Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

25 JUN 2020

FDA ADVISORY
No. 20201222

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

SUBJECT: **Public Health Warning Against the Purchase and Use of the following Unnotified/Unregistered Medical Device Products In Foreign Characters:**

1. **NUO KANG ADHESIVE TAPE**
2. **PENG CHENG GAUZE BANDAGE (4.8 CM X 6 M)**

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

Figure 1. Unnotified/Unregistered Nuo Kang Adhesive Tape

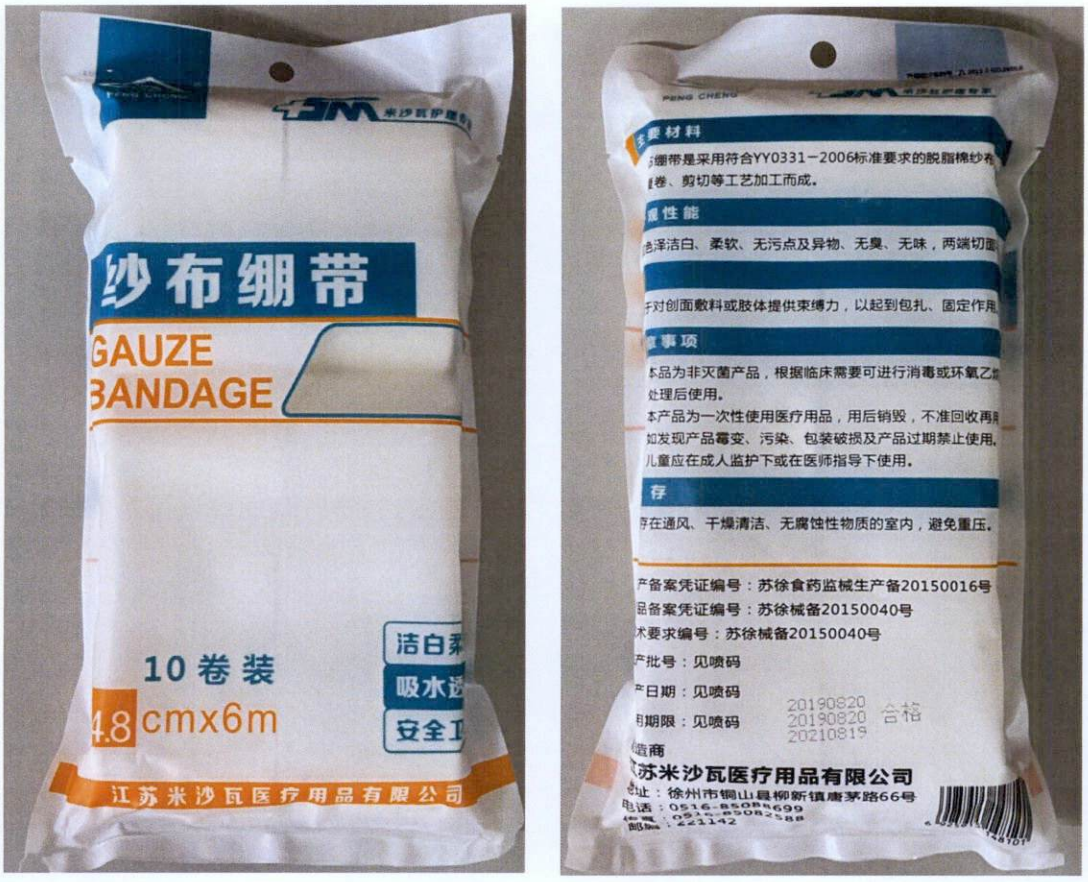

Figure 2. Unnotified/Unregistered Peng Cheng Gauze Bandage (4.8 cm x 6 m)

The FDA verified through post-marketing surveillance that the abovementioned medical device products are not notified/registered and no corresponding Certificate of Medical Device Notification(CMDN)/Certificate of Medical Device Registration (CMDR) has 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/unregistered medical device products have not gone through evaluation process of the FDA, the agency cannot assure their quality and safety.

All concerned establishments are warned not to distribute, advertise, or sell the said violative medical device products until CMDN/CMDR are issued, otherwise, regulatory actions and sanctions shall be strictly pursued. Always check if a product has been registered 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 Registration number on the product label.

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/unregistered 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/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

DTN: 20200529164204
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