



01 JUN 2017

FDA ADVISORY
Nb: **2017-145**

TO: GENERAL CONSUMING PUBLIC

SUBJECT: Public Health Warning Against the Use of Unnotified Cosmetic Products (Batch 37)

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. **ELLESSE MIRACLE CREAM WHITENING ANTI-AGING SPF 55 WITH ARGAN OIL & VIT. E**
2. **ELLESSE GLUTATHIONE LOTION SPF 60**
3. **ELLESSE TRIPPLE WHITEHING LOTION**
4. **ASIAN ESSENTIALS HOME + BODY HEAD-TO-TOE WASH**
5. **ASIAN ESSENTIALS HOME + BODY INVIGORATING BODY SCRUB WITH EXFOLIANTS AND VITAMIN E**
6. **GREEN PEELING OIL**
7. **DROPLETS OF NATURE TRIPLE WHITENING TONER**
8. **DROPLETS OF NATURE MIRACLE CREAM W/ UV PROTECTION**
9. **PREMIUM GLUTA-KOJIC SOAP**
10. **PREMIUM GLUTA-COLLAGEN SOAP**
11. **PREMIUM TRIPLE WHITENING SOAP**
12. **DROPLETS OF NATURE KOJIC ACID LOTION**
13. **TRIPLE WHITENING LOTION W/ SPF 30 PA+++**
14. **DROPLETS OF NATURE REJUVENATING FACIAL SET**
 - a. **DROPLETS OF NATURE REJUVENATING CREAM**
 - b. **DROPLETS OF NATURE SUNBLOCK FOR DRY SKIN**
 - c. **DROPLETS OF NATURE REJUVENATING FACIAL TONER**
 - d. **PREMIUM KOJIC ACID SOAP (W/ GRAPESEED EXTRACT)**
15. **UNDERARM WHITENING TREATMENT SET (WITH PEELING EFFECT)**
 - a. **UNDERARM WHITENING & ANTI-PERSPIRANT SOAP**
 - b. **YELLOW PEELING OIL (EXTRA STRENGTH)**
 - c. **DROPLETS OF NATURE UNDERARM PEELING CREAM**
 - d. **DROPLETS OF NATURE UNDERARM WHITENING & ANTI-PERSPIRANT TONER**

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 20170404084910



ANNEX

Details on the Unnotified Cosmetic Products

PRODUCT NAME	PRODUCT DETAILS	PRODUCT IMAGE/S
<p>1 ELLESSE MIRACLE CREAM WHITENING ANTI-AGING SPF 55 WITH ARGAN OIL & VIT. E</p>	<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>	
<p>2 ELLESSE GLUTATHIONE LOTION SPF 60</p>	<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>	
<p>3 ELLESSE TRIPPLE WHITEHING LOTION</p>	<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>	
<p>4 ASIAN ESSENTIALS HOME + BODY HEAD-TO-TOE WASH</p>	<p>Local Company Responsible for Placing the Product in the Market: MCTG Trading International Corp.</p> <p>Address: Not Indicated</p> <p>Country of Manufacture: Philippines</p>	
<p>5 ASIAN ESSENTIALS HOME + BODY INVIGORATING BODY SCRUB WITH EXFOLIANTS AND VITAMIN E</p>	<p>Local Company Responsible for Placing the Product in the Market: MCTG Trading International Corp.</p> <p>Address: Not Indicated</p> <p>Country of Manufacture: Philippines</p>	

PRODUCT NAME	PRODUCT DETAILS	PRODUCT IMAGE/S
<p>6 GREEN PEELING OIL</p>	<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>	
<p>7 DROPLETS OF NATURE TRIPLE WHITENING TONER</p>	<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>	
<p>8 DROPLETS OF NATURE MIRACLE CREAM W/ UV PROTECTION</p>	<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>	
<p>9 PREMIUM GLUTA-KOJIC 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: Not Indicated</p>	
<p>10 PREMIUM GLUTA-COLLAGEN 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: Not Indicated</p>	

PRODUCT NAME	PRODUCT DETAILS	PRODUCT IMAGE/S
11 PREMIUM TRIPLE WHITENING SOAP	Local Company Responsible for Placing the Product in the Market: Not Indicated Address: Not Indicated Country of Manufacture: Not Indicated	
12 DROPLETS OF NATURE KOJIC ACID LOTION	Local Company Responsible for Placing the Product in the Market: Not Indicated Address: Not Indicated Country of Manufacture: Not Indicated	
13 TRIPLE WHITENING LOTION W/ SPF 30 PA+++	Local Company Responsible for Placing the Product in the Market: Not Indicated Address: Not Indicated Country of Manufacture: Not Indicated	
14 DROPLETS OF NATURE REJUVENATING FACIAL SET	Local Company Responsible for Placing the Product in the Market: Not Indicated Address: Not Indicated Country of Manufacture: Not Indicated	
a DROPLETS OF NATURE REJUVENATING CREAM	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
b DROPLETS OF NATURE SUNBLOCK FOR DRY SKIN	Local Company Responsible for Placing the Product in the Market: Not Indicated Address: Not Indicated Country of Manufacture: Not Indicated	
c DROPLETS OF NATURE REJUVENATING FACIAL TONER	Local Company Responsible for Placing the Product in the Market: Not Indicated Address: Not Indicated Country of Manufacture: Not Indicated	
d PREMIUM KOJIC ACID SOAP (W/ GRAPESEED EXTRACT)	Local Company Responsible for Placing the Product in the Market: Not Indicated Address: Not Indicated Country of Manufacture: Not Indicated	
15 UNDERARM WHITENING TREATMENT SET (WITH PEELING EFFECT)	Local Company Responsible for Placing the Product in the Market: Not Indicated Address: Not Indicated Country of Manufacture: Not Indicated	
a UNDERARM WHITENING & ANTI-PERSPIRANT SOAP	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
b	YELLOW PEELING OIL (EXTRA STRENGTH)	Local Company Responsible for Placing the Product in the Market: Not Indicated Address: Not Indicated Country of Manufacture: Not Indicated	
c	DROPLETS OF NATURE UNDERARM PEELING CREAM	Local Company Responsible for Placing the Product in the Market: Not Indicated Address: Not Indicated Country of Manufacture: Not Indicated	
d	DROPLETS OF NATURE UNDERARM WHITENING & ANTI-PERSPIRANT TONER	Local Company Responsible for Placing the Product in the Market: Not Indicated Address: Not Indicated Country of Manufacture: Not Indicated	