



FDA ADVISORY
No. **2022-1459**


21 JUL 2022

TO: THE GENERAL PUBLIC

SUBJECT: Public Health Warning Against the Purchase and Use of the following Violative Cosmetic Products as Reported in the ASEAN Post-Marketing Alert System (PMAS):

- 1. BIELA BEAUTY GLOWING NIGHT CREAM**
- 2. BL SKINCARE DAY CREAM 1**
- 3. BL SKINCARE DAY VREAM 2**
- 4. BL SKINCARE NIGHT CREAM**

The Food and Drug Administration (FDA) warns the public from purchasing and using the following violative cosmetic products which tested and found to contain **MERCURY**, **HYDROQUINONE** and **TRETINOIN** as reported in the ASEAN Post-Marketing Alert System (PMAS). These ingredients are not allowed to be part of a cosmetic product as per ASEAN Cosmetic Directive (ACD). The table below indicates the particulars of the violative cosmetic product/s:

| Product Details | Product Image/s |
|---|--|
| <p>Product Name: BIELA BEAUTY GLOWING NIGHT CREAM</p> <p>Manufactured by/Local Company Responsible for Placing the Product in the Market: Not Indicated</p> <p>Country of Manufacture: Not Indicated</p> <p>Lot/Batch Number: BBG00014 Manufacturing Date: 2020.06.10 Expiration Date: 2022.06.10</p> |  <p><i>*found to contain Mercury</i></p> |



| Product Details | Product Image/s |
|--|---|
| <p>Product Name: BL SKINCARE DAY CREAM 1</p> <p>Manufactured by/Local Company Responsible for Placing the Product in the Market: Not Indicated</p> <p>Country of Manufacture: Not Indicated</p> <p>Lot/Batch Number: Not Indicated Manufacturing Date: 01-12-2021 Expiration Date: Not Indicated</p> |  <p><i>*found to contain Hydroquinone and Tretinoin</i></p> |
| <p>Product Name: BL SKINCARE DAY CREAM 2</p> <p>Manufactured by/Local Company Responsible for Placing the Product in the Market: Not Indicated</p> <p>Country of Manufacture: Not Indicated</p> <p>Lot/Batch Number: Not Indicated Manufacturing Date: 01-12-2021 Expiration Date: Not Indicated</p> |  <p><i>*found to contain Mercury</i></p> |
| <p>Product Name: BL SKINCARE NIGHT CREAM</p> <p>Manufactured by/Local Company Responsible for Placing the Product in the Market: Not Indicated</p> <p>Country of Manufacture: Not Indicated</p> <p>Lot/Batch Number: Not Indicated Manufacturing Date: 15-12-2021 Expiration Date: Not Indicated</p> |  <p><i>*found to contain Mercury</i></p> |

The aforementioned cosmetic 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 the aforementioned products are not compliant with the technical standards set forth by the ACD.

Mercury, a naturally occurring heavy metal which is known to be severely hazardous to health even in small amount. According to World Health Organization (WHO), the main adverse effect of exposure to inorganic mercury (e.g. ammoniated mercury) is kidney damage. Mercury may also cause skin rashes, skin discoloration and scarring, as well as reduction in the skin's resistance to bacterial and fungal infections. Exposed pregnant women and nursing mothers transfer the mercury to their fetuses, which can later result in neurodevelopmental deficits in the children.

Hydroquinone and **Tretinoin** are not allowed to be part of cosmetic product as these are classified as drug products in the Philippines because of their multiple serious adverse effects, such as sensitivity to light, skin redness and permanent skin discoloration, when used indiscriminately.


In light of the foregoing, the public is advised not to purchase the aforementioned violative 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 violative 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. 8107**.

Dissemination of this advisory to all concerned is hereby requested.


DR. OSCAR G. GUTIERREZ, JR.
Officer-in-Charge Director General

DTN: 20220718144601