Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

26 MAR 2018

FDA ADVISORY
No. 2018-106

TO: **GENERAL CONSUMING PUBLIC**

SUBJECT: **Dissemination of ASEAN Post-Marketing Alert System (PMAS) Report on Adulterated Cosmetic Products With the Reference No. (05)/MOH/DPS/PMAS/032018**

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.	Temulawak New Day & Night Cream Beauty Whitening Cream - NIGHT	Presence of MERCURY

**Attached is a copy of the Brunei Darussalam PMAS Report with Reference No. (05)/MOH/DPS/PMAS/032018*

The aforementioned product has been tested by the Department of Pharmaceutical Services, Ministry of Health, Brunei Darussalam as part of their post-marketing surveillance activities and the result of the laboratory analysis shows that the product is not compliant with the technical standards set forth by the ASEAN Cosmetic Directive (ACD).

The product has been verified to contain mercury beyond the maximum allowed limit of 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.

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

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 20180319092409

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.moh.gov.bn	(√) Adulteration ( ) Counterfeit ( ) Quality defect ( ) Safety aspect ( ) Others, please specify: -	( ) Cancellation of registration ( ) Labelling revision ( ) Recall of product ( ) Suspension of registration (√) Withdrawal of product ( ) Others, please specify: -
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: **Brunei Darussalam, Ministry of Health**	**8. Report reference no.:** **(05)/MOH/DPS/PMAS/032018**
9. Department / Designation of person issuing the alert: **Department of Pharmaceutical Services**	**10. Date of report:** **17 March 2018**
Contact person	
11. Name: **Ms Norhasidah Abd Rahman**	**12. Department / Designation:** **Pharmacy Enforcement Section** **Department of Pharmaceutical Services**
13. Email address: **norhasidah.rahman@moh.gov.bn**	**14. Contact no.** **Telephone no.: +673 2393298 EXT 209** **Fax no.: +673 2393291**

* To provide photograph of product.

Annex I

Report reference no.: (05)/MOH/DPS/PMAS/032018 **Date of report:** 17 March 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 of 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.	Temulawak New Day & Night Cream Beauty Whitening Cream - NIGHT	Not Stated	Dosage Form : Not Stated Pack Size : 50g Batch No: Not Stated Man Date: Not Stated Exp Date: Not Stated	• Eliminate black spots, acne and wrinkles on the skin. The rough and black skin can turn white, clean and luminous.	Not Stated	Buatan Malaysia	Product tested and found to contain **MERCURY**	The product is banned from the market

Picture of Product

Temulawak New Day & Night Cream Beauty Whitening Cream - NIGHT