



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	<p>Level of confidentiality:</p> <p><input type="checkbox"/> Internal / Restricted circulation</p> <p><input checked="" type="checkbox"/> On public domain, specify website: (www.fda.gov.mm)</p> <p><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></p>
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1.2	<p>Issue:</p> <p><input checked="" type="checkbox"/> Adulteration <input type="checkbox"/> Safety aspect</p> <p><input type="checkbox"/> Falsified* <input type="checkbox"/> Unregistered / unlicensed</p> <p><input type="checkbox"/> Quality defect <input type="checkbox"/> Others, please specify: _____</p> <p>Note: * Falsified products that deliberately/ fraudulently misrepresent their identity, composition or source. (Ref: WHO)</p>
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1.3	<p>Action:</p> <p><input type="checkbox"/> Cancellation of registration <input type="checkbox"/> Labelling change</p> <p><input type="checkbox"/> Suspension of registration <input type="checkbox"/> Issuance of press release</p> <p><input type="checkbox"/> Withdrawal of product <input checked="" type="checkbox"/> Others, please specify: <u>Public Announcement and banned</u></p> <p><input type="checkbox"/> Recall of product products in the market</p>
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1.4	<p>Source of alert / Type of signal:</p> <p><input type="checkbox"/> Local ADR reports <input type="checkbox"/> Decision made by other regulatory authorities</p> <p><input type="checkbox"/> Scientific literature / local studies <input type="checkbox"/> Decision made by industry</p> <p><input checked="" type="checkbox"/> Post-marketing testing activities <input type="checkbox"/> Others, please specify:</p>
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SECTION 2 - PRODUCT INFORMATION

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

2.1	<p>Product type:</p> <p><input type="checkbox"/> Biologic <input type="checkbox"/> Pharmaceutical</p> <p><input checked="" type="checkbox"/> Cosmetic <input type="checkbox"/> Traditional medicine</p> <p><input type="checkbox"/> Health Supplement <input type="checkbox"/> Others, please specify:</p>
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2.2	<p>Forensic classification of pharmaceutical/ biologic / traditional medicine in your country:</p> <p><input checked="" type="checkbox"/> General Sales List / Over-the-counter <input type="checkbox"/> Prescription Only Medicine</p> <p><input type="checkbox"/> Pharmacy Only <input type="checkbox"/> Others, please specify: _____</p>
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SECTION 3 - REPORTING COUNTRY / AUTHORITY

3.1	<p>Name of country / issuing authority:</p> <p>Myanmar / Department of Food and Drug Administration</p>	3.2	<p>Department / Designation of person issuing the alert:</p> <p>Department of Food and Drug Administration, Ministry of Health</p>
3.3	<p>Report reference no.:</p> <p>ASEAN Alert 4/2023/Myanmar</p>	3.4	<p>Date of report:</p> <p>10th November 2023</p>

SECTION 4 - CONTACT PERSON			
4.1	Name: Dr. Tin Wah Wah Win	4.2	Department / Designation: Director (Medical Device/Cosmetics) Department of Food and Drug Administration Ministry of Health
4.3	Email address: tinwah29@gmail.com	4.4	Contact number: Telephone no. : 950673403242 Fax no. : 950673403242

Annex I

Report reference no.	ASEAN Alert 4/2023/Myanmar	Date of report	10 th November 2023
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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, PLHolder, 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	HIJA BUEAUTY/ Apple Lipstick	NA	NA	NA	NA	NA	NA	Rhodamine B (+) detected	Public Announcement and banned products in the market
2	PEARL SKIN / Pearl & Ginger Cream	NA	NA	NA	NA	NA	NA	Mercury (+) detected	Public Announcement and banned products in the market
3	ANYLADY / Pretty Girl MAKE UP PALETTE (EYESHADOW/ BLUSHER/ HIGHLIGHTER/ LIPSTICK/ EYEBROW POWDER)	NA	NA	NA	NA	NA	Made in P.R.C	Rhodamine B (+) and Lead(+) detected	Public Announcement and banned products in the market

