



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



FDA ADVISORY
No. **2019-143**

103 JUN 2019

TO: GENERAL CONSUMING PUBLIC

SUBJECT: Dissemination of ASEAN Post-Marketing Alert System (PMAS) Report on Adulterated Cosmetic Products With Reference No. 1007/702 (07 March 2019), 1004.03/983 (19 March 2019)

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 below cosmetic products:

	BRAND / PRODUCT NAME	FINDINGS
1.	B Plus Miracle Gold Cream	Found Ammoniated mercury
2.	Madame Organic Whitening Arbutin	Found Ammoniated mercury
3.	Herbal Turmeric Herbal Cream	Found Ammoniated mercury
4.	Melusma Melasma Brightening Cream	Found Ammoniated mercury and Hydroquinone
5.	Beuty 3 Night Cream	Found Ammoniated mercury and Betamethasone 17-valerate
6.	BeQuala Beauty Quality Lab	Found Ammoniated mercury, Betamethasone 17-valerate, Clobetasol propionate
7.	Ozzy Mask	Found Ammoniated mercury and Clobetasol propionate
8.	Polla Gold Super White Perfects	Found Ammoniated mercury and Betamethasone 17-valerate
9.	O-Ping Wink Winner Ping Whitening Cream	Found Ammoniated mercury, Betamethasone 17-valerate, Clobetasol propionate
10.	Myrina Night Cream	Found Ammoniated mercury, Betamethasone 17-valerate, Clobetasol propionate

* Attached is copy of the Thailand PMAS Report with Reference No. 1007/02 (07 March 2019), 1004.03/983 (19 March 2019)



The aforementioned products were subjected to post-marketing surveillance by the Cosmetic Control Group, Food and Drug Administration, Thailand, and results of the laboratory analyses show that the products are not compliant with the technical standards set forth by the ASEAN Cosmetic Directive (ACD) as these contain ingredients that are not allowed to be part of a cosmetic product.

Mercury is a naturally occurring heavy metal which is known to be severely hazardous to health even in small amount. According to the World Health Organization (WHO), the main adverse effect of exposure to inorganic mercury (e.g. ammoniated mercury) is kidney damage. Mercury may also cause skin rashes, skin discoloration and scarring, as well as a reduction in the skin's resistance to bacterial and fungal infections. Exposed pregnant women and nursing mothers transfer the mercury to their fetuses, which can later result in neurodevelopmental deficits in the children.


Hydroquinone, betamethasone 17-valerate and clobetasol propionate are not allowed to be part of cosmetic products as these are classified as drug products in the Philippines because of their multiple serious adverse effects when used indiscriminately. Such adverse effects linked with hydroquinone use are sensitivity to light, skin redness and permanent skin discoloration. Prolonged use of topical corticosteroids such as betamethasone 17-valerate and clobetasol propionate may cause skin atrophy, contact dermatitis, hyperpigmentation, photosensitization, hypertrichosis (hirsutism), and aggravation of cutaneous infection, among others.

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 20190530112458





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.fda.moph.go.th/sites/Cosmetic/SitePages/Analysis.aspx <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 </div> <div style="width: 45%;"> <input type="checkbox"/> Safety aspect <input type="checkbox"/> Unregistered / unlicensed <input type="checkbox"/> Others, please specify: _____ </div> </div> <i>Note: * Falsified products that deliberately/ fraudulently misrepresent their identity, composition or source. (Ref: WHO)</i>
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 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 checked="" type="checkbox"/> Others: processing the evidence for prosecution </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 checked="" 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 type="checkbox"/> Others, please specify: _____ </div> </div>

SECTION 3 - REPORTING COUNTRY / AUTHORITY

3.1	Name of country / issuing authority: Thailand/ Food and Drug Administration	3.2	Department / Designation of person issuing the alert: Cosmetic Control Group
3.3	Report reference no.: 1007/702 (07 March 2019) 1004.03/983 (19 March 2019)	3.4	Date of report: 21 March 2019

SECTION 4 - CONTACT PERSON

4.1	Name: Mrs.Wimon Suwankaesawong Ms.Pornthip Jiamsuchon	4.2	Department / Designation: Technical and Planning Division, Health Product Vigilance Center
4.3	Email address: adr@fda.moph.go.th	4.4	Contact number: Telephone no. : +66 2 590 7261 Fax no. : +66 2 591 8457

