Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

05 APR 2018

FDA ADVISORY
No. 2018-131

TO: **GENERAL CONSUMING PUBLIC**

SUBJECT: **Dissemination of ASEAN Post-Marketing Alert System (PMAS) Report on Adulterated Cosmetic Products With the Reference No. (03)/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.	Azzalea by Camira – Queen Cream	Verified to contain mercury in excessive amount (15,827.773 ppm)

**Attached is a copy of the Brunei Darussalam PMAS Report with Reference No. (03)/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 20180402091608

ASEAN POST-MARKETING ALERT SYSTEM (Form A)

Tick √ **1. Level of confidentiality**: ( ) Internal / Restricted circulation (√) On public domain, specify website: **www.moh.gov.bn**	**2. Issue**: (√) Adulteration ( ) Counterfeit ( ) Quality defect ( ) Safety aspect ( ) Others, please specify:	**3. Action**: ( ) 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: **Public Feedback**
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:

7. Brand / Product name (or drug class): **Azzalea by Camira – Queen Cream**	**8. Alternative name (e.g. local language)**: **NA**
9. Active ingredient / Generic name / Full formula (for cosmetics, traditional medicines etc.): **Not stated**	
10. Dosage form (if applicable): **NA**	**11. Strength (if applicable)**: **NA**
12. Pack size / Presentation: **NA**	**13. Batch / Lot number**: **Not stated**
14. Expiry date (if applicable): **Not stated**	**15. Date manufactured (if applicable)**: **Not stated**
16. Intended use as listed on label: **Not stated**	
17. Countries which the product is exported to: **NA**	
Company information	
18. Marketing authorisation holder / Product licence holder / Company responsible for placing product in the market: **NA**	
19. Name & country of manufacturer **Not stated**	

Details / Action(s) taken	
20. Details of investigations e.g. • Type of quality defect (e.g. microbial contamination, heavy toxic metals, dissolution test) • Type and amount of adulterant (amount of adulterant is an important criteria for risk management) • Details of ADR and whether there is any fatal or life-threatening ADR report **Product tested and found to contain Mercury (15,827.773 ppm)**	
21. Actions / proposed actions to be taken • Level of recall (e.g. hospital, retail, consumers) • Type of recall (e.g. batch specific, temporary suspension, permanent) • Date of withdrawal or recall ***The product is banned from the market***	
Reporting country / authority	
22. Name of country / Issuing authority: **Brunei Darussalam, Ministry of Health**	**23. Report reference no.:** (03)/MOH/DPS/PMAS/032018
24. Department / Designation of person issuing the alert: **Department of Pharmaceutical Services**	**25. Date of report:** 14 March 2018
Contact person	
26. Name: **Ms Norhasidah Abd Rahman** **Ms Hjh Ellys Hj Mohammed**	**27. Department / Designation:** **Department of Pharmaceutical Services / Pharmacist**
28. Email address: norhasidah.rahman@moh.gov.bn ellys.mohammed@moh.gov.bn	**29. Contact no.** **Telephone no.: +673 2393298 Ext 221** **Fax no.: +6732393297**

Indicate NA whenever the field is not applicable.

- To provide photograph of product and press statement if any.

Picture(s) of product, if any