



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



FDA ADVISORY
No. **2018-147**

17 APR 2018

TO: GENERAL CONSUMING PUBLIC

SUBJECT: Dissemination of ASEAN Post-Marketing Alert System (PMAS) Report on Adulterated Cosmetic Products With the Reference No. ASEAN Alert 1/2018/Myanmar

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	ASDANNE Whitening Freckle Day Cream	The products are found to contain excessive levels of mercury (Hg).
2	ASDANNE Whitening Freckle Night Cream	
3	ASDANNE Whitening Freckle Day Cream + Night Cream	
4	ASDANNE Whitening Refreshing Isolation Cream	
5	FULENZE Whitening Freckle Day Cream	
6	FULENZE Whitening Freckle Night Cream	
7	FULENZE Refreshing Whitening Freckle Day Cream / Night Cream	
8	ROBISIS Fade-out Cream Day Cream	
9	ROBISIS Whitening Cream Night Cream	
10	ROBISIS Anti-Acne Whitening Day & Night Cream	

**Attached is a copy of the PMAS Report from Myanmar with Reference No. ASEAN Alert 1/2018/Myanmar*

The aforementioned products have been tested by the Department of Food and Drug Administration, Ministry of Health & Sports of Myanmar as part of its post-marketing surveillance activities and the results of the laboratory analyses show that the products are not compliant with the technical standards set forth by the ASEAN Cosmetic Directive (ACD).

The products have been verified to contain mercury beyond the maximum allowed limit of one (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 the hands and feet, gingivitis or inflammation of the gums, pink discolouration of the hands and feet especially in



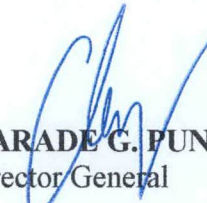
children, irritability, and photophobia or sensitivity to light. Nursing mothers are doubly vulnerable because mercury is passed on to nursing babies through breast milk which can affect the baby's development.

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

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. FUNO, RPh
Director General

DTN 20180414075903



ASEAN POST-MARKETING ALERT SYSTEM (Form B) <i>(Use this form for multiple product alerts of same product type with similar issues)</i>		
Tick ✓ 1. Level of confidentiality: <input type="checkbox"/> Internal / Restricted circulation <input checked="" type="checkbox"/> On public domain, specify website: fdamyanmar.gov.mm _____	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 checked="" type="checkbox"/> Recall of product <input type="checkbox"/> Suspension of registration <input type="checkbox"/> Withdrawal of product <input checked="" type="checkbox"/> Others, please specify: Cancellation of Notification _____
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"/> 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 checked="" 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: Myanmar/Department of Food and Drug Administration	8. Report reference no.: ASEAN Alert 1/2018/Myanmar	
9. Department / Designation of person issuing the alert: Dr. Win Win Shwe Deputy Director (Cosmetics) Department of Food and Drug Administration Ministry of Health & Sports	10. Date of report: 5 April 2018	
Contact person		
11. Name: Dr. Win Win Shwe	12. Department / Designation: Deputy Director (Cosmetics) Department of Food and Drug Administration Ministry of Health & Sports Myanmar	
13. Email address: winwinshwemph@gmail.com	14. Contact no. Telephone no.: +95-673-403242 Fax no.: +95-673-403489	

Annex I

Report reference no.:

ASEAN Alert 1/2018/Myanmar

Date of report:

5 April 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) 	Intended use as listed on label:				
1	ASDANNE Whitening Freckle Day Cream		15g	Day Cream	Hmu Wady Company Limited	Korea Haiya Biotechnology Co., Ltd., Korea	Products tested and found to contain high level of mercury (3828.51 ppm)	<ul style="list-style-type: none"> Level of recall e.g. hospital, retail, consumers Type of recall e.g. batch specific Date of withdrawal or recall etc. <p>Notification of these products has been cancelled.</p> <p>Company has to destroy the recalled products.</p>
2	ASDANNE Whitening Freckle Night Cream		15g	Night Cream			Products tested and found to contain high level of mercury (3828.51 ppm)	
3	ASDANNE Whitening Freckle Day Cream + Night Cream		5gx2				Products tested and found to contain high level of mercury	
4	ASDANNE Whitening Refreshing Isolation Cream		15g	Isolation Cream			Products tested and found to contain high level of mercury (806.87 ppm)	
5	FULENZE Whitening Freckle Day Cream		20g	Day Cream	My Image General Trading Company Limited	Korea Fulenze Co., Ltd., Korea	Products tested and found to contain high level of mercury (6229.11 ppm)	
6	FULENZE Whitening Freckle Night Cream		20g	Night Cream			Products tested and found to contain high level of mercury (5147.13 ppm)	
7	FULENZE Refreshing Whitening Freckle Day Cream / Night Cream		5gx2	Day /Night Cream			Products tested and found to contain high level of mercury	

