



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



FDA ADVISORY
No: **2018-179**

29 MAY 2018

TO: GENERAL CONSUMING PUBLIC

SUBJECT: Dissemination of ASEAN Post-Marketing Alert System (PMAS) Report on Adulterated Cosmetic Product With the Reference No. (08)/MOH/DPS/PMAS/052018

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.	Deeja Cosmetic Keyuan Semula Jadi Set 5 dalam 1 – Star Cream	Presence of HYDROQUINONE

**Attached is a copy of the Brunei Darussalam PMAS Report with Reference No. (08)/MOH/DPS/PMAS/052018*

The aforementioned product has been tested by the Department of Pharmaceutical Services, Ministry of Health of Brunei Darussalam as part of its 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 found to contain hydroquinone, an ingredient which is prohibited in cosmetic and are classified as drug product in the Philippines because of its multiple serious adverse effects (i.e. sensitivity to light, skin redness and permanent skin discoloration) when used indiscriminately.

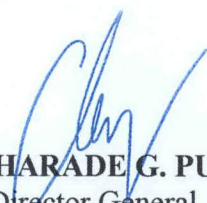
Because of the hazards posed by the aforementioned cosmetic product, the public is strongly advised to be vigilant and report to FDA, through any of the following channels, any encounter with it:

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.

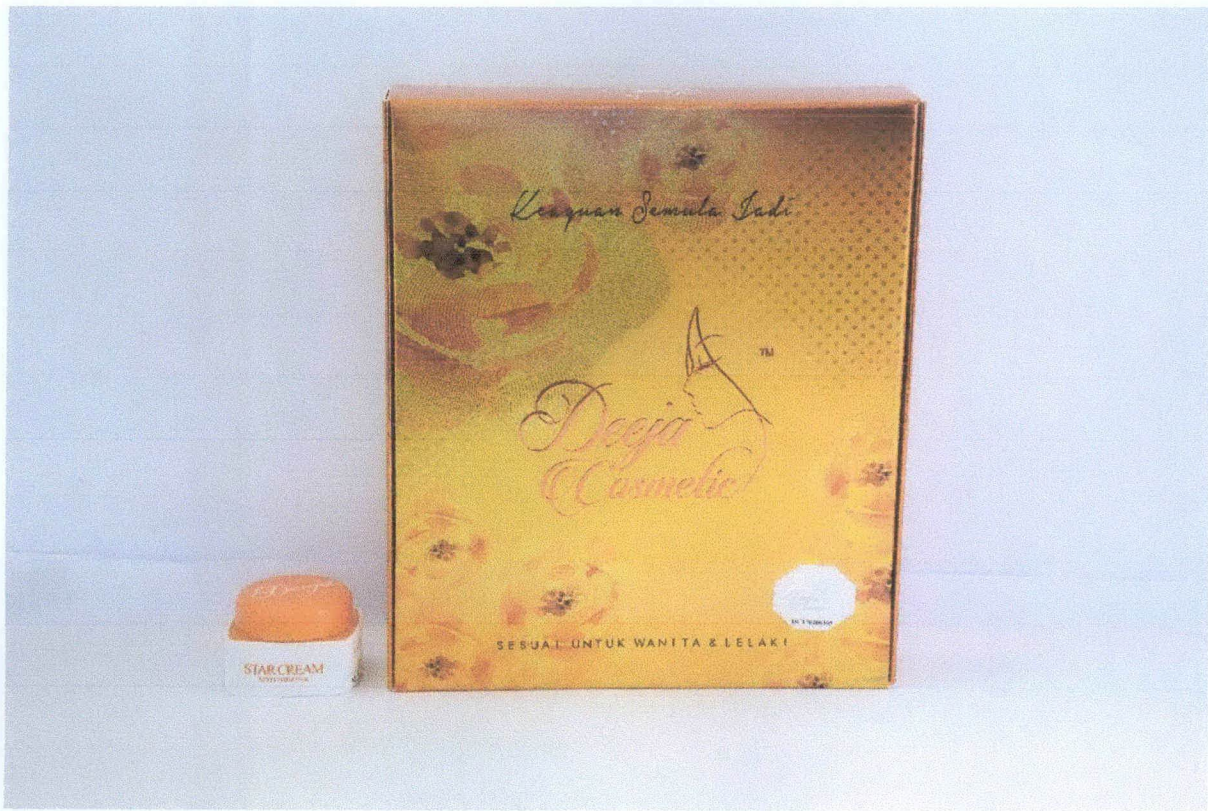
Dissemination of the information to all concerned is requested.


