



FDA ADVISORY
No. **2018-209**

25 JUN 2018

TO: GENERAL CONSUMING PUBLIC

SUBJECT: Dissemination of ASEAN Post-Marketing Alert System (PMAS) Report on Adulterated Cosmetic Products (Reference No. ASEAN ALERT 12-16/2018/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.	Deeja Cosmetic Star Cream	Product tested and found to contain hydroquinone and tretinoin
2.	Deeja Cosmetic Vogue Cream	Product tested and found to contain high level of mercury
3.	Deeja Krim Nano (Night)	Product tested and found to contain high level of mercury
4.	Miracle White – Brightening Cream	Product tested and found to contain high level of mercury
5.	Deluxe Beauty – Ultra Lightening Cream	Product tested and found to contain high level of mercury

**Attached is a copy of the Malaysian PMAS Report with Reference No. ASEAN ALERT 12-16/2018/K*

The aforementioned products have been tested by the National Pharmaceutical Regulatory Agency, Ministry of Health, Malaysia as part of its 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). Thus, the cosmetic notifications issued by the National Pharmaceutical Regulatory Agency to the said products have been cancelled.

Product #1 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.

Products #2 to #5, on the other hand, have been verified to contain mercury exceeding the maximum allowed limit of 1 part per million (ppm). Mercury is a naturally occurring 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 discoloration 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.

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 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 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 20180614085231



ASEAN POST-MARKETING ALERT SYSTEM (Form B)
(Use this form for multiple product alerts of same product type with similar issues)

Tick <input checked="" type="checkbox"/>		
1. Level of confidentiality: <input type="checkbox"/> Internal / Restricted circulation <input checked="" type="checkbox"/> On public domain, specify website: www.npra.moh.gov.my _____	2. Issue: <input checked="" type="checkbox"/> Adulteration <input type="checkbox"/> Counterfeit <input type="checkbox"/> Quality defect <input type="checkbox"/> Safety aspect <input type="checkbox"/> Others, please specify: _____	3. Action: <input type="checkbox"/> Cancellation of registration <input type="checkbox"/> Labelling revision <input checked="" type="checkbox"/> Recall of product <input type="checkbox"/> Suspension of registration <input type="checkbox"/> Withdrawal of product <input checked="" type="checkbox"/> Others, please specify: Cancellation of notification. _____
4. Source / Type of signal:	<input type="checkbox"/> Local ADR reports <input type="checkbox"/> Scientific literature / local studies <input checked="" type="checkbox"/> Post-market sampling and testing activities	<input type="checkbox"/> Decision made by other regulatory authorities &/or industry <input type="checkbox"/> Others, please specify: _____
Product information (whenever possible, please provide an image of the product)		
5. Product type:	<input type="checkbox"/> Biologic <input checked="" type="checkbox"/> Cosmetic <input type="checkbox"/> Health supplement <input type="checkbox"/> Pharmaceutical	<input type="checkbox"/> Traditional medicine <input type="checkbox"/> Others, please specify: _____
6. Forensic classification in your country:	<input checked="" type="checkbox"/> General sales list / Over-the-counter <input type="checkbox"/> Pharmacy only	<input type="checkbox"/> Prescription only <input type="checkbox"/> Others, please specify: _____
Reporting country / authority		
7. Name of country / Issuing authority: Malaysia, National Pharmaceutical Regulatory Agency	8. Report reference no.: 12-16/2018/K	
9. Department / Designation of person issuing the alert: National Pharmaceutical Regulatory Agency, Ministry Of Health Malaysia	10. Date of report: 11 June 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 12-16/2018/K

Date of report:

11 June 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.	Deeja Cosmetic Star Cream	NA	NA	NA	Limajari Marketing	Top On Cosmetics Industries, Malaysia	Products tested and found to contain hydroquinone and tretinoin.	<ul style="list-style-type: none"> Notification of these products has been cancelled. Company has to dispose the recalled products.
2.	Deeja Cosmetic Vogue Cream	NA	NA	NA	Limajari Marketing	Top On Cosmetics Industries, Malaysia	Products tested and found to contain high level of mercury.	
3.	Deeja Krim Nano (Night)	NA	NA	NA	Onew Cosmetics	Yamni Industries Sdn. Bhd., Malaysia	Products tested and found to contain high level of mercury.	
4.	Miracle White - Brightening Cream	NA	EXP : 31 Aug 2019	NA	Miracle Surplus Sdn. Bhd.	Mirade Cosmetics International, Pakistan	Products tested and found to contain high level of mercury.	
5.	Deluxe Beauty - Ultra Lightening Cream	NA	NA	NA	Luna Group Sdn. Bhd.	Royal International, Pakistan	Products tested and found to contain high level of mercury.	

Deeja Cosmetic Star Cream



Deeja Cosmetic Vogue Cream



Deeja Krim Nano (Night)



Miracle White - Brightening Cream



Deluxe Beauty - Ultra Lightening Cream

