



15 JUN 2021

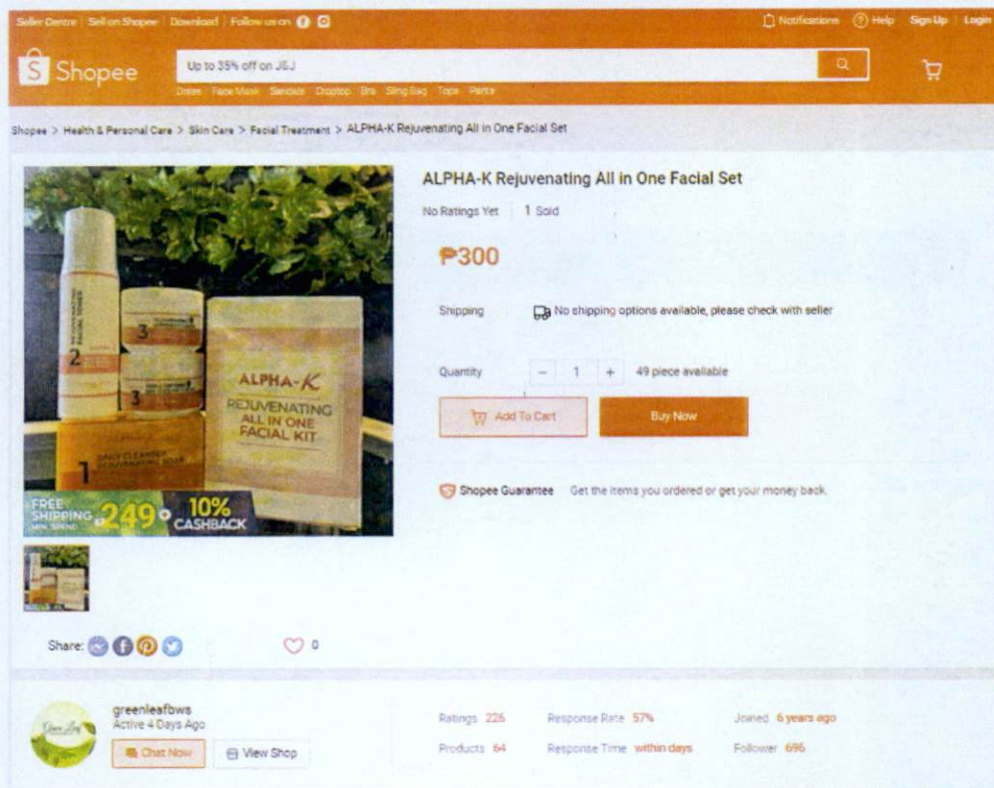
FDA ADVISORY
No. **2021-1354**

TO: GENERAL CONSUMING PUBLIC

SUBJECT: Public Health Warning Against the Purchase and Use of the following Unauthorized Cosmetic Products:

1. ALPHA-K REJUVENATING SET: FACIAL TONER
2. ALPHA-K REJUVENATING SET: OVERNIGHT CREAM
3. ALPHA-K REJUVENATING SET: TRIPLE DEFENSE DAY COOLING CREAM
4. ALPHA-K REJUVENATING SET: DAILY CLEANSER REJUVENATING SOAP

The Food and Drug Administration (FDA) warns the public from purchasing and using the following unauthorized cosmetic products. (Refer to the image below)



(Source: <https://shopee.ph/ALPHA-K-Rejuvenating-All-in-One-Facial-Set-i.387879.1931196318>)

Figure 1. Unauthorized Product ALPHA-K REJUVENATING SET



The abovementioned product was verified by FDA through post marketing surveillance and shows no valid Certificate of Product Notification (CPN) as of 10 June 2021. Pursuant to Book II, Article I, Section 1 (a) of the Rules and Regulations Implementing Republic Act No. 9711, otherwise known as the "Food and Drug Administration Act of 2009", the manufacture, importation, exportation, sale, offering for sale, distribution, transfer, non-consumer use, promotion, advertising, or sponsorship of any health product without the proper authorization from the FDA is prohibited.

Since the abovementioned unauthorized cosmetic product has not gone through the notification process of the FDA, the agency cannot assure their quality and safety. The use of such violative product may pose health risks to consumers.

Potential hazards may come from ingredients that are not allowed to be part of a cosmetic product or from the contamination of heavy metals. 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 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 products, the online reporting facility, **eReport** can be accessed at ereport@fda.gov.ph, or call us at the Center for Cosmetics and Household/Urban Hazardous Substances Regulation and Research (CCHUHSRR) 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

DTN: 20210607085741