



FDA ADVISORY


No. 2020-2045

16 NOV 2020

TO: GENERAL CONSUMING PUBLIC

SUBJECT: Public Health Warning Against the Purchase and Use of the Non-Compliant Cosmetic Product " LUXE ORGANIX MIRACLE SOLUTIONS PIMPLE CORRECTOR "

The Food and Drug Administration (FDA) warns the general public from purchasing and using the non-compliant cosmetic product, " **LUXE ORGANIX MIRACLE SOLUTIONS PIMPLE CORRECTOR** " with details specified below:

PRODUCT DETAILS	PRODUCT IMAGE/S
<p>Local Company Responsible for Placing the Product in the Market: GENSON DISTRIBUTION, INC.</p> <p>Address: #65-67, 16th Avenue, Barangay San Roque, Murphy Cubao, Quezon City, Metro Manila</p> <p>Country of Manufacture: Korea, Republic of</p> <p>Lot/Batch Number: AFV</p> <p>Manufacturing Date: 19/06/2019</p> <p>Expiration Date: 18/16/2022</p>	
<p>NON-COMPLIANCE/S</p>	
<p>1. The ingredients listed on the label are inconsistent with the information declared in the acknowledged product notification.</p> <p>2. The product claim on tea tree (helps calms redness, swelling and inflammation) is not appropriate for a cosmetic product.</p>	



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.

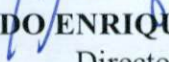
In light of the foregoing, the public is advised not to purchase the aforementioned violative cosmetic product. Moreover, the public is advised to always check if a cosmetic product is notified with the FDA through its website (www2.fda.gov.ph). It has a *Search* feature which may be used by typing in 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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