



FDA ADVISORY

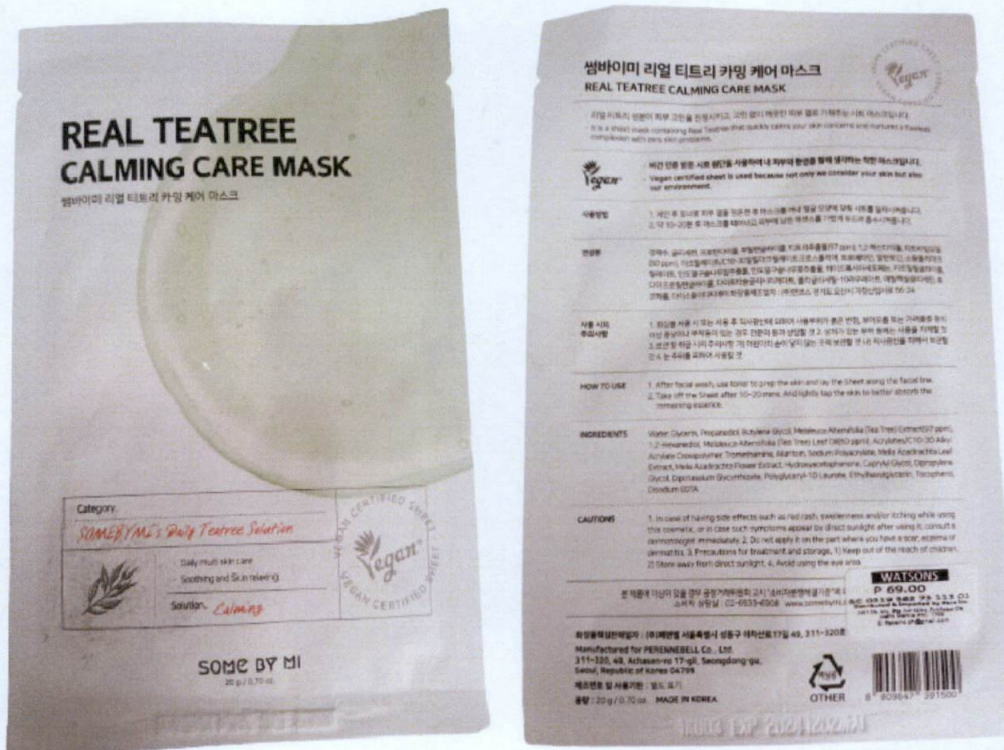
No. 2022-2067

16 DEC 2022

TO: GENERAL CONSUMING PUBLIC

SUBJECT: Public Health Warning Against the Purchase and Use of Unauthorized Cosmetic SOME BY MI REAL TEATREE CALMING CARE MASK

The Food and Drug Administration (FDA) warns the public from purchasing and using the unauthorized cosmetic product, **SOME BY MI REAL TEATREE CALMING CARE MASK**. (Refer to the image below)



The abovementioned product was verified by FDA through postmarketing surveillance and shows no valid Certificate of Product Notification (CPN) as of 07 November 2022. 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. Always check if a product is notified with the FDA by using the FDA Verification Portal feature accessible at <https://verification.fda.gov.ph>, which may be used by typing in the name of the product before the purchase and/or using the cosmetic products.

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.


DR. SAMUEL A. ZACATE
Director General 

DTN: 20221107132908