



FDA ADVISORY


27 JUL 2020

No. 20201423

TO: GENERAL CONSUMING PUBLIC

SUBJECT: Public Health Warning Against the Purchase and Use of the Non-Compliant Cosmetic Product "LUMI SUN PROTECTION GEL"

The Food and Drug Administration (FDA) warns the general public from purchasing and using the non-compliant cosmetic product, "LUMI SUN PROTECTION GEL" with details specified below:

PRODUCT PARTICULARS	PRODUCT IMAGE/S
<p>Local Company Responsible for Placing the Product in the Market: SKIN MEDICINE INC.</p> <p>Address: G/F LGC Bldg. 1595 Quezon Avenue, Quezon City, Metro Manila 1104</p> <p>Country of Manufacture: Not Indicated</p> <p>Lot/Batch Number: 1806005</p> <p>Manufacturing Date: 07 June 2018</p> <p>Expiration Date: 07 June 2020</p>	
NON-COMPLIANCE/S	
<ol style="list-style-type: none"> The ingredients listed on the label are inconsistent with the information declared in the acknowledged product notification. Failure to declare the country of manufacture on the label. 	

The Food and Drug Administration has verified that the abovementioned product is **NON-COMPLIANT** through its postmarketing surveillance (PMS) pursuant to Book I, Article II, Section 2 of the Rules and Regulations Implementing Republic Act No. 9711, otherwise known as the "Food and Drug Administration Act of 2009" which provides for the relevant functions, powers and duties of the agency, including the conduct of PMS activities in the monitoring of health products.



Based on the Certificate of Product Notification issued to the company, any subsequent changes to the information previously submitted to the FDA will render the notification invalid, thus, a new notification will have to be submitted.

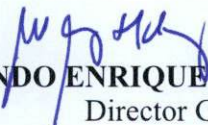
In light of the foregoing, the public is advised not to purchase the aforementioned violative cosmetic product. Moreover, the public is advised to always check if a cosmetic product is notified with the FDA through its website (www.fda.gov.ph). It has a *Search* feature which may be used by typing in the name of the product before deciding on purchasing and/or using the said product.

All concerned establishments are warned not to distribute violative cosmetic product until they have fully complied with the rules and regulation of the FDA.

All FDA Regional Field Offices and Regulatory Enforcement Units, in coordination with law enforcement agencies and Local Government Units, are requested to ensure that violative products are not sold or made available in the market or areas of their jurisdiction.

To report any sale, distribution, complaint and/or adverse event on the use of the violative cosmetic product, the online reporting facility, **eReport** can be accessed at ereport@fda.gov.ph, or call us at the Center for Cosmetics Regulation and Research (CCRR) hotline **(02) 8857-1900 loc. 8113 or 8107**.

Dissemination of this advisory to all concerned is hereby requested.


ROLANDO ENRIQUE D. DOMINGO, MD
Director General

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