



03 AUG 2018

FDA ADVISORY
No. **2018-238**

TO : ALL HEALTH CARE PROFESSIONALS AND THE GENERAL PUBLIC

SUBJECT : Public Health Warning Against the Purchase and Use of Unregistered Medical Device Products:

1. Elastic Bandage 3"
2. Elastic Bandage 4"

The Food and Drug Administration (FDA) hereby advises the general public and healthcare professionals against the purchase and use of the following medical device products:



Figure 1. Elastic Bandage 3"



Figure 2. Elastic Bandage 4"

FDA post-marketing surveillance (PMS) activities have verified that the abovementioned medical device products have not gone through the registration process of the agency and have not been issued the proper authorization in the form of Certificate of Product Registration. 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.

In this regard, the public is hereby advised not to purchase and use the above-mentioned products and to be vigilant against the medical device products that are not registered with the FDA.

All Local Government Units (LGUs) and Law Enforcement Agencies (LEAs) are requested to ensure that these products are not sold in any market.

For more information and inquiries, please email us at cdrhr_prsdd@fda.gov.ph or call the Product Research and Development Division – Center for Device Regulation, Radiation Health and Research of the FDA at telephone no. (02) 857-1900 loc. 8301.

Dissemination of the information to all concerned is requested.



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