

Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



FDA ADVISORY No. 2019-050 22 FEB 2019

TO:

GENERAL CONSUMING PUBLIC

SUBJECT:

<u>Public Health Warning Against the Use of Counterfeit</u> <u>Cosmetic Products (Batch 2)</u>

The Food and Drug Administration (FDA) hereby advises the public against the purchase and use of the following counterfeit cosmetic products whose particulars/details are provided below:

PRODUCT NAME	PRODUCT DETAILS	PRODUCT IMAGE/S
FIRMAX3 FIRMING & LIFTING CREAM	Local Company Responsible for Placing the Product in the Market: Not Indicated	FIRMAS REGING A DEFINE CREAN BRANE LINE OF THE CREAN BRANE LINE OF T
	Address: Not Indicated	See Exercise
	Country of Manufacture: Malaysia	Specially for residuated in and Distribution by: 40 70 cold files that ATT STATE AND In 15 July have been as the second of the
	Batch/Lot No: R180901	O de l'antido de la constantina della constantin
O2 MAX 3 REVITALIZING SERUM	Local Company Responsible for Placing the Product in the Market: Revofirm Three Enterprises, Inc.	O Max3 O Max3 O Max3 O Max3 O Max3 O Max4 O Max6 O Max6
	Address: Unit 9G 9 th Floor Strata 100 Bldg., Emerald, Ave., Ortigas Center, San Antonio, Pasig City 1600, Philippines	Amount of the residency of the control of the contr
	Country of Manufacture: Malaysia	Dine Man



Batch/Lot No.: R180603

FDA, in coordination with the Market Authorization Holder (MAH), Revofirm Three Enterprises, Inc., has verified that the aforementioned cosmetic products are **COUNTERFEIT**.

According to the MAH, the company has two (2) memorandum dated 21 October 2018 to immediately stop and suspend the selling of the aforementioned cosmetic products; and memorandum dated 30 October 2018 to voluntarily recall the specific batch of product Firmax3 Firming & Lifting Cream due to non-compliance to the ASEAN Cosmetic Directive on Labeling Requirements.

Counterfeit products, not having gone through the required safety assessment and the verification process of the FDA, pose potential health hazards to the consuming public since their safety and purity cannot be guaranteed. The dangers/hazards may come from ingredients that are not allowed to be part of a cosmetic product or from the contamination of heavy metals such as lead and mercury. The use of substandard and possibly adulterated cosmetic products may result to adverse reactions including but not limited to skin irritation, itchiness, anaphylactic shock and organ failure.

In light of the above, the public is advised to be vigilant against buying and using the aforementioned counterfeit cosmetic products. Moreover, the public is also advised to be vigilant against cosmetic products that might not be duly notified with FDA. Always check if a cosmetic product has been notified with FDA before purchasing it by making use of the embedded *Search* feature of the FDA website accessible at www.fda.gov.ph.

All concerned establishments are warned not to distribute the above-identified violative cosmetic product, otherwise, regulatory actions and sanctions shall be strictly pursued.

All Local Government Units (LGUs) and Law Enforcement Agencies (LEAs) are requested to ensure that the product is not sold or made available in their localities or areas of jurisdiction.

To report any suspicious and/or illegal activity involving the said products, the public may contact FDA through its online reporting facility, **eReport**, at www.fda.gov.ph/ereport, or e-mail us at report@fda.gov.ph, or call the Center for Cosmetics Regulation and Research (CCRR) hotline (02) 857-1900 local 8107/8113.

Dissemination of the information to all concerned is requested

NELA CHARADE G. PUNO, RPh Director General

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