration (FDA) hereby issues this public health warning to inform the public of the ASEAN Post-Marketing Alert System (PMAS) report on below cosmetic product:

	BRAND / PRODUCT NAME	FINDINGS
1.	ASHLEY EVERYDAY'S LIPSTICK 20 G	Product Tested and Found to Contain Colouring agent CI 15585 (INCI)

**Attached is a copy of the Thailand PMAS Report with Reference No. FDA 1008.5/327 (8 February 2019) & FDA 1004.03/746 (4 March 2019)*

The aforementioned product has been tested by the Health Product Vigilance Center, Food and Drug Administration, Thailand, as part of their post-marketing surveillance activities and results of the laboratory analyses show that the product is not compliant with the technical standards set forth by the ASEAN Cosmetic Directive (ACD).

The aforementioned product has been verified to contain the banned colorant CI 15585 (INCI) (CAS No. 5160-02-1) (CAS No. 2092-56-01). According to the prevailing cosmetic regulation, CI 15585 (INCI) is not allowed to be part of a cosmetic product intended to be distributed in the ASEAN region, including the Philippines, because of its potential to cause serious adverse effects including but not limited to cancer.

Because of the hazards posed by the aforementioned products, the public is strongly advised to be vigilant and report to FDA, through any of the following channels, any encounter with these products:

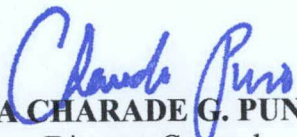
1. Send an e-mail via report@fda.gov.ph
2. Call the Center for Cosmetics Regulation and Research (CCRR) hotline **(02) 857-1900 local 8107 or 8113**
3. Utilize the agency's online reporting facility, **eReport**, at www2.fda.gov.ph/ereport.

Furthermore, the public is also advised to only buy cosmetic products that have been notified with FDA. If unsure of a product's notification status, consumers may verify whether the product is authorized by FDA through the *Search* engine embedded in the FDA website



accessible at www2.fda.gov.ph. For more information and inquiries, please e-mail us at info@fda.gov.ph or call the CCRR hotline.

Dissemination of the information to all concerned is requested.


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