Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 2018-056

05 MAR 2018

TO: **GENERAL CONSUMING PUBLIC**

SUBJECT: **Dissemination of ASEAN Post-Marketing Alert System (PMAS) Report on Adulterated Cosmetic Products (Reference No. ASEAN ALERT 1-4/2018/K)**

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.	**NURIZ SHOPPE – UV PEARL CREAM**	Products tested and found to contain high level of mercury
2.	**NURIZ – D'SOLVE**	
3.	**AURA GORGEOUS NIGHT CREAM**	
4.	**NV ANTI BLEMISH TONER 1**	Products tested and found to contain hydroquinone and tretinoin

**Attached is a copy of the Malaysian PMAS Report with Reference No. ASEAN ALERT 1-4/2018/K*

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

Products #1 to #3 have been verified to contain mercury exceeding 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 which include 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 #4, 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 but are classified as drugs in the Philippines because of its multiple serious adverse (i.e. sensitivity to light, skin redness and permanent skin discoloration) when used indiscriminately. Additionally, tretinoin may also cause harm to developing fetus and 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) 857-1984**
3. Utilize the agency's online reporting facility, **eReport**, at www.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 has been 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 20180125095831

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.npra.moh.gov.my	(√) 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: Cancellation of notification
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: Malaysia, National Pharmaceutical Regulatory Agency	**8. Report reference no.**: 1-4/2018/K
9. Department / Designation of person issuing the alert: National Pharmaceutical Regulatory Agency, Ministry Of Health Malaysia	**10. Date of report**: 2 January 2018
Contact person	
11. Name: MS WAN MOHAINA BINTI WAN MOHAMMAD	**12. Department / Designation:** Deputy Director Centre of Post Registration of Product and Cosmetic Control, National Pharmaceutical Regulatory Agency, Ministry Of Health Malaysia
13. Email address: wanmohaina@npra.gov.my	**14. *Contact no.*** **Telephone no.:** +6-03-78835538 **Fax no.:** + 6-03-79567151

Annex I

Report reference no.: ASEAN ALERT 1-4/2018/K **Date of report:** 2 January 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.	Nuriz Shoppe -UV Pearl Cream	NA	NA	NA	Progressive Mix Industries	Progressive Mix Industries, Malaysia	Products tested and found to contain high level of mercury.	• Notification of these products has been cancelled. • Company has to destroy the recalled products.
2.	Nuriz- D'solve	NA	NA	NA				
3.	Aura Gorgeous Night Cream	NA	BN: AG201	NA	Aura Gorgeous Beauty & Healthy	Anfa International Laboratoires, Morocco		
4.	NV Anti Blemish Toner 1	NA	NA	NA	Nouvelle Beauty Centre Sdn Bhd	QEMRICH SDN. BHD., Malaysia	Products tested and found to contain hydroquinone and tretinoin.	

Nuriz Shoppe -UV Pearl Cream

Nuriz- D'solve

Aura Gorgeous Night Cream

NV Anti Blemish Toner 1