Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

17 DEC 2019

FDA ADVISORY
No. 2019-524

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

SUBJECT : **Public Health Warning Against the Purchase and Use of Unregistered Medical Device " Qinlishu Flex Freely Abacterial Flexible Fabric Bandage"**

The Food and Drug Administration (FDA) warns all concerned healthcare professionals and the public against the purchase and use of the unregistered medical device:

Figure 1. Qinlishu Flex Freely Abacterial Flexible Fabric Bandage

Civic Drive, Filinvest Corporate City, Alabang 1781 Muntinlupa, Philippines
Trunk Line +63 2 857 1900 Fax +63 2 807 0751
Website: www.fda.gov.ph Email: info@fda.gov.ph

The FDA verified through post-marketing surveillance that the abovementioned medical device is not registered and the Certificate of Product Registration (CPR) has not yet been issued. Pursuant to 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 from FDA is prohibited.

Since these unregistered medical device has not gone through evaluation and testing process of the FDA, the agency cannot guarantee its quality and safety.

In light of the foregoing, the public is advised not to purchase this violative product and in the market.

All concerned establishments are warned not to distribute the above-identified violative medical device until the Certificate of Product Registration is issued. otherwise, regulatory actions and sanctions shall be strictly pursued.

All FDA Field Officer and Regulatory Enforcement Unit in coordination with law enforcement Agencies and Local Government Unit are requested to ensure that this product is not sold or made available in their localities or areas or jurisdiction.

The Bureau of Customs is urged to retain the entry of this unregistered product.

For more information and inquiries, kindly contact the FDA Center for Device Regulation, Radiation Health and Research through e-mail at **cdrrhr@fda.gov.ph** or call (02) **857-1900 loc. 8301.**

Dissemination of the information to all concerned is requested.

ROLANDO ENRIQUE D. DOMINGO, MD, DPBO
Undersecretary of Health
Officer-in-Charge, Director General

DTN: 20191010011448