Annex I			
Report reference no.	1007/702 (07 March 2019) 1004.03/983 (19 March 2019)	Date of report	21 March 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	Investigations / findings	Actions –e.g.
	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		• Name • Address (including Country)	e.g. • Type of quality defect i.e. microbial contamination, heavy toxic metals, dissolution test • Type and amount of adulterant • Details of ADR	• Level of recall e.g. hospital, retail, consumers • Type of recall e.g. batch specific • Date of withdrawal or recall
1	B Plus Miracle Gold Cream (Notification number 10-1-5718192)	Deionized Water, Raffinose, Panthenol, Niocinamide, Glyceryl Monostearate, C12-15, Alkyl Benzoate, Steric acid, Cetyl Alcohol	Not Stated	whitening	Not Stated	Not Stated	Beauty For You 128/3 PrachaUtis Road, DonMueng District, Donmueng Area, Bangkok, Thailand	Found Ammoniated mercury	On processing of prosecution
2	Madame Organic Whitening Arbutin Notification number 10-1-5507742	Arbutin, Glutathione, Kojic acid dipalmitate, Limonene	Batch number 001	whitening	Not Stated	Madam Organic 706/1 PoKlang Road, Mueng Area, Nakornrachasima Province, Thailand	Guangzhou Beauty Natural Cosmetic Factory, China	Found Ammoniated mercury	On processing of prosecution
3	Herbal Turmeric Herbal Cream Notification number 10-1-5928106	Not Stated	Not Stated	whitening	Not Stated	Farida 29 Moo 13, Yuan District, Chiangkam Area, Payao Province, Thailand	Not Stated	Found Ammoniated mercury	On processing of prosecution
4	Melusma Melasma Brightening Cream Notification number 10-1-5937869	Radish Extract, Arbutin, AHA, Water, Takum, Vitamin B3	Batch number 09	Anti Melasma	Not Stated	Tidamar Co.Ltd, 109 Kanchanapisek Road, Samaedam District, Bangkuntien Area, Thailand	Not Stated	Found Ammoniated mercury and Hydroquinone	On processing of prosecution
5	Beauty 3 Night Cream Notification number 10-1-5706532	Paraffinum liquidum, Titanium dioxide, Zinc Oxide, Polytolatum, Isopropyl myristate, Kojic dipalmitate, Curcuma longa leaf extract, CI 11920, CI 13015, Propyl paraben	Batch number 180110	Night Cream	Not Stated	JirakulThanun Co. Ltd. 39/1-2 Soi Sawaireang, Mukmontri Road, Naimueng District, Mueng Area, Nakornrachasima Province, Thailand	JirakulThanun Co. Ltd. 39/1-2 Soi Sawaireang, Mukmontri Road, Naimueng District, Mueng Area, Nakornrachasima Province, Thailand	Found Ammoniated mercury and Betamethasone 17-valerate	On processing of prosecution

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	Investigations / findings e.g.	Actions –e.g.
	Brand / Product name / Alternative name (e.g. local language) <i>Please include local registration no. (if applicable)</i>	<ul style="list-style-type: none"> Active ingredients / Generic name / Full formula: 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	Countries which the product is exported to				
6	BeQuala Beauty Quality Lab Notification number 10-1-5944991	Water, Glycerin, Sorbitol, Stearic acid, Lauric acid, Propylene Glycol, Artocarpus Lakoocha Wood Extract, Centella Asiatica Leaf Extract	Not Stated	Whitening	Not Stated	Aiem Prof Skin Care Co. Ltd., 27/278 Samwatawanton district, Klongsamwa Area, Bangkok, Thailand	Aiem Prof Skin Care Co. Ltd., 27/278 Samwatawanton district, Klongsamwa Area, Bangkok, Thailand	Found Ammoniated mercury, Betamethasone 17-valerate, Clobetasol propionate	On processing of prosecution
7	Ozzy Mask	Not Stated	Not Stated	facial mask	Not Stated	Chai Pharmacy, 4/2 Sullaganugul Road, Piman District, Mueang Area, Satool Province, Bangkok	Not Stated	Found Ammoniated mercury and Clobetasol propionate	On processing of prosecution
8	Polla Gold Super White Perfects	Not Stated	Batch Number B0008/60	Whitening	Not Stated	Not Stated	MY 8 Manufacturing Co.Ltd., 314/5 Moo17, Paknam Area, Samutprakan Province, Thailand	Found Ammoniated mercury and Betamethasone 17-valerate	On processing of prosecution
9	O-Ping Wink Winner Ping Whitening Cream Notification number 10-1-5725377	Not Stated	Batch number OPN88088	Whitening	Not Stated	O-PING WINK WINNER, 423/1 Moo 4, Suantang District, Mueng Area, Supanburi Province, Thailand	Not Stated	Found Ammoniated mercury, Betamethasone 17-valerate, Clobetasol propionate	On processing of prosecution
10	Myrina Night Cream Notification number 10-1-6010021734	Tranxenic acid, Kojic dipalmitate, Alpha Arbutin, Retinol, Vitamin C, Vitamin E Acetate, Licorice	Batch number 07P221117L	Night Cream	Not Stated	Mireena, 121 Moo 1, Tacare district, Mueng Area, Patthalung Province, Thailand	Mireena, 121 Moo 1, Tacare district, Mueng Area, Patthalung Province, Thailand	Found Ammoniated mercury, Betamethasone 17-valerate, Clobetasol propionate	On processing of prosecution

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.B Plus Miracle Gold Cream



2.Madame Organic Whitening Arbutin



3.Herbal Turmeric Herbal Cream



4. Melusma Melasma Brightening Cream



5. Beauty 3 Night Cream



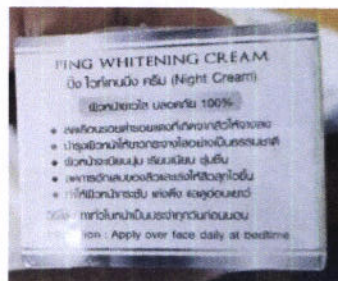
6. BeQuaLa Beauty Quality Lab



7. Ozzy Mask



8. Polla Gold Super White Perfects



9. O-Ping Wink Winner Ping Whitening Cream



10. Myrina Night Cream