Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 2018-146

17 APR 2018

TO: **GENERAL CONSUMING PUBLIC**

SUBJECT: **Dissemination of ASEAN Post-Marketing Alert System (PMAS) Report on Adulterated Cosmetic Products With the Reference No. FDA 1004.04.1059**

The Food and Drug Administration (FDA) hereby issues this public health warning to inform the public of the ASEAN Post-Marketing Alert System (PMAS) report on the following cosmetic product/s:

	BRAND / PRODUCT NAME	FINDINGS
1	Cream Farsai Spirulina	Product tested and found to contain ammoniated mercury.
2	OMOHOLIC Whitening Body Lotion	Product tested and found to contain Clobetasol Propionate, a corticosteroid.

**Attached is a copy of the PMAS Report from Thailand with Reference No. FDA 1004.04.1059*

The aforementioned products have been tested by the Food and Drug Administration of Thailand as part of its post-marketing surveillance activities and the results of the laboratory analyses show that the products are not compliant with the technical standards set forth by the ASEAN Cosmetic Directive (ACD).

Product #1 has been verified to contain mercury in the form of ammoniated mercury beyond the maximum allowed limit of one (1) part per million (ppm). Mercury is a naturally occuring heavy metal which is known to be severely hazardous to health even in small amount. People exposed to mercury exhibits symptoms including but not limited to tremors, numbness and tingling in the hands and feet, gingivitis or inflammation of the gums, pink discolouration of the hands and feet especially in children, irritability, and photophobia or sensitivity to light. Nursing mothers are doubly vulnerable because mercury is passed on to nursing babies through breast milk which can affect the baby's development.

Product # 2, on the other hand, has been verified to contain a drug active ingredient which is not allowed in cosmetic products.

Because of the hazards posed by the aforementioned cosmetic products, the public is strongly advised to be vigilant and report to FDA, through any of the following channels, any encounter with them:

1. Send an e-mail via **report@fda.gov.ph**;
2. Call the Center for Cosmetics Regulation and Research (CCRR) hotline **(02) 857-1900 local 8113 or 8107**; or
3. Utilize the agency's online reporting facility, **eReport**, at ww2.fda.gov.ph/ereport.

Furthermore, the public is also advised to only buy cosmetic products that have been notified with FDA. If unsure of a product's notification status, consumers may verify whether the product is authorized by FDA using the *Search* engine embedded in the FDA website which is accessible at www.fda.gov.ph. For more information and inquiries, please e-mail us at **info@fda.gov.ph** or call the CCRR hotline mentioned above.

Dissemination of the information to all concerned is requested.

NELA CHARADE G. PUNO, RPh
Director General

DTN 20180414085634

ASEAN POST-MARKETING ALERT SYSTEM(Form B)

(Use this form for multiple product alerts of same product type with similar issues)

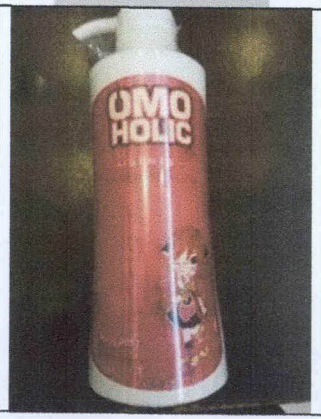
Tick √	**2. Issue:**	**3. Action:**
1. Level of confidentiality: ( )Internal / Restricted circulation (√) On public domain, specify website: www.fda.moph.go.th	(√) Adulteration ( ) Counterfeit ( ) Quality defect ( ) Safety aspect ( ) Others, please specify:	( )Cancellation of registration ( ) Labeling revision ( )Recall of product ( )Suspension of registration ( ) Withdrawal of product (√) Others, please specify: process the evidence for prosecution
4. Source / Type of signal:	( )Local ADR reports ( )Scientific literature / local studies (√)Post-market sampling and testing activities	( )Decision made by other regulatory authorities &/or industry ( ) Others, please specify:
Product information (whenever possible, please provide an image of the product)		
5. Product type:	( ) Biologic (√) Cosmetic ( ) Health supplement ( ) Pharmaceutical	( ) Traditional medicine ( ) Others, please specify:
6. Forensic classification in your country:	(√) General sales list / Over-the-counter ( ) Pharmacy only	( ) Prescription only ( )Others, please specify:

Reporting country / authority	
7. Name of country / Issuing authority: Thailand/ Food and Drug Administration	**8. Report reference no.:** FDA 1004.04.1059
9. Department / Designation of person issuing the alert: Mrs. Wimon Suwankaesawong, Director, Technical and Planning Division, Food and Drug Administration	**10. Date of report:** 10 April 2018
Contact person	
11. Name: Mrs. Wimon Suwankaesawong Ms. Yaowares Oppamayun	**12. Department / Designation:** Technical and Planning Division Health Product Vigilance Center (HPVC)
13. Email address: adr@fda.moph.go.th	**14. Contact no.** ***Telephone:*** *66 2 590 7261* **Fax:** 66 2 591 8457

Annex I

Report reference no.: **FDA 1004.04.1059**

Date of report: **April 2018**

No	Description of product *				Marketing authorisation holder / Product licence holder /Company responsible for placing product in the market	Manufacturer • Name • Country	Investigations i.e. • Type of quality defect i.e. microbial contamination, heavy toxic metals, dissolution test • Type and amount of adulterant • Details of ADR	Actions i.e. • Level of recall e.g. hospital, retail, consumers • Type of recall e.g. batch specific • Date of withdrawal or recall etc.
	Brand / Product name / Alternative name (e.g. local language)	• **Active ingredients / Generic name / Full formula (for cosmetics, traditional medicines etc.)** • **Strength (if applicable):**	• **Dosage form / Pack size (if applicable)** • **Batch / Lot number** **Date of Expiry or Manufacture (if applicable)**	**Intended use as listed on label:**				
1	Cream Farsai Spirulina (notification number not stated)		Date off Manufacture non	whitening	non	Thailand	Product tested and found to contain Ammoniated Mercury	On process of prosecution
2	OMOHOLIC whitening body lotion Notification number: 10-1-5902450		Batch number 06D800T800 MFD 28/11/2016	whitening	Omoholic Skincare Factory	Thailand	Product tested and found to contain clobetasol propionate, a corticosteroid	On process of prosecution