Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

07 JUL 2021

FDA ADVISORY
No. 2021-1685

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

SUBJECT: **Public Health Warning Against the Purchase and Use of the following Unauthorized Yongrow Medical Device Products:**

1. PULSE OXIMETER
2. NON-CONTACT INFRARED THERMOMETER

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

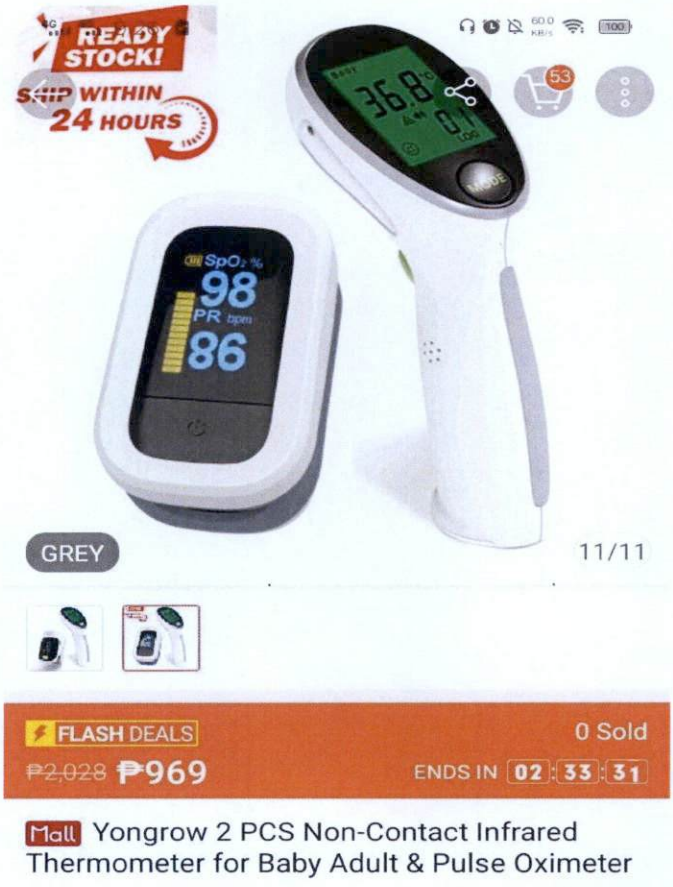

Figure 1. Unauthorized Yongrow Pulse Oximeter and Yongrow Non-contact Infrared Thermometer

The FDA verified through post-marketing surveillance that the above mentioned medical device products are not notified and registered and no corresponding Product Registration and Notification Certificates 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 unauthorized medical device products have not gone through the evaluation process of the FDA, the agency cannot assure its quality and safety.

Additionally, with the issuance of FDA Circular No. 2020-010 entitled "Prohibition of Online Selling of Unregistered/Unnotified Medical Devices," the FDA prohibits the online selling of medical devices and supplies without their corresponding authorizations.

All concerned establishments are warned not to distribute, advertise, or sell the said violative medical device product until the Product Registration and Notification Certificates are issued, otherwise, regulatory actions and sanctions shall be strictly pursued. Always check if a product has been notified 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 Notification and Registration number on the product label in the form of CMDN-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 unauthorized 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 unnotified or unregistered medical device, the online reporting facility, **eReport** can be accessed at **www.fda.gov.ph/ereport**.

Dissemination of this advisory to all concerned is hereby requested.

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Director General

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