



FDA ADVISORY
No. **2019-049**

22 FEB 2019

TO: GENERAL CONSUMING PUBLIC

SUBJECT: Dissemination of ASEAN Post-Marketing Alert System (PMAS) Report entitled, "HSA Alert: Five Cosmetic Creams Found to Contain Potent Undeclared Ingredients & Very High Levels of Mercury" Released by the Health Sciences Authority (HSA), Singapore

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 entitled, "HSA Alert: Five Cosmetic Creams Found to Contain Potent Undeclared Ingredients & Very High Levels of Mercury" on below cosmetic products:

| | BRAND / PRODUCT NAME | FINDINGS |
|----|---|--|
| 1. | Deeja Cosmetic Sun Cream | Found to contain high level of Mercury |
| 2. | Deeja Cosmetic Wrinkle Cream | Found to contain high level of Mercury |
| 3. | Deeja Cosmetic Dream Cream | Found to contain Hydroquinone |
| 4. | RDL Babyface Whitening Cream Night Cream 5 in 1 | Detected to contain Mercury |
| 5. | RDL Face Off Fade-Out Cream Day Cream 5 in 1 | Detected to contain Mercury |

**Attached is a copy of the Singapore PMAS Report with Reference No. HSA072723102018 & HAS073804022019*

The aforementioned products were subjected to post-marketing surveillance by the Vigilance and Compliance Branch, Health Sciences Authority (HSA), Singapore and were reported as not compliant with the technical standards set forth by the ASEAN Cosmetic Directive (ACD) as they "contain undeclared potent ingredients such as hydroquinone, a skin lightening agent, and, mercury, a toxic metal."

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.



Hydroquinone is no longer allowed to be part of a cosmetic product and is classified as a drug product in the Philippines because of its multiple serious adverse effects (i.e. sensitivity to light, skin redness and permanent skin discoloration) when used indiscriminately.

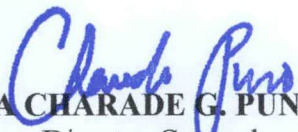
The FDA is currently monitoring the availability of the reported cosmetic products in the Philippine market through heightened Post Marketing Surveillance (PMS) operations, and shall exercise its authority in ensuring that non-compliant health products are recalled and/or seized from the market in accordance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