Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

03 JUN 2019

FDA ADVISORY
No. 2019-139

TO: **GENERAL CONSUMING PUBLIC**

SUBJECT: **Dissemination of ASEAN Post-Marketing Alert System (PMAS) Report on Adulterated Cosmetic Product With Reference No. HSA074310052019**

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 Cosmetic Product **ELIXIR OF LUMOS MASK** which was found to contain **ARSENIC.**

The aforementioned product has been tested by the Health Sciences Authority, Singapore 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 was found to contain Arsenic, a substance that is not allowed to be part of a cosmetic product based on the ACD. According to the World Health Organization (WHO), acute arsenic poisoning includes vomiting, abdominal pain and diarrhea, followed by numbness and tingling of the extremities, muscle cramping and death, in extreme cases. The International Agency for Research on Cancer (IARC) has classified arsenic and arsenic compounds as carcinogenic to humans. Skin lesions and skin cancer are the most characteristic long-term effects of arsenic.

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.

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

DTN 20190522164407

FORM A

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:

☐ Internal / Restricted circulation

☑ On public domain, specify website: www.hsa.gov.sg

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.

1.2 Issue:

☐ Adulteration
☐ Falsified*
☐ Quality defect
***Note:** * Falsified products that deliberately/ fraudulently misrepresent their identity, composition or source. (Ref: WHO)*

☐ Safety aspect
☐ Unregistered / unlicensed
☑ Others, please specify: Arsenic detected

1.3 Action:

☐ Cancellation of registration
☐ Suspension of registration
☐ Withdrawal of product
☑ Recall of product

☐ Labelling change
☐ Issuance of press release
☐ Others, please specify: _____

1.4 Source of alert / Type of signal:

☐ Local ADR reports
☐ Scientific literature / local studies
☑ Post-marketing testing activities

☐ Decision made by other regulatory authorities
☐ Decision made by industry
☐ Others, please specify: _____

SECTION 2 - PRODUCT INFORMATION

(Whenever possible, please also provide the image of the product and press statement (if any) in Section 7)

2.1 Product type:

☐ Biologic
☑ Cosmetic
☐ Health Supplement

☐ Pharmaceutical
☐ Traditional medicine
☐ Others, please specify: _____

2.2 Forensic classification of pharmaceutical/ biologic / traditional medicine in your country:

☐ General Sales List / Over-the-counter
☐ Pharmacy Only

☐ Prescription Only Medicine
☑ Others, please specify: Not applicable

2.3	**Brand / Product name (or drug class):**	2.4	**Alternative name (*e.g. local language*):**
	Elixir of Lumos Mask		

2.5 Local Registration no. *(if applicable)*:
CCPN1850795

2.6 Active ingredient / Generic name / Full formula:

Not Stated

2.7	**Dosage form** *(if applicable)*:	2.8	**Strength** *(if applicable)* :
	Cream		

2.9	**Pack size / Presentation:** 100g/jar	2.10	**Batch / Lot number:** 180/125
2.11	**Expiry date** *(if applicable)* **:** 12/2021	2.12	**Date manufactured** *(if applicable)* **:**
2.13	**Intended use as listed on label:** Labelled that red Clay detoxes the skin while argan oil, and rose extracts clarifies and moisturizes the skin to improve skin elasticity		
2.14	**Countries which the product is exported to:**		

SECTION 3 - COMPANY INFORMATION

3.1	**Name & address of Marketing Authorisation Holder / Product Licence Holder / company responsible for placing the product in the market:** VIYAAN
3.2	**Status of the company:** ☐ Manufacturer ☐ MAH/PL Holder/ Product registrant ☐ Exporter ☑ Importer ☐ Wholesaler ☐ Retailer ☐ Others:_____
3.3	**Name & address (including country) of manufacturer:** Morocco

SECTION 4 - DETAILS / ACTION(S) TAKEN

4.1	**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* Arsenic detected
4.2	**Actions / proposed actions to be taken: e.g.** • *Level of recall (e.g. hospital, retail, consumers)* • *Type of recall (e.g. batch specific, temporary suspension, permanent)* • *Date of withdrawal or recall* Batch specific Class 2 Retail level recall

SECTION 5 - REPORTING COUNTRY / AUTHORITY

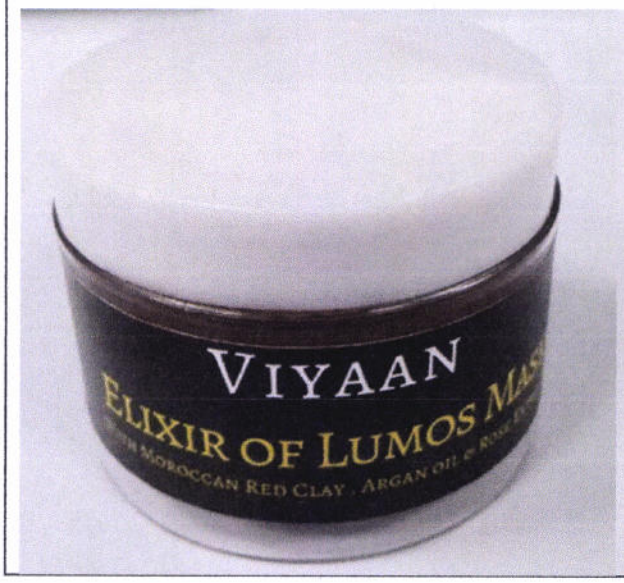
5.1	**Name of country / issuing authority:** Singapore	5.2	**Department / Designation of person issuing the alert:** Vigilance and Compliance Branch
5.3	**Report reference no.:** HSA074310052019	5.4	**Date of report:** 10 May 2019

SECTION 6 - CONTACT PERSON

6.1	**Name:** Choong Chih Tzer	6.2	**Department / Designation:** Vigilance and Compliance Branch
6.3	**Email address:** Choong_chih_tzer@hsa.gov.sg	6.4	**Contact number:** **Telephone no. : 68663548** **Fax no. : 64789069**

SECTION 7 - 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)


VIYAAN
ELIXIR OF LUMOS MAS
MOROCCAN RED CLAY . ARGAN OIL


Red Clay detoxes the skin
while argan oil and rose
extracts clarifies and
moisturises the skin to
improve skin elasticity
How to use:
Apply mask to skin as desired
and leave it for 10-15 minutes
When the mask is completely
dry, wipe off with wet towel
and enjoy smooth skin!