



FDA ADVISORY

20 MAY 2020

No. 2020-981

TO: GENERAL CONSUMING PUBLIC

SUBJECT: Public Health Warning Against the Purchase and Use of Unnotified
Cosmetic O-ZONE I°D I'M DIFFERENT MATERNAL TOOTHPASTE
(SPEARMINT)

The Food and Drug Administration (FDA) warns the public from purchasing and using the unnotified cosmetic product, **O-ZONE I°D I'M DIFFERENT MATERNAL TOOTHPASTE (SPEARMINT)**. (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 19 May 2020. 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 unnotified 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 product. Moreover, the public is advised to always check if a cosmetic product is notified with the FDA. The FDA website (www.fda.gov.ph) has a *Search* feature which may be used by typing in the name of the product before purchasing.

All concerned establishments are warned not to distribute violative cosmetic product until they have been issued the appropriate authorization, a License to Operate (LTO) for the establishment, and a Certificate of Product Notification (CPN) for the cosmetic product.

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 jurisdiction.

To report any sale or distribution of unnotified cosmetic products, 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.


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