

Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



0 4 APR 2017

FDA ADVISORY No. 2017-130

TO:

GENERAL CONSUMING PUBLIC

SUBJECT:

Public Health Warning Against the Use of Unnotified

Cosmetic Products (Batch 35)

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. BN WHITENING SHOPPE EXTREME WHITENING FACE AND BODY SOAP
- 2. BN WHITENING SHOPPE ULTRA WHITE TONER
- 3. BN WHITENING SHOPPE FACIAL SCRUB
- 4. BN WHITENING SHOPPE EXTREME WHITENING LOTION SPF 40
- 5. TAILAIME LIP GLOSS #07
- 6. TAILAIME LIP GLOSS #22
- 7. MELS COSMETICS LIP GLOSS 01
- 8. MELS COSMETICS LIP GLOSS 02
- 9. MELS COSMETICS LIP GLOSS 04
- 10. MELS COSMETICS LIP GLOSS 10
- 11. MELS COSMETICS LIP GLOSS 12
- 12. ELLEFAR PRINCESS NUDY LIP PEACH 57
- 13. OCEAN POTION® PROTECT & NOURISH ENRICHED WITH SEA PLANT BOTANICALS™ SPF 50 SUN PROTECTION LOTION SCENT OF SUMMER
- 14. CASINO EAU COIFFANTE ANTI-EPIS SPRAY
- 15. BEAUTY SECRET 4 RADISH SOAP

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 20170320152722

ANNEX Details on the Unnotified Cosmetic Products

	PRODUCT NAME	PRODUCT DETAILS	PRODUCT IMAGE/S
1	BN WHITENING	Local Company Responsible for	
	SHOPPE EXTREME	Placing the Product in the Market:	PRODUCTION AND INCIDENCE.
	WHITENING FACE	Not Indicated	
	AND BODY SOAP		
		Address:	EXTREME
		Not Indicated	
			- 2007
		Country of Manufacture:	
		Not Indicated	
2	BN WHITENING	Local Company Responsible for	
	SHOPPE ULTRA	Placing the Product in the Market:	
	WHITE TONER	Not Indicated	
		Address:	69993
		Not Indicated	2
		Country of Manufactures	1
		Country of Manufacture:	
		Not Indicated	
3	BN WHITENING	Local Company Responsible for	
,	SHOPPE FACIAL	Placing the Product in the Market:	
	SCRUB	Not Indicated	6721
	SCRUB	Not indicated	
		Address:	Bolus
		Not Indicated	基本
		Country of Manufacture:	
		Not Indicated	
	BN WHITENING	Local Company Responsible for	
	SHOPPE EXTREME	Placing the Product in the Market:	
	WHITENING LOTION	Patricia Bianca Beauty Solutions	and the second
	SPF 40		A STATE OF THE PARTY OF THE PAR
		Address:	
		Not Indicated	7856-976. 3.0000
		Country of Manufacture:	
		Not Indicated	
	TAILAIME LIP GLOSS	Local Company Responsible for	
5	#07	Placing the Product in the Market:	
	no /	Not Indicated	
		Not indicated	
		Address:	
		Not Indicated	
		1 vot indicated	
		Country of Manufacture:	
		Not Indicated	4
		Not illulcated	The state of the s

	PRODUCT NAME	PRODUCT DETAILS	PRODUCT IMAGE/S
6	TAILAIME LIP GLOSS	Local Company Responsible for	
	#22	Placing the Product in the Market:	
		Not Indicated	
		Address:	
		Not Indicated	
		Not indicated	
		Country of Manufacture:	
		Not Indicated	
7	MELS COSMETICS	Local Company Responsible for	
/	LIP GLOSS 01	Placing the Product in the Market:	-
	LIF GLOSS 01	Not Indicated	
		Not indicated	
		Address:	
		Not Indicated	
		Country of Manufacture:	
		Not Indicated	
8	MELS COSMETICS	Local Company Responsible for	
0	LIP GLOSS 02	Placing the Product in the Market:	
	LIF GLOSS 02	Not Indicated	
		Not indicated	NAME OF TAXABLE PARTY.
		Address:	
		Not Indicated	
		Tot maleured	
		Country of Manufacture:	
		Not Indicated	
9	MELS COSMETICS	Local Company Responsible for	
	LIP GLOSS 04	Placing the Product in the Market:	
		Not Indicated	41
		Address:	
		Not Indicated	
		NOT HIGHCATED	
		Country of Manufacture:	
		Not Indicated	
10	MELS COSMETICS	Local Company Responsible for	
	LIP GLOSS 10	Placing the Product in the Market:	
		Not Indicated	2.1
		Address:	No.
		Not Indicated	1.5
		110t Illulcated	
		Country of Manufacture:	
		Not Indicated	

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	PRODUCT NAME	PRODUCT DETAILS	PRODUCT IMAGE/S
11	MELS COSMETICS	Local Company Responsible for	
	LIP GLOSS 12	Placing the Product in the Market:	
		Not Indicated	
		4.11	
		Address: Not Indicated	Lin
		Not indicated	
		Country of Manufacture:	
		Not Indicated	
	ELL EEL D DDENGEGG	I 10 P 71 C	
12	ELLEFAR PRINCESS	Local Company Responsible for	- Common
	NUDY LIP - PEACH 57	Placing the Product in the Market: Not Indicated	
		Not indicated	(3-74-1922)
		Address:	A TABLE OF THE PARTY OF THE PAR
		Not Indicated	1
		Country of Manufacture:	
		China	Contract of the second
13	OCEAN POTION®	Local Company Responsible for	
10	PROTECT & NOURISH	Placing the Product in the Market	A CONTRACTOR OF THE PARTY OF TH
	ENRICHED WITH SEA	RPG Distribution Services, Inc.	(SEED)
	PLANT		-01007
	BOTANICALS™ SPF 50	Address:	a50
	SUN PROTECTION	#898 M. Eusebio Avenue Brgy. San	
	LOTION - SCENT OF	Miguel Pasig City 1600	
	SUMMER		
		Country of Manufacture:	
		United States of America (U.S.A.)	
14	CASINO EAU	Local Company Responsible for	
-	COIFFANTE ANTI-	Placing the Product in the Market:	100
	EPIS SPRAY	Not Indicated	100
		10 WW	3000
		Address:	
		Not Indicated	
		Country of Manufacture:	TO THE TEN
		Not Indicated	The same of the sa
15	BEAUTY SECRET 4	Local Company Responsible for	
10	RADISH SOAP	Placing the Product in the Market:	
	THE POST OF THE	Not Indicated	
			The state of the s
		Address:	SOAP
		Not Indicated	THE REAL PROPERTY.
		C	
		Country of Manufacture:	-
		Thailand	