



FDA ADVISORY
No. 2021-3485

13 DEC 2021

TO: ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

SUBJECT: Public Health Warning Against the Purchase and Use of the Medical Device Product "TOPCARE ENDOTRACHEAL TUBE CUFFED" with Expired Certificate of Product Registration

The Food and Drug Administration (FDA) warns all healthcare professionals and the general public **NOT TO PURCHASE AND USE** the medical device product with expired Certificate of Product Registration:



Figure 1. TOPCARE Endotracheal Tube Cuffed with Expired Certificate of Product Registration

The FDA verified through post-marketing surveillance that the above-mentioned medical device product has an expired Certificate of Product Registration (CPR). 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.

All concerned establishments are warned not to distribute, advertise, or sell the said violative medical device product until the Product Registration Certificate is renewed, 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 either 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 the abovementioned product.

For more information and inquiries about this advisory, kindly contact the FDA CDRRHR through e-mail at cdrhr@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 the online reporting facility eReport through e-mail at ereport@fda.gov.ph.

Dissemination of this advisory to all concerned is hereby requested.


ROLANDO ENRIQUE D. DOMINGO, MD
Director General

DTN 20210915155042