



FDA ADVISORY
No. **2017-141**

TO: GENERAL CONSUMING PUBLIC

SUBJECT: Public Health Warning Against the Use of Unnotified Cosmetic Products (Batch 39)

The Food and Drug Administration (FDA) advises the public against the purchase and use of the following unnotified cosmetic products whose particulars/details are provided in the attached annex:

1. **SPEAKS G SKIN ESSENTIAL REJUVENATING SET**
 - a. **SPEAKS G SKIN ESSENTIAL ORANGE WHITENING SOAP**
 - b. **SPEAKS G SKIN ESSENTIAL BRIGHTENING REJUVENATING TONER**
 - c. **SPEAKS G SKIN ESSENTIAL BRIGHTENING REJUVENATING CREAM**
 - d. **SPEAKS G SKIN ESSENTIAL SUNBLOCKER GEL**
2. **SKIN ESSENTIAL FLAWLESS WHITENING TONER**
3. **SPEAKS G SKIN ESSENTIAL ORANGE WHITENING SOAP**
4. **XIMISO MOISTURE BRILLIANT CRAYON LIPSTICK**
5. **XIMISO REFINED SNOWY DEWY BB CREAM**
6. **DORLENE HERBAL FIRMING SOAP 5 DAY ANTI-CELLULITE & FAT BURNER**
7. **DORLENE HERBAL FIRMING BUST CREAM WITH GINSENG AND PUERARIA**
8. **THE QUEEN'S SECRET WHITE ILLUMINA FACE AND BODY LUSCIOUS CREAM**
9. **THE QUEEN'S SECRET WHITENING MOUSSE**
10. **HB HEAVENLY BEAUTY PREMIUM PAPAYA GOATMILK BEAUTY BAR**
11. **MENOW GENERATION-II TRUE LIPS LIP LINER PENCIL**
12. **MENOW · PRO 15 COLOR CONTOUR CREAM SERIES 01**
13. **ANIMATE E FACIAL OIL**
14. **MENGDIE PROFESSIONAL (TONIC) CARE**
15. **CASINO GEL LAVANT PURETÉ AUX AGENTS ASSAINISSANTS**

FDA post-marketing surveillance (PMS) activities have verified that the abovementioned cosmetic products have not gone through the verification process of the agency and have not been issued the proper authorization in the form of acknowledged cosmetic notifications. Pursuant to Republic Act No. 9711, otherwise known as the "Food and Drug Administration Act of 2009", the manufacture, importation, exportation, sale, offering for sale, distribution, transfer, non-consumer use, promotion, advertising or sponsorship of health products without the proper authorization from FDA is prohibited.



Accordingly, because unnotified cosmetic products have not gone through the verification process of the FDA, the agency cannot guarantee their quality and safety. The use of such violative products may pose potential health hazards to the consuming public. Potential hazards may come from ingredients that are not allowed to be part of a cosmetic product or from the contamination of heavy metals such as mercury especially in whitening cosmetic products. The use of substandard and possibly adulterated cosmetic products may result to adverse reactions including but not limited to skin irritation, itchiness, anaphylactic shock and organ failure.

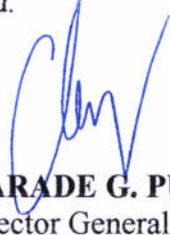
In light of the above, the public is advised not to purchase the aforementioned violative products. Moreover, the public is also advised to be vigilant against cosmetic products that might not be duly notified with FDA. Always check if a cosmetic product has been notified with FDA before purchasing it by making use of the embedded *Search* feature of the FDA website accessible at www.fda.gov.ph.

All concerned establishments are warned not to distribute the above-identified violative cosmetic products until they have already been covered by the appropriate authorization (cosmetic notification), otherwise, regulatory actions and sanctions shall be strictly pursued.

All Local Government Units (LGUs) and Law Enforcement Agencies (LEAs) are requested to ensure that these products are not sold or made available in their localities or areas of jurisdiction.

For more information and inquiries, please e-mail us at info@fda.gov.ph. To report continuous sale or distribution of the above unnotified cosmetic products, utilize our online reporting facility, **eReport**, at www.fda.gov.ph/ereport, or e-mail us via report@fda.gov.ph, or call us at the Center for Cosmetics Regulation and Research (CCRR) hotline **(02) 857-1979** or **(02) 857-1984**.

Dissemination of the information to all concerned is requested.


NELA CHARADE G. PUNO, RPh
Director General

DTN 20170406093929



ANNEX

Details on the Unnotified Cosmetic Products

PRODUCT NAME	PRODUCT DETAILS	PRODUCT IMAGE/S
1 SPEAKS G SKIN ESSENTIAL REJUVENATING SET	Local Company Responsible for Placing the Product in the Market: Not Indicated Address: Not Indicated Country of Manufacture: Not Indicated	
a SPEAKS G SKIN ESSENTIAL ORANGE WHITENING SOAP	Local Company Responsible for Placing the Product in the Market: SGSE Ent. Address: Not Indicated Country of Manufacture: Not Indicated	
b SPEAKS G SKIN ESSENTIAL BRIGHTENING REJUVENATING TONER	Local Company Responsible for Placing the Product in the Market: SGSE Ent. Address: Not Indicated Country of Manufacture: Not Indicated	
c SPEAKS G SKIN ESSENTIAL BRIGHTENING REJUVENATING CREAM	Local Company Responsible for Placing the Product in the Market: Not Indicated Address: Not Indicated Country of Manufacture: Not Indicated	
d SPEAKS G SKIN ESSENTIAL SUNBLOCKER GEL	Local Company Responsible for Placing the Product in the Market: Not Indicated Address: Not Indicated Country of Manufacture: Not Indicated	

	PRODUCT NAME	PRODUCT DETAILS	PRODUCT IMAGE/S
2	SKIN ESSENTIAL FLAWLESS WHITENING TONER	Local Company Responsible for Placing the Product in the Market: Not Indicated Address: Not Indicated Country of Manufacture: Not Indicated	
3	SPEAKS G SKIN ESSENTIAL ORANGE WHITENING SOAP	Local Company Responsible for Placing the Product in the Market: SGSE Ent. Address: Not Indicated Country of Manufacture: Not Indicated	
4	XIMISO MOISTURE BRILLIANT CRAYON LIPSTICK	Local Company Responsible for Placing the Product in the Market: Not Indicated Address: Not Indicated Country of Manufacture: Label is in Foreign Language	
5	XIMISO REFINED SNOWY DEWY BB CREAM	Local Company Responsible for Placing the Product in the Market: Not Indicated Address: Not Indicated Country of Manufacture: Label is in Foreign Language	
6	DORLENE HERBAL FIRMING SOAP 5 DAY ANTI-CELLULITE & FAT BURNER	Local Company Responsible for Placing the Product in the Market: Not Indicated Address: Not Indicated Country of Manufacture: Thailand	