NELA CHARADE G. PUNO, RPh
Director General

DTN 20180515105317



Pictures of products:



Deeja Cosmetic Keyuan Semula Jadi Set 5 dalam 1 – Star Cream

ASEAN POST-MARKETING ALERT SYSTEM (Form B) <i>(Use this form for multiple product alerts of same product type with similar issues)</i>		
<p>Tick <input checked="" type="checkbox"/></p> <p>1. Level of confidentiality:</p> <p><input type="checkbox"/> Internal / Restricted circulation</p> <p><input checked="" type="checkbox"/> On public domain, specify website:</p> <p>www.moh.gov.bn</p> <p>_____</p>	<p>2. Issue:</p> <p><input checked="" type="checkbox"/> Adulteration</p> <p><input type="checkbox"/> Counterfeit</p> <p><input type="checkbox"/> Quality defect</p> <p><input type="checkbox"/> Safety aspect</p> <p><input type="checkbox"/> Others, please specify:</p> <p>-</p> <p>_____</p>	<p>3. Action:</p> <p><input type="checkbox"/> Cancellation of registration</p> <p><input type="checkbox"/> Labelling revision</p> <p><input type="checkbox"/> Recall of product</p> <p><input type="checkbox"/> Suspension of registration</p> <p><input checked="" type="checkbox"/> Withdrawal of product</p> <p><input type="checkbox"/> Others, please specify:</p> <p>-</p> <p>_____</p>
<p>4. Source / Type of signal:</p>	<p><input type="checkbox"/> Local ADR reports</p> <p><input type="checkbox"/> Scientific literature / local studies</p> <p><input checked="" type="checkbox"/> Post-market sampling and testing activities</p>	<p><input type="checkbox"/> Decision made by other regulatory authorities &/or industry</p> <p><input type="checkbox"/> Others, please specify:</p> <p>-</p> <p>_____</p>
<p>Product information (whenever possible, please provide an image of the product)</p>		
<p>5. Product type:</p>	<p><input type="checkbox"/> Biologic</p> <p><input checked="" type="checkbox"/> Cosmetic</p> <p><input type="checkbox"/> Health supplement</p> <p><input type="checkbox"/> Pharmaceutical</p>	<p><input type="checkbox"/> Traditional medicine</p> <p><input type="checkbox"/> Others, please specify:</p> <p>-</p> <p>_____</p>
<p>6. Forensic classification in your country:</p>	<p><input type="checkbox"/> General sales list / Over-the-counter</p> <p><input type="checkbox"/> Pharmacy only</p>	<p><input type="checkbox"/> Prescription only</p> <p><input type="checkbox"/> Others, please specify:</p> <p>-</p> <p>_____</p>
<p>Reporting country / authority</p>		
<p>7. Name of country / Issuing authority:</p> <p>Brunei Darussalam, Ministry of Health</p>	<p>8. Report reference no.:</p> <p>(08)/MOH/DPS/PMAS/052018</p>	
<p>9. Department / Designation of person issuing the alert:</p> <p>Department of Pharmaceutical Services</p>	<p>10. Date of report:</p> <p>03 May 2018</p>	
<p>Contact person</p>		
<p>11. Name:</p> <p>Ms Norhasidah Abd Rahman</p>	<p>12. Department / Designation:</p> <p>Pharmacy Enforcement Section</p> <p>Department of Pharmaceutical Services</p>	
<p>13. Email address:</p> <p><u>norhasidah.rahman@moh.gov.bn</u></p>	<p>14. Contact no.</p> <p>Telephone no.: +673 2393298 EXT 209</p> <p>Fax no.: +673 2393291</p>	

* To provide photograph of product.

Annex I

Report reference no.: (08)/MOH/DPS/PMAS/052018

Date of report: 03 May 2018

No	Description of product*				Marketing authorisation holder/ Product licence holder/ Company responsible for placing product in the market	Manufacturer	Investigations i.e.	Actions i.e.
	Brand/ Product name/ Alternative name (e.g. local language)	<ul style="list-style-type: none"> Active ingredients/ Generic name/ Full formula (for cosmetics, traditional medicines etc.) Strength (if applicable) 	<ul style="list-style-type: none"> Dosage form/ Pack size (if applicable) Batch/ Lot number Date of Expiry or Manufacture (if applicable) 	<ul style="list-style-type: none"> Intended use as listed on label: 				
1.	Deeja Cosmetic Keyuan Semula Jadi Set 5 dalam 1 – Star Cream	Not Stated	Not Stated	<ul style="list-style-type: none"> White Glaze, glowing as early as 5 days, suitable for facial skin, acne, pigmentation, oily, dull, dark & grated face (Anti-ageing) 	Not Stated	Malaysia	<ul style="list-style-type: none"> Type of quality defect i.e. microbial contamination, heavy toxic metals, dissolution test Type and amount of adulterant Details of ADR Product tested and found to contain Hydroquinone	<ul style="list-style-type: none"> Level of recall e.g. hospital, retail, consumers Type of recall e.g. batch specific Date of withdrawal of recall etc The product is banned from the market