



FDA ADVISORY
No. **2017-197**

05 JUL 2017

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 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 20170703121600 ✓



ANNEX

Details on the Unnotified Cosmetic Products

PRODUCT NAME	PRODUCT DETAILS	PRODUCT IMAGE/S
<p>1 TRI & 1 PROFESSIONAL KERATIN HAIR REBORN TREATMENT</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 TRUMAY® HAIR COLORANT / TRUMAY® HAIR COLOR CREAM PERMANENT HAIR COLORANT K-12 COFFEE</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 MB® MISS BEAUTY BATH SALT SCRUB - MILK</p>	<p>Local Company Responsible for Placing the Product in the Market: Not Indicated</p> <p>Address: Not Indicated</p> <p>Country of Manufacture: China</p>	
<p>4 GINGER ONLY 60™ HYDRA PROFESSIONAL NOURISH EXTRACARE DOUBLE MOISTURIZE</p>	<p>Local Company Responsible for Placing the Product in the Market: Not Indicated</p> <p>Address: Not Indicated</p> <p>Country of Manufacture: Label is in Foreign Language</p>	
<p>5 VITALIS® HAIR TONIC WITH V7</p>	<p>Local Company Responsible for Placing the Product in the Market: Not Indicated</p> <p>Address: Not Indicated</p> <p>Country of Manufacture: United States of America (U.S.A.)</p>	

	PRODUCT NAME	PRODUCT DETAILS	PRODUCT IMAGE/S
6	POLYCLEAN SOFTSOAP – ROSE / POLYCLEAN ROSE HAND SOAP	Local Company Responsible for Placing the Product in the Market: Not Indicated Address: Not Indicated Country of Manufacture: Label is in Foreign Language	
7	KCZA PROFESSIONAL DEEPNESS REPAIRING	Local Company Responsible for Placing the Product in the Market: Not Indicated Address: Not Indicated Country of Manufacture: Label is in Foreign Language	
8	PIZZI HANDSOAP WITH MOISTURIZING FACTOR – GREEN APPLE	Local Company Responsible for Placing the Product in the Market: Not Indicated Address: Not Indicated Country of Manufacture: Indonesia	
9	GEVEMIA PERMANENT HAIR COLOR CREAM 6.66 FLOWERY VIOLET	Local Company Responsible for Placing the Product in the Market: Not Indicated Address: Not Indicated Country of Manufacture: China	
10	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	<p>Local Company Responsible for Placing the Product in the Market: Owen Manufacturing</p> <p>Address: Brgy. Ugong, Valenzuela City</p> <p>Country of Manufacture: Not Indicated</p>	
12 WONDER HERB ALOE VERA ANTI-ACNE HAND MADE LUXURY SOAP	<p>Local Company Responsible for Placing the Product in the Market:</p> <ul style="list-style-type: none"> a. E&W Davao Trade & Import Corporation b. Springdew Resource & Technology Corp. <p>Address:</p> <ul style="list-style-type: none"> a. Not Indicated b. Toril, Davao City <p>Country of Manufacture: Not Indicated</p>	
13 ILOG MARIA HONEYBEE FARM HONEY FACE SCRUB	<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>	
14 ILOG MARIA ROYAL JELLY HAIR OIL	<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>	
15 PSORIFIX FOR VERY DRY SKIN	<p>Local Company Responsible for Placing the Product in the Market: Not Indicated</p> <p>Address: Not Indicated</p> <p>Country of Manufacture: EU (Country Not Indicated)</p>	