

Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



FDA ADVISORY No. 2018~208 2 6 JUN 2018

TO:

THE GENERAL PUBLIC AND ALL HEALTHCARE

CONCERNED PROFESSIONALS

SUBJECT:

Public Health Warning Against the purchase and Use of Unregistered Medical Device Product "Bang-ze Abacterial

Flexible Fabric Bandage"

The Food and Drug Administration (FDA) hereby advises the general public and healthcare professionals against the purchase and use of Bang-ze Abacterial Flexible Fabrid bandage.





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 product 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 e-mail us at cdrrhr_prsdd@fda.gov.ph. or call us at the Center for Device Regulation, Radiation Health and Research (CDRRHR) hotline (02) 857-1900 local 8301.

Dissemination of the information to all concerned is requested.

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Director General

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