



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



22 FEB 2019

FDA ADVISORY
No. **2019-046**

TO: GENERAL CONSUMING PUBLIC

SUBJECT: Dissemination of ASEAN Post-Marketing Alert System (PMAS) Report on Adulterated Cosmetic Products With Reference No. (01)/MOH/DPS/PMAS/022019 and (03)/MOH/DPS/PMAS/022019

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.	BEAUTÉDERM Underarm Peeling Cream	Product tested and found to contain Hydroquinone
2.	Jelita Farra Serlah Kejelitaanmu Skincare 5 in 1 – Day Cream	Product tested and found to contain Mercury
3.	Jelita Farra Serlah Kejelitaanmu Skincare 5 in 1 – Cream Treatment	Product tested and found to contain Tretinoin
4.	Jelita Farra Serlah Kejelitaanmu Skincare 5 in 1 – Cream Herbal	Product tested and found to contain Mercury
5.	L’Abeauty Set Jeragat – Pigment Booster Night Cream	Product tested and found to contain Mercury

**Attached is a copy of the Brunei PMAS Report with Reference No. (01)/MOH/DPS/PMAS/022019 and (03)/MOH/DPS/PMAS/022019*

The aforementioned products have been tested by the Department of Pharmaceutical Services, Ministry of Health, Brunei Darussalam 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, and #5 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.

The FDA is currently monitoring the availability of the reported cosmetic products in the Philippine market through heightened Post Marketing Surveillance (PMS) operations, and shall exercise its authority in ensuring that non-compliant health products are recalled and/or seized from the market in accordance with the law.

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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