

Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



FDA ADVISORY No. 2017-056

2 8 FEB 2017

TO:

GENERAL CONSUMING PUBLIC

SUBJECT:

Public Health Warning Against the Use of Unnotified

Cosmetic Products (Batch 12)

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. AS MAKE UP CINEMA STICK CONCEALER WITH SPF-15 VITAMIN-E & UVB FILTER AS8037
- 2. AS ASHLEY SHINE MAGIC GIRL LIPSTICK
- 3. AS ASHLEY SHINE RED POMEGRANATE BB FIRMING MINERAL POWDER
- 4. CRYSTAL INFINITY BEAUTY PRODUCTS OVERNIGHT REPAIR CREAM
- 5. CRYSTAL INFINITY BEAUTY PRODUCTS UA DERM
- 6. CRYSTAL INFINITY BEAUTY PRODUCTS GLUTA PEELING SOAP
- 7. EVER BILENA™ DAILY SUNBLOCK MOISTURIZING CREAM FACE UVA UVB PROTECTION
- 8. HORTALEZA, MD® DERMATOX RETAIN HAND AND BODY LOTION
- 9. ORANGE PEELING LOTION
- 10. TIANNUO® HIDE THE BLEMISH CONCEALER PASHA

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. Alwayscheck 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 C. PUNO, RP

DTN 20170120140122

ANNEX

Details on the Unnotified Cosmetic Products

	PRODUCT NAME	PRODUCT DETAILS	PRODUCT IMAGE/S
1	AS MAKE UP CINEMA STICK CONCEALER WITH SPF-15 VITAMIN-E & UVB FILTER AS8037	Local Company Responsible for Placing the Product in the Market: Not Indicated Address: Not Indicated	
		Country of Manufacture: Not Indicated	-
2	AS ASHLEY SHINE MAGIC GIRL	Local Company Responsible for Placing the Product in the Market:	
	LIPSTICK	Not Indicated	15 mg
		Address:	
		Not Indicated	
		Country of Manufacture: Not Indicated	
3	AS ASHLEY SHINE RED	Local Company Responsible for Placing the Product in the Market:	Ashley SMLS
	POMEGRANATE BB FIRMING MINERAL	Elegant Fumes Beauty Products Inc.	RED POMEGRANATE
	POWDER	Address:	
		1 St Flr. 707 Sto Cristo St. San Nicolas,	BB BB
		Manila	Control of the Contro
		Country of Manufacture: China	
4	CRYSTAL INFINITY	Local Company Responsible for Placing the Product in the Market:	
	BEAUTY PRODUCTS OVERNIGHT REPAIR CREAM	Not Indicated	Overnight Repair Cream
	REI AIR CREAM	Address:	
		Not Indicated	
		Country of Manufacture: Not Indicated	K. 6 33 1 45
5	CRYSTAL INFINITY	Local Company Responsible for Placing the Product in the Market:	
	BEAUTY PRODUCTS UA DERM	Not Indicated	A PROPERTY OF
		Address:	Marie of the same
		Not Indicated	
		Country of Manufacture:	
		Not Indicated	

PRODUCT NAME

PRODUCT DETAILS

PRODUCT IMAGE/S

6 CRYSTAL INFINITY
BEAUTY PRODUCTS
GLUTA PEELING
SOAP

Local Company Responsible for Placing the Product in the Market:

Not Indicated

Address: Not Indicated

Country of Manufacture:

Not Indicated



7 EVER BILENATM
DAILY SUNBLOCK
MOISTURIZING
CREAM FACE UVA
UVB PROTECTION

Local Company Responsible for Placing the Product in the Market:

Ever Bilena Cosmetics Inc.

Address:

289 Reparo Road, Sta Quiteria, Caloocan

City, Phils.

Country of Manufacture:

China



8 HORTALEZA, MD® DERMATOX RETAIN HAND AND BODY LOTION Local Company Responsible for Placing the Product in the Market:

HBC

Address:

548 Mindanao Avenue, 1116 Quezon City,

Philippines

Country of Manufacture:

Philippines



9 ORANGE PEELING LOTION Local Company Responsible for Placing the

Product in the Market:

Not Indicated

Address:

Not Indicated

Country of Manufacture:

Not Indicated

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10 TIANNUO® HIDE THE BLEMISH CONCEALER PASHA Local Company Responsible for Placing the

Product in the Market:

Not Indicated

Address: Not Indicated

Country of Manufacture:

Not Indicated