4	lameila / 16 COLOR EYESHADOW-01	NA	NA	NA	NA	NA	Made in China	Lead(+) detected	Public Announcement and banned products in the market
5	Lidanxiu / LIP STICK	NA	NA	NA	NA	NA	NA	Rhodamine B (+) detected and imitated with notified product	Public Announcement and banned products in the market
6	Anylady/ 12 color Eyeshadow Palette (01)	NA	NA	NA	NA	NA	Made in P.R.C	Rhodamine B (+) and Lead(+) detected	Public Announcement and banned products in the market
7	Collagen Plus Vit E / Day & Night Cream	NA	NA	NA	NA	NA	NA	Mercury (+) detected	Public Announcement and banned products in the market
8.	IMAN OF NOBLE / Liquid shadow fashion Eyeshadow (03)	NA	NA	NA	NA	NA	Made in P.R.C	Rhodamine B (+) detected	Public Announcement and banned products in the market
9.	MILA COLOR / PRIMER EYEBROW kit - 01	NA	NA	NA	NA	NA	NA	Lead(+) detected	Public Announcement and banned products in the market
10.	IU Beauty / LIP GLOSS - 02	NA	NA	NA	NA	NA	Made in China	Rhodamine B (+) detected	Public Announcement and banned products in the market
11.	Kiss Beauty / FASHION COLOUR MAKEUP KIT-2	NA	NA	NA	NA	NA	Made in P.R.C	Rhodamine B (+) and Lead(+) detected	Public Announcement and banned products in the market
12.	L`CHEAR / To Love Sweet Make Up Kit-2	NA	NA	NA	NA	NA	NA	Lead(+) detected	Public Announcement and banned products in 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)

1. HIJA BUEAUTY/ Apple Lipstick



2. PEARL SKIN / Pearl & Ginger Cream



3. ANYLADY / Pretty Girl MAKE UP PALETTE

(EYESHADOW/BLUSHER/ HIGHLIGHTER/LIPSTICK/ EYEBROW POWDER)



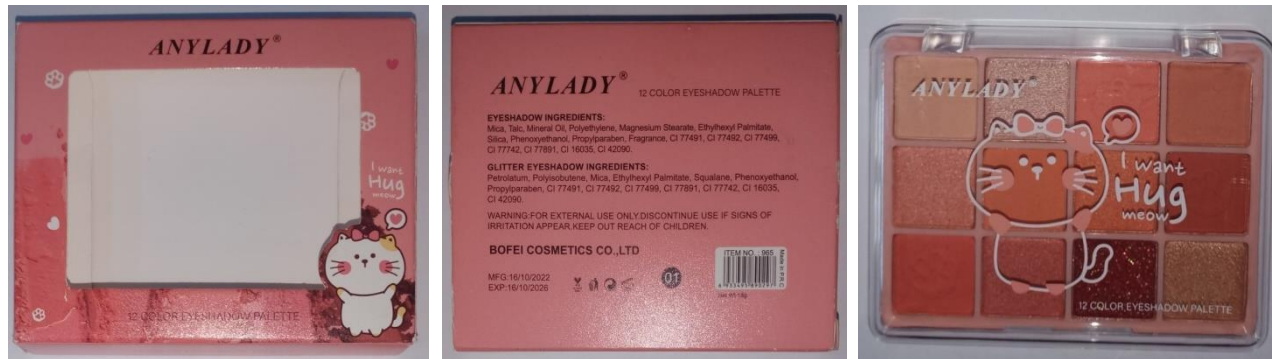
4. lameila / 16 COLOR EYESHADOW-01



5. Lidanxiu / LIP STICK



6. Anylady/ 12 color Eyeshadow Palette(01)



7. Collagen Plus Vit E / Day & Night Cream



10. IU Beauty / LIP GLOSS - 02



11. Kiss Beauty / FASHION COLOUR MAKEUP KIT-2



12. L`CHEAR / To Love Sweet Make Up Kit-2