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	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) 	Intended use as listed on label:				
8	ROBISIS Fade-out Cream Day Cream		8ml	Day Cream	Myanmar Sea Dragon Trading Co., Ltd.	Yon Sing Trading (M) Sdn. Bhd./ Sky Resources Sdn. Bhd., Malaysia	Products tested and found to contain high level of mercury 3171.03 ppm	Notification of these products has been cancelled. Company has to destroy the recalled products.
9	ROBISIS Whitening Cream Night Cream		8ml	Night Cream			Products tested and found to contain high level of mercury 6274.37 ppm	
10	ROBISIS Anti-Acne Whitening Day & Night Cream		15g	Day & Night Cream	Myanmar Sea Dragon Trading Co., Ltd.	Yon Sing Trading (M) Sdn. Bhd., Malaysia/ Cosmaprof Co., Ltd., Thailand	Products tested and found to contain high level of mercury 485.90ppm	

* To provide photograph of product.

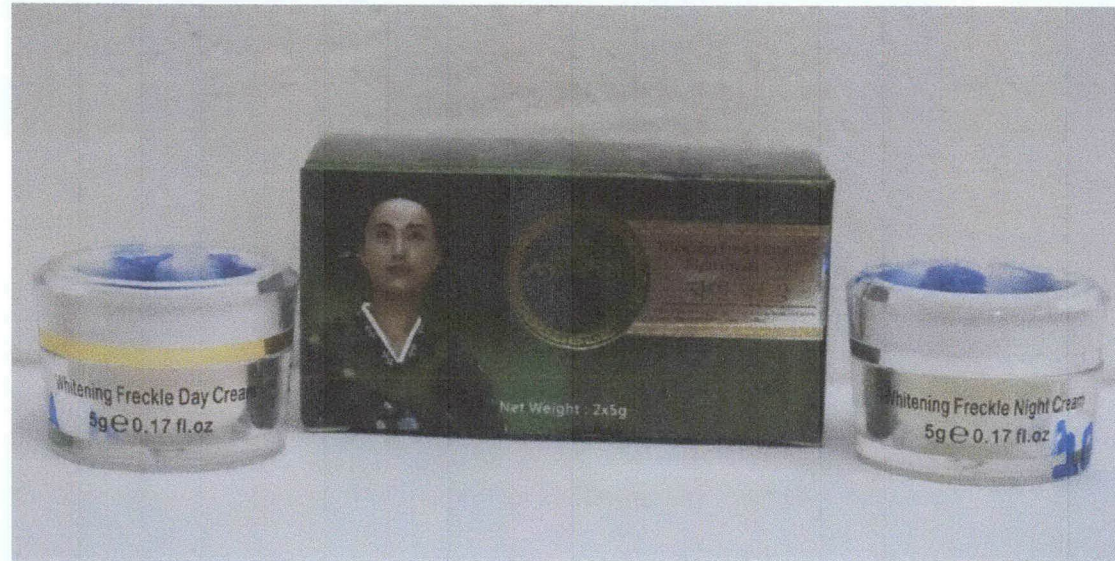
ASDANNE Whitening Freckle Day Cream



ASDANNE Whitening Freckle Night Cream



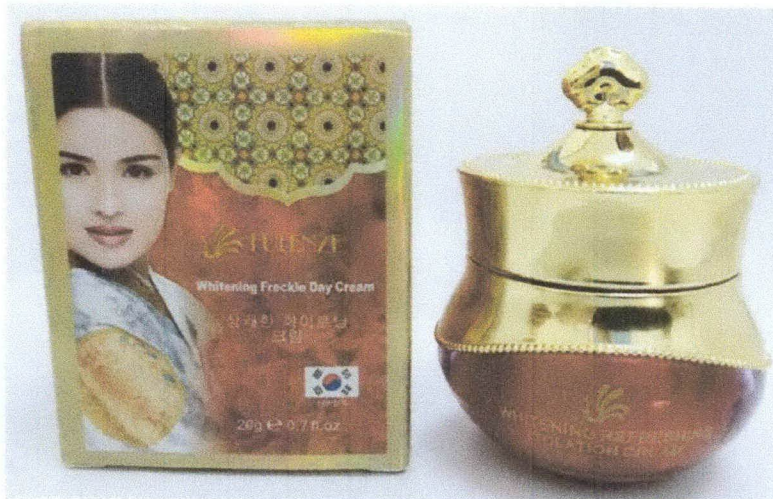
ASDANNE Whitening Freckle Day Cream + Night Cream



