Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

24 SEP 2021

FDA ADVISORY
No. 2021-2363

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

SUBJECT: **Public Health Warning Against the Purchase and Use of the Unnotified Medical Device Product ANEROID SPHYGMOMANOMETERS**

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

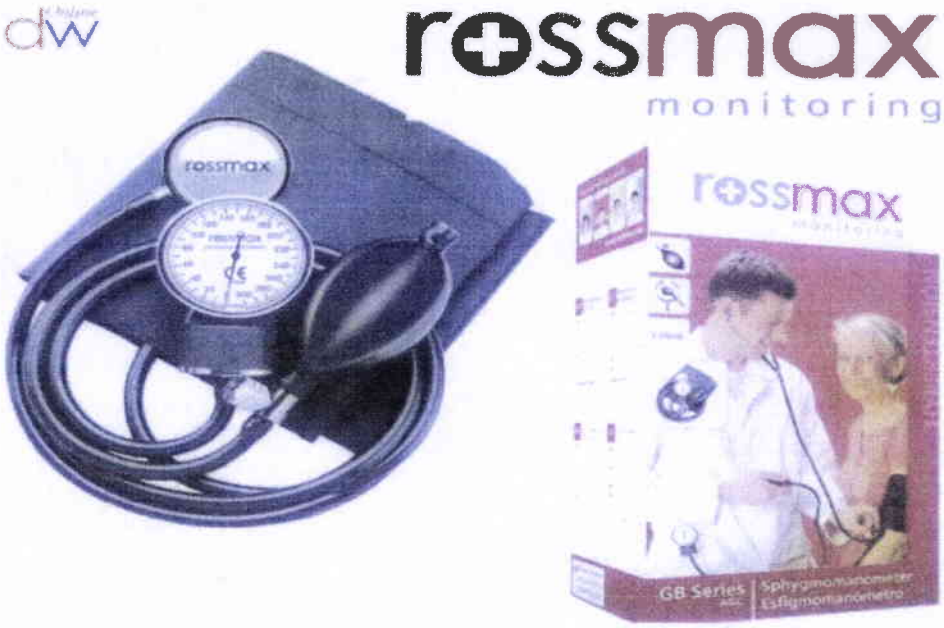

Figure 1. Unnotified Rossmax GB Series AGC Aneroid Sphygmomanometer Blood Pressure with Stethoscope Manual (Black)

Figure 2. Unnotified Alpk2 Aneroid Sphygmomanometer

Figure 3. Unnotified Prohealthcare Desk Type Aneroid Sphygmomanometer

Figure 4. Unnotified Yuwell Aneroid Sphygmomanometer Blood Pressure Monitor

Figure 5. Unnotified Great® Aneroid Sphygmomanometer

The FDA verified through post-marketing surveillance that the above mentioned medical device products are not notified and no corresponding Product 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 unnotified medical device products have not gone through evaluation process of the FDA, the agency cannot assure their 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 products until the Product 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 number on the product label in the form of CMDN-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 unnotified 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 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

DTN 20210802152519, 20210802152538, 20210802152611, 20210802152658, 20210802153314