



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



FDA ADVISORY
No. **2019-072**

05 MAR 2019

TO: GENERAL CONSUMING PUBLIC

SUBJECT: Dissemination of ASEAN Post-Marketing Alert System (PMAS) Report on Adulterated Cosmetic Products With Reference No. 1-7/K/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 the following cosmetic products:

	BRAND / PRODUCT NAME	FINDINGS
1.	Tati Ultra Treatment	Product tested and found to contain Hydroquinone & Tretinoin
2.	Tati Ultra Night Cream	Product tested and found to contain Mercury
3.	Deeja Dream Cream	Product tested and found to contain Hydroquinone
4.	Deeja Wrinkle Cream	Product tested and found to contain Mercury
5.	ROBISIS – Anti-Acne Whitening Day & Night Cream	Product tested and found to contain Mercury
6.	Asdanne Whitening Freckle Day Cream	Product tested and found to contain Mercury
7.	Fulenze – Whitening Freckle Day Cream	Product tested and found to contain Mercury

**Attached is a copy of the Malaysia PMAS Report with Reference No. 1-7/K/2019*

The aforementioned products have been tested by the National Pharmaceutical Regulatory Agency, Ministry of Health, Malaysia as part of their post-marketing surveillance activities and results of the laboratory analyses show that these products are not compliant with the technical standards set forth by the ASEAN Cosmetic Directive (ACD).

Product #1 and Product #3 have been found to contain hydroquinone and tretinoin, respectively, both of which are no longer allowed to be part of a cosmetic product and are classified as drug products in the Philippines because of its multiple serious adverse effects (i.e. sensitivity to light, skin redness and permanent skin discoloration) when used indiscriminately.

Additionally, tretinoin may also cause harm to developing fetus. Women planning to get pregnant or are already expecting are strongly advised to avoid using products containing tretinoin.


Products #2, #4, #5, #6 and #7 have been verified to contain mercury beyond the maximum allowed limit of 1 part per million (ppm). Mercury is a naturally occurring heavy metal which is known to be severely hazardous to health even in small amount. People exposed to mercury exhibits symptoms including but not limited to tremors, numbness and tingling in hands and feet, gingivitis or inflammation of the gums, pink discolouration of the hands and feet especially in children, irritability, and photophobia or sensitivity to light. Nursing mothers are doubly vulnerable because mercury are passed on to nursing babies through breast milk which can affect the baby's development.

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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