ASDANNE Whitening Refreshing Isolation Cream



FULENZE Whitening Freckle Day Cream



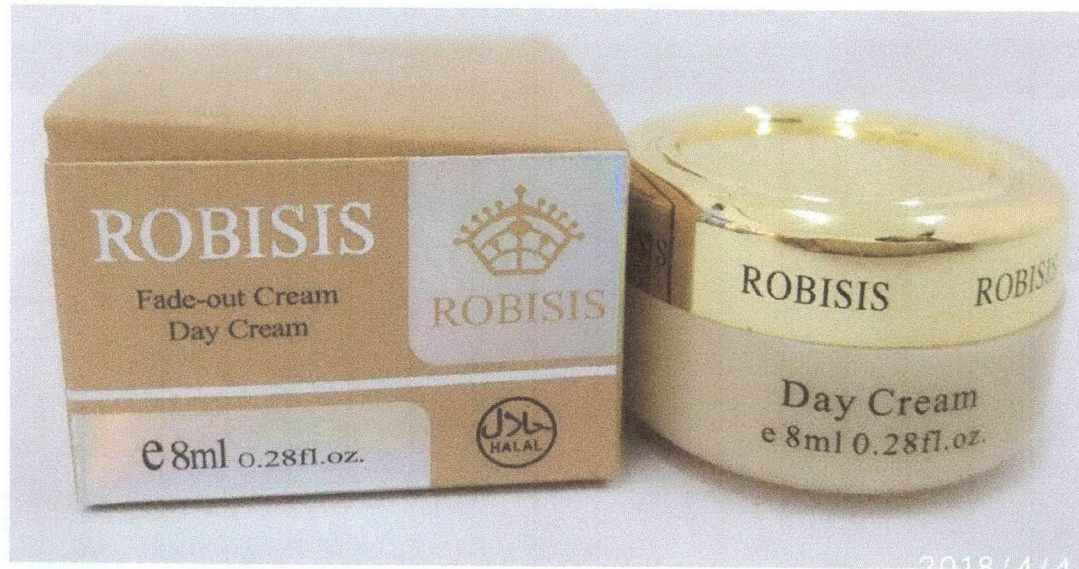
FULENZE Whitening Freckle Night Cream



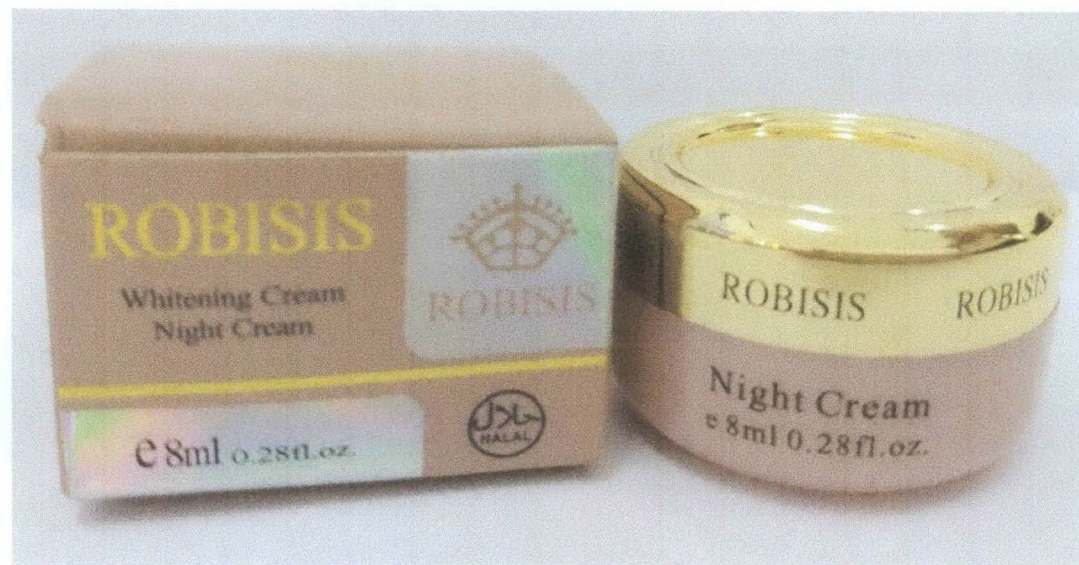
FULENZE Refreshing Whitening Freckle Day Cream + Night Cream



ROBISIS Fade-out Cream Day Cream



ROBISIS Whitening Cream Night Cream



ROBISIS Anti-Acne Whitening Day & Night Cream

