



03 APR 2017

FDA ADVISORY
No. **2017-126**

TO: GENERAL CONSUMING PUBLIC

SUBJECT: Public Health Warning Against the Use of Unnotified Cosmetic Products (Batch 31)

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. LM NAIL POLISH COLOR 157
2. KYLIE MATTE LIQUID LIPSTICK BIRTHDAY EDITION – KRISTEN
3. KYLIE MATTE LIQUID LIPSTICK - DOLCE K
4. KYLIE KYLINER EYELINER AND GEL LINER (KIT)
 - a. KYLIE EYELINER
 - b. KYLIE GEL LINER
5. HELLO KITTY BABY WIPES
6. NAKED8 URBAN DECAY FLUSHED
7. DOVE 3 IN 1 FACIAL CLEANSING WIPES FRESH BLUE (BLUE)
8. DOVE 3 IN 1 FACIAL CLEANSING WIPES FRESH BLUE (WHITE)
9. DOVE 3 IN 1 FACIAL CLEANSING WIPES FRESH RED
10. SOFTSOAP® COCONUT & WARM GINGER HAND SOAP
11. DR. BRONNER'S 18-IN-1 HEMP PEPPERMINT PURE-CASTILE SOAP
12. CREST® 3D WHITE™ LUXE MULTI-CARE WHITENING RINSE
GLAMOROUS WHITE – FRESH MINT
13. TSUBAKI EXTRA MOIST CONDITIONER
14. THE HONEST CO.® HONEST® SHAMPOO + BODY WASH PERFECTLY
GENTLE - SWEET ORANGE VANILLA
15. MISS BEAUTY SALON HAIR-CARE SERIES MOISTURIZING COLOR –
PROTECTING HAIR GEL

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 20170310072330



ANNEX
 Details on the Unnotified Cosmetic Products

PRODUCT NAME	PRODUCT DETAILS	PRODUCT IMAGE/S
1 LM NAIL POLISH COLOR 157	Local Company Responsible for Placing the Product in the Market: Not Indicated Address: Not Indicated Country of Manufacture: Not Indicated	
2 KYLIE MATTE LIQUID LIPSTICK BIRTHDAY EDITION - KRISTEN	Local Company Responsible for Placing the Product in the Market: Not Indicated Address: Not Indicated Country of Manufacture: United States of America (U.S.A.)	
3 KYLIE MATTE LIQUID LIPSTICK - DOLCE K	Local Company Responsible for Placing the Product in the Market: Not Indicated Address: Not Indicated Country of Manufacture: USB	
4 KYLIE KYLINER EYELINER AND GEL LINER (KIT)	Local Company Responsible for Placing the Product in the Market: Not Indicated Address: Not Indicated Country of Manufacture: United States of America (U.S.A.)	
a KYLIE EYELINER	Local Company Responsible for Placing the Product in the Market: Not Indicated Address: Not Indicated Country of Manufacture: United States of America (U.S.A.)	

PRODUCT NAME	PRODUCT DETAILS	PRODUCT IMAGE/S
b KYLIE GEL LINER	<p>Local Company Responsible for Placing the Product in the Market: Not Indicated</p> <p>Address: Not Indicated</p> <p>Country of Manufacture: United States of America (U.S.A.)</p>	
5 HELLO KITTY BABY WIPES	<p>Local Company Responsible for Placing the Product in the Market: Not Indicated</p> <p>Address: Not Indicated</p> <p>Country of Manufacture: Not Indicated</p>	
6 NAKED8 URBAN DECAY FLUSHED	<p>Local Company Responsible for Placing the Product in the Market: Not Indicated</p> <p>Address: Not Indicated</p> <p>Country of Manufacture: Not Indicated</p>	
7 DOVE 3 IN 1 FACIAL CLEANSING WIPES FRESH BLUE (BLUE)	<p>Local Company Responsible for Placing the Product in the Market: Not Indicated</p> <p>Address: Not Indicated</p> <p>Country of Manufacture: Not Indicated</p>	
8 DOVE 3 IN 1 FACIAL CLEANSING WIPES FRESH BLUE (WHITE)	<p>Local Company Responsible for Placing the Product in the Market: Not Indicated</p> <p>Address: Not Indicated</p> <p>Country of Manufacture: Not Indicated</p>	
9 DOVE 3 IN 1 FACIAL CLEANSING WIPES FRESH RED	<p>Local Company Responsible for Placing the Product in the Market: Not Indicated</p> <p>Address: Not Indicated</p> <p>Country of Manufacture: Not Indicated</p>	

PRODUCT NAME	PRODUCT DETAILS	PRODUCT IMAGE/S
10 SOFTSOAP® COCONUT & WARM GINGER HAND SOAP	Local Company Responsible for Placing the Product in the Market: Not Indicated Address: Not Indicated Country of Manufacture: United States of America (U.S.A.)	
11 DR. BRONNER'S 18-IN-1 HEMP PEPPERMINT PURE-CASTILE SOAP	Local Company Responsible for Placing the Product in the Market: Not Indicated Address: Not Indicated Country of Manufacture: United States of America (U.S.A.)	
12 CREST® 3D WHITE™ LUXE MULTI-CARE WHITENING RINSE GLAMOROUS WHITE - FRESH MINT	Local Company Responsible for Placing the Product in the Market: Not Indicated Address: Not Indicated Country of Manufacture: Not Indicated	
13 TSUBAKI EXTRA MOIST CONDITIONER	Local Company Responsible for Placing the Product in the Market: Not Indicated Address: Not Indicated Country of Manufacture: Japan	
14 THE HONEST CO.® HONEST® SHAMPOO + BODY WASH PERFECTLY GENTLE - SWEET ORANGE VANILLA	Local Company Responsible for Placing the Product in the Market: Not Indicated Address: Not Indicated Country of Manufacture: United States of America (U.S.A.)	
15 MISS BEAUTY SALON HAIR-CARE SERIES MOISTURIZING COLOR – PROTECTING HAIR GEL	Local Company Responsible for Placing the Product in the Market: Not Indicated Address: Not Indicated Country of Manufacture: China	