Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

13 SEP 2022

FDA ADVISORY
No. 20221618

TO: **ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC**

SUBJECT: **Public Health Warning Against the Purchase and Use of the Following Unregistered Medical Device Product**

1. **"PULPDENT® TUFF-TEMP™ PLUS 50ML A2 SHADE**
2. **PULPDENT® TUFF-TEMP™ PLUS 50ML A3 SHADE"**

The Food and Drug Administration (FDA) warns all healthcare professionals and the general public **NOT TO PURCHASE AND USE** the unregistered medical device products:

Figure 1. Unregistered Pulpdent® Tuff-Temp™ Plus 50mL A2 Shade

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Website: www.fda.gov.ph Email: info@fda.gov.ph

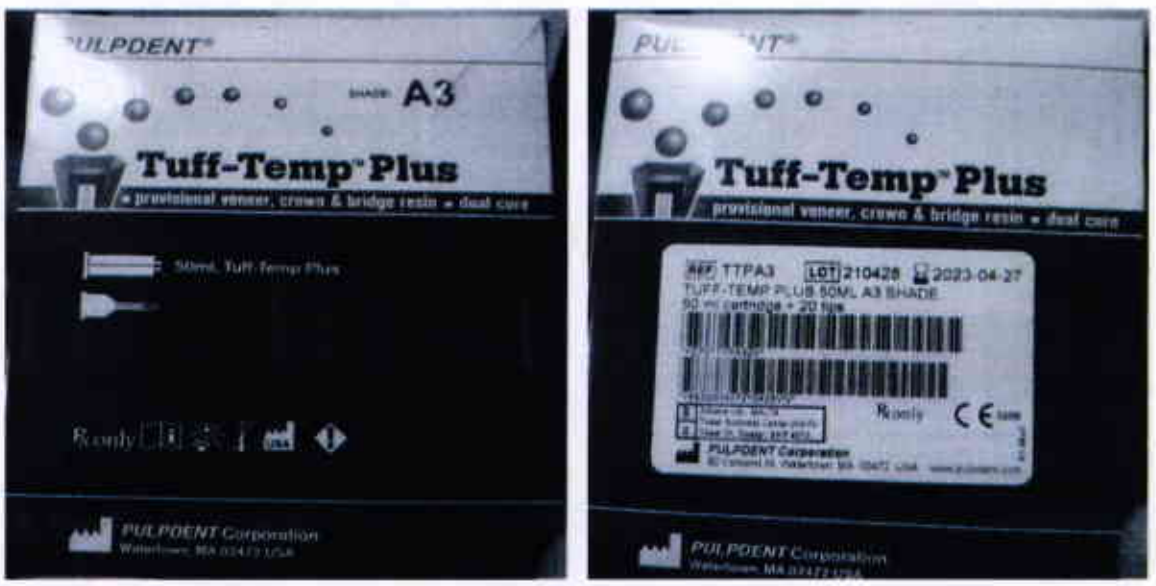

Figure 2. Unregistered Pulpdent® Tuff-Temp™ Plus 50mL A2 Shade

The FDA verified through post-marketing surveillance that the above mentioned medical device products are not registered and no corresponding Product Registration Certificate have been issued. Pursuant to the 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 health products without the proper authorization is prohibited.

Since these unregistered medical device products have not gone through evaluation process of the FDA, the agency cannot assure its quality and safety.

All concerned establishments are warned not to distribute, advertise, or sell the said violative medical device products until the Product Registration Certificate are issued, otherwise, regulatory actions and sanctions shall be strictly pursued. Always check if a product has been registered with the FDA before purchasing it by making use of the embedded Search feature of the FDA website accessible at www.fda.gov.ph. You may also look for the FDA Registration number on the product label in the form of CMDR-xxx, DVR-xxx, or MDR-xxx.

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

The Bureau of Customs is urged to restrain the entry of these unregistered products.

For more information and inquiries about this advisory, kindly contact the FDA CDRRHR through e-mail at **cdrrhr@fda.gov.ph** indicating on the subject the concerned Advisory, or call **(02) 8857-1900 loc. 8301.**

To report any sale or distribution of unregistered medical device, contact the online reporting facility eReport through e-mail at **ereport@fda.gov.ph.**

Dissemination of this advisory to all concerned is hereby requested.

DR. SAMUEL A. ZACATE
Director General

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