Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

03 JUN 2019

FDA ADVISORY
No. 2019-141

TO: **GENERAL CONSUMING PUBLIC**

SUBJECT: **Dissemination of ASEAN Post-Marketing Alert System (PMAS) Report on Adulterated Cosmetic Products With Reference No. 8-9/2019/K**

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 are found to contain **DIPHENHYDRAMINE**:

	BRAND / PRODUCT NAME
1.	Bao Fu Ling Snow Lotus Cream 15g
2.	Bao Fu Ling Skincare Cream

**Attached is a copy of the Malaysia PMAS Report with Reference No. 8-9/2019/K*

The aforementioned products have been tested by the National Pharmaceutical Regulatory Agency, Ministry of Health, Malaysia 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 were found to contain Diphenhydramine, an antihistamine that is not allowed to be part of a cosmetic product based on the ACD. Adverse effects associated with topical application of Diphenhydramine include mild stinging, allergic reactions such as rash, hives, itching, swelling of the mouth, face, lips, tongue, or throat, and skin irritation. Side effects common to all antihistamines include nausea, dizziness, anxiety, dry mouth, blurred vision, difficulty urinating, and constipation.

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 20190522151722

FORM B

Use this form for multiple product alerts of same product type with similar issues

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.npra.gov.my

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: _____

1.3 Action:

☐ Cancellation of registration

☐ Suspension of registration

☐ Withdrawal of product

☐ Recall of product

☐ Labelling change

☐ Issuance of press release

☑ Others, please specify: Cancellation of notification

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 Annex I)

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: _____

SECTION 3 - REPORTING COUNTRY / AUTHORITY

3.1	**Name of country / issuing authority:** Malaysia/National Pharmaceutical Regulatory Agency	3.2	**Department / Designation of person issuing the alert:** National Pharmaceutical Regulatory Agency, Ministry of Health Malaysia
3.3	**Report reference no.:** 8-9/2019/K	3.4	**Date of report:** 02.04.2019

SECTION 4 - CONTACT PERSON

4.1	**Name:** MS WAN MOHAINA WAN MOHAMMAD	4.2	**Department / Designation:** Deputy Director Centre of Post Registration of Product and Cosmetic Control, National Pharmaceutical Regulatory Agency, Ministry of Health Malaysia

4.3	**Email address:** wanmohaina@npra.gov.my	4.4	**Contact number:** **Telephone no. : +6-03-78835488** **Fax no. : +6-03-79567151**

Annex I

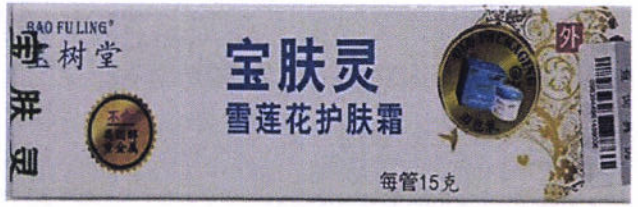
Report reference no.	8-9/K/2019	**Date of report**	02.04.2019

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) *Please include local registration no. (if applicable)*	• **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.	Bao Fu Ling Snow Lotus Cream 15g	NA	NA	NA	NA	Bao Fu Ling Global Enterprise Sdn. Bhd.	Beijing Bao Shu Tang Sci-Tech Pharmaceutical Co., Ltd. Changping Shahe Xiaozhai ,Beijing, P.R.O. CHINA	Product tested and found to contain Diphenhydramine.	• Notification of these products has been cancelled. • Company has to destroy the recalled products.
2.	Bao Fu Ling Skincare Cream	NA	NA	NA	NA	AMG Wellness Sdn. Bhd.	Yantai Baofuling Biotechnology Co., Ltd. No. 7, Beijing Road, Economic Development Zone, Pengtai City, Shandong Province, P.R. China	Product tested and found to contain Diphenhydramine.	

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)

1) Nama Produk/ Product Name: Bao Fu Ling Snow Lotus Cream 15g (NOT180202851K)



2) Nama Produk/ Product Name: Bao Fu Ling Skincare Cream (NOT180103663K)