

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



0 5 JUL 2017

FDA ADVISORY No. 2017-197

TO:

GENERAL CONSUMING PUBLIC

SUBJECT: Public Health Warning Against the Use of Unnotified

Cosmetic Products (Batch 58)

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. TRI & 1 PROFESSIONAL KERATIN HAIR REBORN TREATMENT
- 2. TRUMAY® HAIR COLORANT / TRUMAY® HAIR COLOR CREAM PERMANENT HAIR COLORANT K-12 COFFEE
- 3. MB® MISS BEAUTY BATH SALT SCRUB MILK
- 4. GINGER ONLY 60" HYDRA PROFESSIONAL NOURISH EXTRACARE DOUBLE MOISTURIZE
- 5. VITALIS® HAIR TONIC WITH V7
- 6. POLYCLEAN SOFTSOAP ROSE / POLYCLEAN ROSE HAND SOAP
- 7. KCZA PROFESSIONAL DEEPNESS REPAIRING
- 8. PIZZI HANDSOAP WITH MOISTURIZING FACTOR GREEN APPLE
- 9. GEVEMIA PERMANENT HAIR COLOR CREAM 6.66 FLOWERY VIOLET
- 10. BLEACHING ORIGINAL SOAP
- 11. UNIFRESH PAPAYA WHITENING SOAP
- 12. WONDER HERB ALOE VERA ANTI-ACNE HAND MADE LUXURY SOAP
- 13. ILOG MARIA HONEYBEE FARM HONEY FACE SCRUB
- 14. ILOG MARIA ROYAL JELLY HAIR OIL
- 15. PSORIFIX FOR VERY DRY SKIN

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>

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 <a href="mailto:info@fda.gov.ph">info@fda.gov.ph</a>. To report continuous sale or distribution of the above unnotified cosmetic products, utilize our online reporting facility, eReport, at <a href="mailto:www.fda.gov.ph/ereport">www.fda.gov.ph/ereport</a>, or e-mail us via <a href="mailto:report@fda.gov.ph">report@fda.gov.ph</a>, 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 20170703121600

## ANNEX Details on the Unnotified Cosmetic Products

	PRODUCT NAME	PRODUCT DETAILS	PRODUCT IMAGE/S
1	TRI & 1	Local Company Responsible for	
	PROFESSIONAL	Placing the Product in the Market:	Kergtin
	KERATIN HAIR	Not Indicated	
	REBORN	7.1.	
	TREATMENT	Address:	
		Not Indicated	THE THE
		Country of Manufacture:	THE RESERVE TO THE PARTY OF THE
		Not Indicated	
		110t Illinoutou	
2	TRUMAY® HAIR	Local Company Responsible for	
	COLORANT /	Placing the Product in the Market:	FRUMAYA 750 HO MENTAGO
	TRUMAY® HAIR	Not Indicated	
	COLOR CREAM		<b>國之風</b>
	PERMANENT HAIR	Address:	
	COLORANT K-12	Not Indicated	Hairmile
	COFFEE	Country of Manufacture	Colorai - Pi 00
		Country of Manufacture: Not Indicated	OTHER DESIGNATION OF THE PERSON OF THE PERSO
		Not indicated	
3	MB® MISS BEAUTY	Local Company Responsible for	
	BATH SALT SCRUB -	Placing the Product in the Market:	<b>建</b>
	MILK	Not Indicated	
		Address:	
		Not Indicated	Seek hate.
		Country of Manufacture:	
		China	
4	GINGER ONLY 60"	Local Company Responsible for	
	HYDRA	Placing the Product in the Market:	
	PROFESSIONAL	Not Indicated	
	NOURISH		cinger
	EXTRACARE DOUBLE	Address:	CO CONTRACTOR OF THE PARTY OF T
	MOISTURIZE	Not Indicated	NOURISH (
		Contractive Contractive	- A 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
		Country of Manufacture:	A DI
		Label is in Foreign Language	
5	VITALIS® HAIR	Local Company Responsible for	
	TONIC WITH V7	Placing the Product in the Market:	
		Not Indicated	
		O BOROLOGIC	Vilalis
		Address:	Halls
		Not Indicated	
		0 01 0	
		Country of Manufacture:	
		United States of America (U.S.A.)	

	PRODUCT NAME
6	POLYCLEAN
	SOFTSOAP - ROSE /
	POLYCLEAN ROSE HAND SOAP
7	KCZA PROFESSIONA DEEPNESS REPAIRING
8	PIZZI HANDSOAP WITH MOISTURIZING
	FACTOR - GREEN
	APPLE

## PRODUCT DETAILS

Local Company Responsible for Placing the Product in the Market: Not Indicated

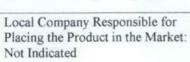
Address: Not Indicated

Country of Manufacture: Label is in Foreign Language

#### L Local Company Responsible for Placing the Product in the Market: Not Indicated

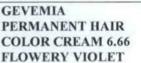
Address: Not Indicated

Country of Manufacture: Label is in Foreign Language



Address: Not Indicated

Country of Manufacture: Indonesia



Local Company Responsible for Placing the Product in the Market: Not Indicated

Address: Not Indicated

Country of Manufacture: China

#### BLEACHING ORIGINAL 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

#### 11 UNIFRESH PAPAYA WHITENING SOAP

Local Company Responsible for Placing the Product in the Market: Owen Manufacturing

Address:

Brgy. Ugong, Valenzuela City

Country of Manufacture: Not Indicated



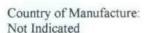
#### 12 WONDER HERB ALOE VERA ANTI-ACNE HAND MADE LUXURY SOAP

Local Company Responsible for Placing the Product in the Market:

- E&W Davao Trade & Import Corporation
- Springdew Resource & Technology Corp.

#### Address:

- a. Not Indicated
- b. Toril, Davao City







#### 13 ILOG MARIA HONEYBEE FARM HONEY FACE SCRUB

Local Company Responsible for Placing the Product in the Market: Not Indicated

Address: Not Indicated

Country of Manufacture: Not Indicated



#### 14 ILOG MARIA ROYAL JELLY HAIR OIL

Local Company Responsible for Placing the Product in the Market: Not Indicated

Address: Not Indicated

Country of Manufacture: Not Indicated



### 15 PSORIFIX FOR VERY DRY SKIN

Local Company Responsible for Placing the Product in the Market: Not Indicated

Address: Not Indicated

Country of Manufacture: EU (Country Not Indicated)

