

# Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



FDA ADVISORY No. 2016-145

0 6 DEC 2016

TO:

GENERAL CONSUMING PUBLIC

**SUBJECT:** 

Public Health Warning Against the Use of Unnotified

Cosmetic Products (Batch 23)

The Food and Drug Administration (FDA) advises the public against the purchase and use of the following unnotified cosmetic products:

- 1. RX ARBUTIN TONER
- 2. RX KOJIC ACID SOAP SKIN WHITENING WITH KOJIC AND PAPAINE EXTRACT
- 3. RX PEELING SOAP SKIN EXFOLIANTING SOAP
- 4. RX PLACENTA SOAP SKIN WHITENING WITH ANTI-AGEING
- 5. RX BLEACHING BLACK SOAP SKIN WHITENING WITH BEARBERRY EXTRACT
- 6. RX GLUTATHIONE W/ ROSEHIP SOAP
- 7. RX SLIMMING SOAP SKIN WHITENING WITH SEAWEED EXTRACT

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 <a href="https://www.fda.gov.ph">www.fda.gov.ph</a>.



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

Dissemination of the information to all concerned is requested.

NELA CHARADE G. PUNO, RPh

Director General

## ANNEX Details on the Unnotified Cosmetic Products

	PRODUCT NAME	PRODUCT DETAILS	PRODUCT IMAGE/S
1	RX ARBUTIN TONER	Manufacturer's Name: Not Indicated	
		Country of Manufacture: Not Indicated	*Arbutin
		Local Company Responsible for Placing the	
		Product in the Market:	Toner Bases
		Not Indicated	And the second s
		Address: Not Indicated	
2	RX KOJIC ACID SOAP SKIN WHITENING	Manufacturer's Name: Not Indicated	
	WITH KOJIC AND	Country of Manufacture: Not Indicated	B
	PAPAINE EXTRACT	Legal Company Bornancible for Placing the	Kojic Acid Soan
		Local Company Responsible for Placing the Product in the Market:	Salking white ad type loss
		Not Indicated	DERMATOLOGISTS TEXTED For Extend Use Day
		Address: Not Indicated	
3	RX PEELING SOAP SKIN EXFOLIANTING	Manufacturer's Name: Not Indicated	
		G (N. C . N. T. F . 1	
	SOAP	Country of Manufacture: Not Indicated	R Dooling Coon
		Local Company Responsible for Placing the	Peeling Soap
		Product in the Market:	Skin Exfolianting Scap
		Not Indicated	Per External Cas Oxly
		Address: Not Indicated	
4	RX PLACENTA SOAP SKIN WHITENING WITH ANTI-AGEING	Manufacturer's Name: Not Indicated	
		Country of Manufacture: Not Indicated	
	WITH ANTI-AGEING	Country of Manufacture. Not indicated	The state of the s
		Local Company Responsible for Placing the	Placenta Soap
		Product in the Market:	CEARACOLOGITE TESTED
		Not Indicated	For Dispose that Obj.
		Address: Not Indicated	
5	RX BLEACHING BLACK SOAP SKIN WHITENING WITH	Manufacturer's Name: Not Indicated	
		Country of Manufacture: Not Indicated	R
	BEARBERRY		Bleaching Black Soan
	EXTRACT	Local Company Responsible for Placing the	Sile Whitestag with Seurberry Correct
		Product in the Market: Not Indicated	SINNAR Marians Textus Fee burner textus
		Not indicated	
		Address: Not Indicated	

#### PRODUCT NAME

#### PRODUCT DETAILS

### PRODUCT IMAGE/S

6 RX GLUTATHIONE W/ ROSEHIP SOAP Manufacturer's Name: Not Indicated

Country of Manufacture: Not Indicated

Local Company Responsible for Placing the Product in the Market:

Not Indicated

Address: Not Indicated

R. Clatathione w/ Rosehip Soap

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7 RX SLIMMING SOAP SKIN WHITENING WITH SEAWEED EXTRACT Manufacturer's Name: Not Indicated

Country of Manufacture: Not Indicated

Local Company Responsible for Placing the Product in the Market:

Not Indicated

Address: Not Indicated

