



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



FDA ADVISORY

No. 2021-2872-A

25 MAR 2022

TO: THE GENERAL PUBLIC

SUBJECT: Lifting the Advisory on "OPALESCENCE TOOTH WHITENING SYSTEMS 20% PF MINT" under FDA Advisory No. 2021-2872 "Public Health Warning Against the Purchase and Use of Unauthorized Cosmetic OPALESCENCE TOOTH WHITENING SYSTEMS 20% PF MINT : 1. OPALESCENCE TOOTH WHITENING SYSTEMS 20% PF MINT CARBAMIDE PEROXIDE, 2. ULTRADENT LC BLOCK-OUT RESIN, 3. OPALESCENCE WHITENING TOOTHPASTE FLUORIDE TOOTHPASTE ORIGINAL COOL MINT" dated 11 November 2021

The Food and Drug Administration (FDA) informs the public that OPALESCENCE TOOTH WHITENING SYSTEMS 20% PF MINT has been notified as Medical Device product by the Market Authorization Holder, Dental Domain Corporation with Notification No. CDRRHR-CMDN-2022-901920, in accordance with existing FDA rules and regulations.

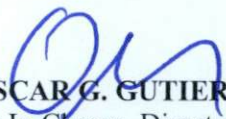
Accordingly, the warning against the purchase and use of the subject product as mentioned in FDA Advisory No. 2021-2872 and its corresponding FDA Order is hereby lifted.

The public is advised to always check if a health product is notified/registered 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 purchasing. For more information or inquiries, please email us at cchuhsrr_prsdd@fda.gov.ph. You may also call the Center for Cosmetics and Household/Urban Hazardous Substances Regulation and Research at telephone number (02) 8857-1900 loc. 8113 or 8117.

To report the sale or distribution of any unnotified/unregistered health products, kindly email FDA via ereport@fda.gov.ph.

Furthermore, the issuance of this advisory shall not in any manner preclude this Office from issuing subsequent orders it may deem necessary and appropriate, should there be findings of any violation of the company to the existing laws, rules, and regulations.

Dissemination of this advisory to all concerned is hereby requested.


DR. OSCAR G. GUTIERREZ JR.
Officer-In-Charge, Director General

DTN : ~~2021/1~~ 09092638

