



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



05 OCT 2018

FDA ADVISORY
No. **2018-290**

TO: GENERAL CONSUMING PUBLIC

SUBJECT: Dissemination of ASEAN Post-Marketing Alert System (PMAS) Report on Adulterated Cosmetic Product With the Reference No. (15)/MOH/DPS/PMAS/092018

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:

	BRAND / PRODUCT NAME	FINDINGS
1.	SS-II Cosmetic 5 in 1 Serlahkan Kejelitaanmu – Herbal Cream	Product tested and found to contain MERCURY

**Attached is a copy of the Brunei Darussalam PMAS Report with Reference No. (15)/MOH/DPS/PMAS/092018*

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 results of the laboratory analysis show that this product is not compliant with the technical standards set forth by the ASEAN Cosmetic Directive (ACD).

The aforementioned product has been verified to contain mercury beyond 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 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.

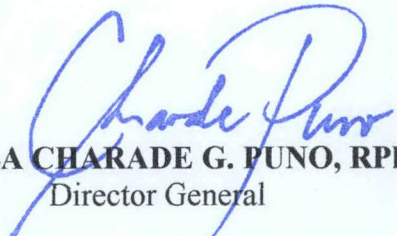
Because of the hazards posed by the aforementioned product, the public is strongly advised to be vigilant and report to FDA through any of the following channels any encounter with this product:

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 www2.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 20180919165509



ASEAN POST-MARKETING ALERT SYSTEM (Form B) <i>(Use this form for multiple product alerts of same product type with similar issues)</i>		
<i>Tick ✓</i> 1. Level of confidentiality: <input type="checkbox"/> Internal / Restricted circulation <input checked="" type="checkbox"/> On public domain, specify website: www.moh.gov.bn _____	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 type="checkbox"/> Recall of product <input type="checkbox"/> Suspension of registration <input checked="" type="checkbox"/> Withdrawal of product <input type="checkbox"/> Others, please specify: - _____
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 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: Brunei Darussalam, Ministry of Health	8. Report reference no.: (15)/MOH/DPS/PMAS/092018	
9. Department / Designation of person issuing the alert: Department of Pharmaceutical Services	10. Date of report: 13 September 2018	
Contact person		
11. Name: Ms Norhasidah Abd Rahman	12. Department / Designation: Compliance and Licensing 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.: (15)MOH/DPS/PMAS/092018

Date of report: 13 September 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/ name/ 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.	SS-II Cosmetic 5 in 1 Serlahkan Kejelitaanmu – Herbal Cream	Not stated	Dosage Form : Not Stated Pack Size : 7g Batch No: Not Stated Man Date: Not Stated Exp Date: Not Stated	• Not Stated	Establishment Kecantikan Kesihatan Imayani Tjonang Dan Anak-Anak	Qemrich Sdn Bhd, Malaysia	Product tested and found to contain MERCURY	The product is banned from the market

Picture of Product



SS-II Cosmetic 5 in 1 Serlahkan Kejelitaanmu – Herbal Cream