

Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



FDA ADVISORY No. 2017-007 2 4 JAN 2017

TO:

GENERAL CONSUMING PUBLIC

SUBJECT:

Public Health Warning Against the Use of Unnotified

Cosmetic Products (Batch 5)

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. ABSOLUT KERATIN SHAMPOO WITH KERALISS (3)
- 2. TRUMAY BY HZX HANZHIXIU (T-16 DARK BROWN)
- 3. TRUMAY HAIR COLORANT (K-2 MAROON BROWN)
- 4. HANFEI PROFESSIONAL HAIR HAIR COLOR
- 5. BATH2BASICS FIERCE FOR MEN EAU DE TOILETTE POUR HOMME
- 6. LIPSTICK (NO BRAND NAME)
- 7. HAIR COLOR (LABEL IN FOREIGN CHARACTERS)

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, RPb
Director General



ANNEXDetails on the Unnotified Cosmetic Products

	PRODUCT NAME	PRODUCT DETAILS	PRODUCT IMAGE/S
1	ABSOLUT KERATIN SHAMPOO WITH	Country of Manufacture: Not Indicated	1 I
	KERALISS (3)	Local Company Responsible for Placing the	ABO
	는 10 mm (1, 40 mm) - 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	Product in the Market:	
		Not Indicated	ATN
		Address: Not Indicated	
2	TRUMAY BY HZX HANZHIXIU (T-16	Country of Manufacture: Not Indicated	
	DARK BROWN)	Local Company Responsible for Placing the	the state of the s
		Product in the Market:	
		Not Indicated	
		Address: Not Indicated	RUMAY
3	TRUMAY HAIR COLORANT (K-2	Country of Manufacture: Not Indicated	PARAMETERS SOFTAND LINES ELECTRONS
	MAROON BROWN)	Local Company Responsible for Placing the	M Ka
		Product in the Market:	Exercise Section 1
		Not Indicated	- Till
		Address: Not Indicated	Colorant
4	HANFEI	Country of Manufacture: Not Indicated	HANEEL
	PROFESSIONAL HAIR	I 10 P 31 C P 3	
	- HAIR COLOR	Local Company Responsible for Placing the Product in the Market:	
		Not Indicated	SALV SERVICE
		Address: Not Indicated	
5	BATH2BASICS FIERCE FOR MEN EAU DE	Country of Manufacture: Not Indicated	Section Asserts Section Assert
	TOILETTE POUR	Local Company Responsible for Placing the	The state of the s
	HOMME	Product in the Market:	₩ ±
		Island Vanities Enterprise	一一
		Address: 2808 Entrata Urban Complex,	ALL TAKES
		2609 Civic Drive Filinvest City, Muntinlupa	
6	LIPSTICK (NO BRAND NAME)	Country of Manufacture: Not Indicated	
	NAME)	Local Company Responsible for Placing the	168
		Product in the Market:	
		Not Indicated	
		Address: Not Indicated	
7	HAIR COLOR (LABEL IN FOREIGN	Country of Manufacture: Not Indicated	- occocco
	CHARACTERS)	Local Company Responsible for Placing the	D. Marie
		Product in the Market:	排學
		Not Indicated	W 6
		Address: Not Indicated	Et i
		10 mm (1971) 16 (1971) 17 mm (1	