



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



FDA ADVISORY
No. **2019-140**

03 JUN 2019

TO: GENERAL CONSUMING PUBLIC

SUBJECT: Dissemination of ASEAN Post-Marketing Alert System (PMAS) Report on Adulterated Cosmetic Products With Reference No. (12)/MOH/DPS/PMAS/05/2019

The Food and Drug Administration (FDA) hereby issues this public health warning to inform the public on the report from ASEAN Post-Marketing Alert System (PMAS) on the following Cosmetic Products which were found to contain **MERCURY**:

	BRAND / PRODUCT NAME
1.	Glow Skin White French Technology Smart Pack – Whitening Cleanser
2.	Glow Skin White French Technology Smart Pack – Whitening Cream
3.	Glow Skin White French Technology Smart Pack – SPF 50 Cream

**Attached is a copy of the Brunei PMAS Report with Reference No. (12)/MOH/DPS/PMAS/05/2019*

The aforementioned products have 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 analyses show that these products are not compliant with the technical standards set forth by the ASEAN Cosmetic Directive (ACD).

The aforementioned products have been verified to contain Mercury, 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.

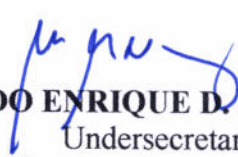
Because of the hazards posed by the aforementioned products, the public is strongly advised to be vigilant and report to FDA, through any of the following channels, any encounter with these products:

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 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.


ROLANDO ENRIQUE D. DOMINGO, MD, DPBO
Undersecretary of Health
Officer-In-Charge, Director General

DTN 20190522165600





ASEAN POST-MARKETING ALERT SYSTEM

Instructions:

1. Complete the form by entering all the details required.
2. Please tick ☒ where applicable.
3. Indicate **NA** whenever the field is not applicable.
4. Please provide photograph of the product and press statement if any.

SECTION 1 - ALERT INFORMATION

1.1	Level of confidentiality: <input type="checkbox"/> Internal / Restricted circulation <input checked="" type="checkbox"/> On public domain, specify website: http://www.moh.gov.bn <i>Note: Appreciate that Member State can share the alert via ASEAN PMAS as soon as the information is made available on public domain e.g. online press release, media report.</i>
1.2	Issue: <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <input checked="" type="checkbox"/> Adulteration <input type="checkbox"/> Falsified* <input type="checkbox"/> Quality defect <i>Note: * Falsified products that deliberately/ fraudulently misrepresent their identity, composition or source. (Ref: WHO)</i> </div> <div style="width: 45%;"> <input type="checkbox"/> Safety aspect <input type="checkbox"/> Unregistered / unlicensed <input type="checkbox"/> Others, please specify: _____ </div> </div>
1.3	Action: <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <input type="checkbox"/> Cancellation of registration <input type="checkbox"/> Suspension of registration <input checked="" type="checkbox"/> Withdrawal of product <input type="checkbox"/> Recall of product </div> <div style="width: 45%;"> <input type="checkbox"/> Labelling change <input type="checkbox"/> Issuance of press release <input type="checkbox"/> Others, please specify: _____ </div> </div>
1.4	Source of alert / Type of signal: <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <input type="checkbox"/> Local ADR reports <input type="checkbox"/> Scientific literature / local studies <input checked="" type="checkbox"/> Post-marketing testing activities </div> <div style="width: 45%;"> <input type="checkbox"/> Decision made by other regulatory authorities <input type="checkbox"/> Decision made by industry <input type="checkbox"/> Others, please specify: _____ </div> </div>

SECTION 2 - PRODUCT INFORMATION

(Whenever possible, please also provide the image of the product and press statement (if any) in Annex I)

2.1	Product type: <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <input type="checkbox"/> Biologic <input checked="" type="checkbox"/> Cosmetic <input type="checkbox"/> Health Supplement </div> <div style="width: 45%;"> <input type="checkbox"/> Pharmaceutical <input type="checkbox"/> Traditional medicine <input type="checkbox"/> Others, please specify: _____ </div> </div>
2.2	Forensic classification of pharmaceutical/ biologic / traditional medicine in your country: <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <input type="checkbox"/> General Sales List / Over-the-counter <input type="checkbox"/> Pharmacy Only </div> <div style="width: 45%;"> <input type="checkbox"/> Prescription Only Medicine <input checked="" type="checkbox"/> Others, please specify: <u>Cosmetic</u> </div> </div>

SECTION 3 - REPORTING COUNTRY / AUTHORITY

3.1 Name of country / issuing authority: Brunei Darussalam, Ministry of Health	3.2 Department / Designation of person issuing the alert: Department of Pharmaceutical Services
3.3 Report reference no.: (12)/MOH/DPS/PMAS/05/2019	3.4 Date of report: 22 May 2019

SECTION 4 - CONTACT PERSON

4.1 Name: Mr Wee Shyue Liang	4.2 Department / Designation: Compliance and Licensing Section Department of Pharmaceutical Services
4.3 Email address: shyueliang.wee@moh.gov.bn	4.4 Contact number: Telephone no. : +6732393298 ext 209 Fax no. : +6732393291

Annex I			
Report reference no.	(12)/MOH/DPS/PMAS/05/2019	Date of report	22 May 2019

No	Description of product*					Marketing Authorisation Holder / Product Licence Holder / Company responsible for placing the product in the market (please indicate the status of the company e.g. Manufacturer, MAH, PL Holder, Product Registrant/ Importer, Exporter, Wholesaler, Retailer)	Manufacturer • Name • Address (including Country)	Investigations / findings e.g. • Type of quality defect i.e. microbial contamination, heavy toxic metals, dissolution test • Type and amount of adulterant • Details of ADR	Actions –e.g • Level of recall e.g. hospital, retail, consumers • Type of recall e.g. batch specific • Date of withdrawal or recall
	Brand / Product name / Alternative name (e.g. local language) <i>Please include local registration no. (if applicable)</i>	• Active ingredients / Generic name / Full formula: • 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	Countries which the product is exported to				
1	Glow Skin White French Technology Smart Pack – Whitening Cleanser	Not Stated	<ul style="list-style-type: none"> Pack size: 50ml Batch number: Not Stated Expiry date : Not stated 	<ul style="list-style-type: none"> Removes dirt, excess oil and other skin impurities while whitening your skin's dark and age spots 	Not Stated	Not Stated	Not stated	Product tested and found to contain Mercury	The product is banned from the market
2	Glow Skin White French Technology Smart Pack – Whitening Cream	Not Stated	<ul style="list-style-type: none"> Pack size: Not stated Batch number: Not Stated Expiry date : Not stated 	<ul style="list-style-type: none"> Brightens dark patches and spots, and promotes cell renewal 	Not Stated	Not Stated	Not stated	Product tested and found to contain Mercury	The product is banned from the market
3	Glow Skin White French Technology Smart Pack – SPF 50 Cream	Not Stated	<ul style="list-style-type: none"> Pack size: Not stated Batch number: Not Stated Expiry date : Not stated 	<ul style="list-style-type: none"> All in one day cream that gives you protection from strong UV rays, pollution and dirt 	Not Stated	Not Stated	Not stated	Product tested and found to contain Mercury	The product is banned from the market

IMAGE OF THE PRODUCT(S) AND PRESS STATEMENT (IF ANY):

Please attach the pictures of products clearly from different sides of packaging that contain information of the product, including primary packaging, secondary packaging, labels, or brochure (if any)



Glow Skin White French Technology
Smart Pack – Whitening Cleanser



Glow Skin White French Technology Smart
Pack – Whitening Cream



Glow Skin White French Technology Smart Pack – Whitening Cream