



FDA ADVISORY
No. **2017-200**

11 JUL 2017

TO: GENERAL CONSUMING PUBLIC

**SUBJECT: Public Health Warning Against the Use of Unnotified
Cosmetic Products (Batch 56)**

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. ORIGINAL FLAWLESS® EVERYDAY SUNBLOCK LOTION + WHITENING SPF 21
2. ORIGINAL FLAWLESS® EVERYDAY SUNBLOCK LOTION + MOISTURIZING SPF 21
3. YOKO WHITENING CREAM POMEGRANATE CREAM
4. CHANLANYA® PROFESSIONAL MAKEUP BRONZER FACE SCULPTOR
5. MAC BB HUANYAN FLAWLESS POWDER
6. LUCKY® TALCUM POWDER FLOWER BOQUET
7. LACTIC ACID LOTION 10%
8. SPA-COLORANT CRYSTAL HAIR COLOR 6.4 GOLDEN BROWN
9. SPA-COLORANT CRYSTAL HAIR COLOR 8.86 BEHIND RED
10. ALPEN SECRETS® EPSOM SALT BATH SOAK LAVENDER
11. MATSU SHINZU'I SKIN LIGHTENING SOAP
12. CARICA® HERBALCLEAN HERBAL TOOTHPASTE AND MOUTHWASH
13. NAKED3 URBAN DECAY 6 COLOR BLUSH 05
14. ATELIER A. YSABEL GOLDEN SUNFLOWER HAND & NAIL CREAM
15. LeAMOURE FRENCH FRAGRANCES FOR WOMEN

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 20170630135339



ANNEX
Details on the Unnotified Cosmetic Products

PRODUCT NAME	PRODUCT DETAILS	PRODUCT IMAGE/S
1 ORIGINAL FLAWLESS® EVERYDAY SUNBLOCK LOTION + WHITENING SPF 21	Local Company Responsible for Placing the Product in the Market: F. Cosmetics Address: Valenzuela City, Philippines Country of Manufacture: Not Indicated	
2 ORIGINAL FLAWLESS® EVERYDAY SUNBLOCK LOTION + MOISTURIZING SPF 21	Local Company Responsible for Placing the Product in the Market: F. Cosmetics Address: Valenzuela City, Philippines Country of Manufacture: Not Indicated	
3 YOKO WHITENING CREAM POMEGRANATE CREAM	Local Company Responsible for Placing the Product in the Market: Not Indicated Address: Not Indicated Country of Manufacture: Thailand	
4 CHANLANYA® PROFESSIONAL MAKEUP BRONZER FACE SCULPTOR	Local Company Responsible for Placing the Product in the Market: Not Indicated Address: Not Indicated Country of Manufacture: People's Republic of China (P.R.C.)	
5 MAC BB HUANYAN FLAWLESS POWDER	Local Company Responsible for Placing the Product in the Market: Not Indicated Address: Not Indicated Country of Manufacture: Italy	

6	PRODUCT NAME LUCKY® TALCUM POWDER FLOWER BOQUET	PRODUCT DETAILS	PRODUCT IMAGE/S
		Local Company Responsible for Placing the Product in the Market: Benzal Cosmetics Industries Address: Carmona City, Cavite Country of Manufacture: Not Indicated	
7	LACTIC ACID LOTION 10%	Local Company Responsible for Placing the Product in the Market: Not Indicated Address: Not Indicated Country of Manufacture: Not Indicated	
8	SPA-COLORANT CRYSTAL HAIR COLOR 6.4 GOLDEN BROWN	Local Company Responsible for Placing the Product in the Market: Not Indicated Address: Not Indicated Country of Manufacture: Label is in Foreign Language	
9	SPA-COLORANT CRYSTAL HAIR COLOR 8.86 BEHIND RED	Local Company Responsible for Placing the Product in the Market: Not Indicated Address: Not Indicated Country of Manufacture: Label is in Foreign Language	
10	ALPEN SECRETS® EPSOM SALT BATH SOAK LAVENDER	Local Company Responsible for Placing the Product in the Market: Not Indicated Address: Not Indicated Country of Manufacture: China	

PRODUCT NAME	PRODUCT DETAILS	PRODUCT IMAGE/S
<p>11 MATSU SHINZU'I SKIN LIGHTENING SOAP</p>	<p>Local Company Responsible for Placing the Product in the Market: Not Indicated</p> <p>Address: Not Indicated</p> <p>Country of Manufacture: Label is in Foreign Language</p>	
<p>12 CARICA® HERBALCLEAN HERBAL TOOTHPASTE AND MOUTHWASH</p>	<p>Local Company Responsible for Placing the Product in the Market: Exal Industries Corporation / Carica Herbal Health Products, Inc.</p> <p>Address: Carmona, Cavite / 2626 Dian St., Manila 1004 Phils.</p> <p>Country of Manufacture: Not Indicated</p>	
<p>13 NAKED3 URBAN DECAY 6 COLOR BLUSH 05</p>	<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.) / China</p>	
<p>14 ATELIER A. YSABEL GOLDEN SUNFLOWER HAND & NAIL CREAM</p>	<p>Local Company Responsible for Placing the Product in the Market: Not Indicated</p> <p>Address: Not Indicated</p> <p>Country of Manufacture: People's Republic of China (P.R.C.)</p>	
<p>15 LeAMOURE FRENCH FRAGRANCES FOR WOMEN</p>	<p>Local Company Responsible for Placing the Product in the Market: Le Amoure Fashion Sales Inc.</p> <p>Address: Not Indicated</p> <p>Country of Manufacture: Philippines</p>	