



07 JUL 2020

FDA ADVISORY
No. **2020-1316**

TO: ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

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

- 1. NUO KANG ADHESIVE BANDAGES**
- 2. BAND-AID BRAND ADHESIVE BANDAGES
BENZALKONIUM CHLORIDE PATCHES**

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



Figure 1. Unnotified Nuo Kang Adhesive Bandages





Figure 2. Unnotified Band-Aid Brand Adhesive Bandages Benzalkonium Chloride Patches

The FDA verified through post-marketing surveillance that the abovementioned medical device products are unnotified and no corresponding product notification certificate 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 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 the product notification certificate is 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 Notification number in the form of either DVR-xxxx or MDR-xxxx on the product label.


All FDA Regional Field Offices and Regulatory Enforcement Units in coordination with law enforcement agencies and Local Government Units are requested to ensure that these products are 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, kindly contact the FDA Center for Device Regulation, Radiation Health, and Research through e-mail at cdrhr-prsdd@fda.gov.ph, or call (02) 8857-1900 loc. 8301.

To report any sale or distribution of unregistered/unnotified medical device product, 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

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