Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

27 JUL 2018

FDA ADVISORY No. 2018-233

TO: **GENERAL CONSUMING PUBLIC**

SUBJECT: **Dissemination of ASEAN Post-Marketing Alert System (PMAS) Report on Adulterated Cosmetic Products With the Reference No. (11)/MOH/DPS/PMAS/072018)**

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 products:

	BRAND / PRODUCT NAME	FINDINGS
1.	Dnars Dinar Cream	Presence of MERCURY
2.	Dnars Honey Cream	Presence of HYDROQUINONE and TRETINOIN

**Attached is a copy of the Brunei Darussalam PMAS Report with Reference No. (11)/MOH/DPS/PMAS/072018*

The aforementioned products have been tested by the Department of Pharmaceutical Services, Ministry of Health, Brunei Darussalam as part of their post-marketing surveillance activities and results of the laboratory analyses show that these products are not compliant with the technical standards set forth by the ASEAN Cosmetic Directive (ACD).

Product #1 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 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 are passed on to nursing babies through breast milk which can affect the baby's development.

Product #2, on the other hand, has been found to contain hydroquinone and tretinoin, both of which are no longer allowed to be part of a cosmetic product and are classified as drug products in the Philippines because of its multiple serious adverse effects (i.e. sensitivity to light, skin redness and permanent skin discoloration) when used indiscriminately. Additionally, tretinoin may also cause harm to developing fetus. Women planning to get pregnant or are already expecting are strongly advised to avoid using products containing tretinoin.

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

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 8107 or 8113**
3. Utilize the agency's online reporting facility, **eReport**, at www2.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 through the *Search* engine embedded in the FDA website 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.

Dissemination of the information to all concerned is requested.

NELA CHARADE G. PUNO, RPh
Director General

DTN 20180723100044

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.:** **(11)/MOH/DPS/PMAS/072018**
9. Department / Designation of person issuing the alert: **Department of Pharmaceutical Services**	**10. Date of report:** **18 July 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**

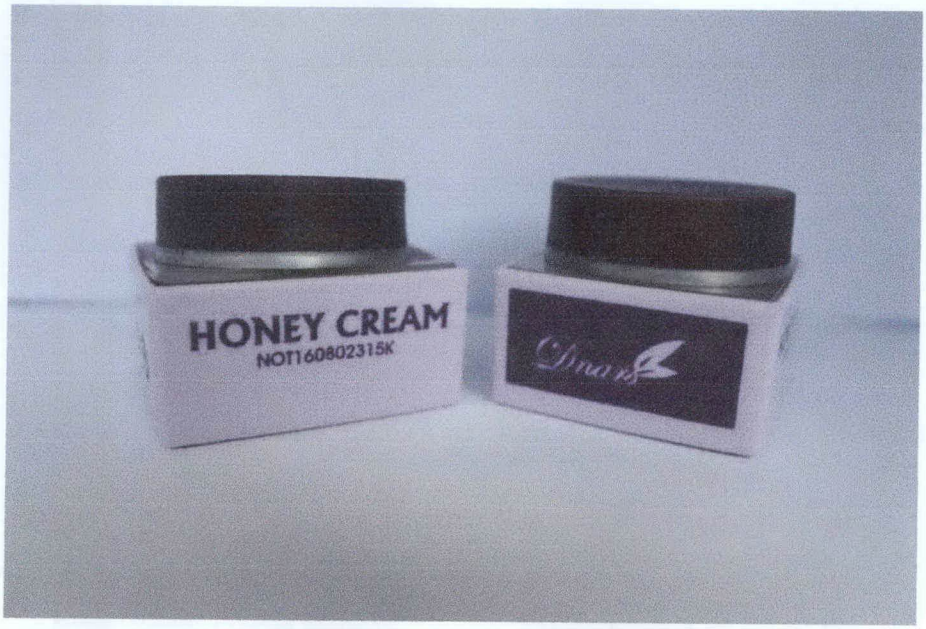
* To provide photograph of product.

Annex I

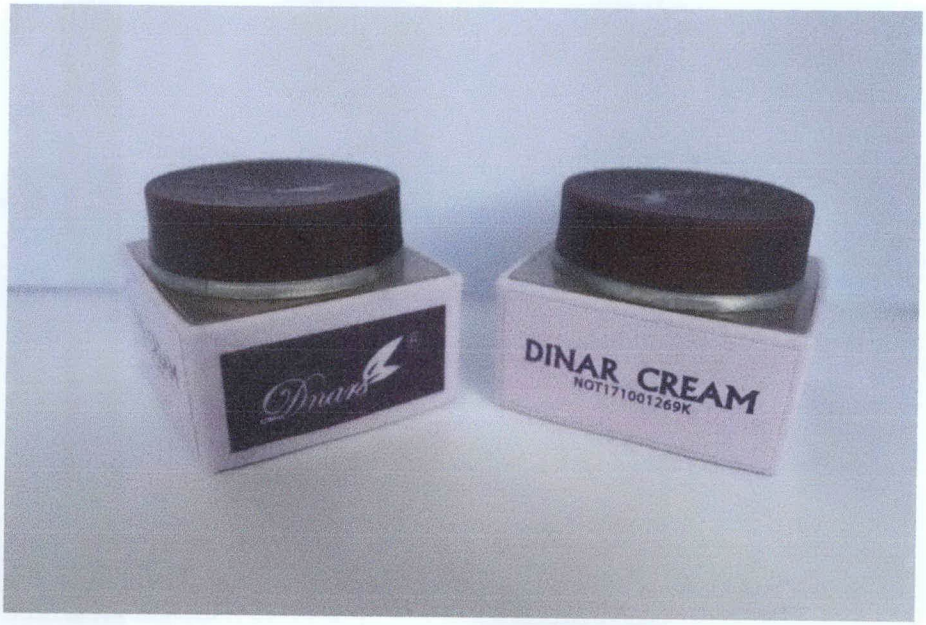
Report reference no.: (11)/MOH/DPS/PMAS/072018 **Date of report:** 18 July 2018

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.	Dnars Dinar Cream	Not Stated	Dosage Form : Not Stated Pack Size : +/- 6g Batch No: Not Stated Man Date: Not Stated Exp Date: Not Stated	• Not Stated	Not Stated	Made in Malaysia	Product tested and found to contain MERCURY	The product is banned from the market
2.	Dnars Honey Cream	Not Stated	Dosage Form : Not Stated Pack Size : +/- 6g Batch No: Not Stated Man Date: Not Stated Exp Date: Not Stated	• Not Stated	Not Stated	Made in Malaysia	Product tested and found to contain HYDROQUINONE & TRETINOIN	The product is banned from the market

Picture of Product



Dnar's Honey Cream



Dnar's Dinar Cream