

Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



0 6 NOV 2020

FDA ADVISORY No. 20202036

TO:

ALL HEALTHCARE PROFESSIONALS AND THE

GENERAL PUBLIC

SUBJECT:

Public Health Warning Against the Purchase and Use of the

Unregistered/Unnotified Medical Device Product "DAISO

EMERGENCY PLASTER"

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



Figure 1. Unregistered/Unnotified Daiso Emergency Plaster





Website: www.fda.gov.ph

Email: info@fda.gov.ph

The FDA verified through post-marketing surveillance that the above-mentioned medical device product is not registered/notified and no corresponding Product Registration/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 this unregistered/unnotified medical device product has not gone through evaluation process of the FDA, the agency cannot assure its quality and safety.

All concerned establishments are warned not to distribute, advertise, or sell the said violative medical device product until the Product Registration/Notification Certificate is issued, otherwise, regulatory actions and sanctions shall be strictly pursued. Always check if a product has been registered/notified 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/Notification number on the product label in the form of either DVR-xxx, MDR-xxx, or CMDN-xxx.

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 this unregistered/unnotified product.

For more information and inquiries about this advisory, kindly contact the FDA CDRRHR through e-mail at <u>cdrrhr@fda.gov.ph</u> indicating on the subject the concerned Advisory, or call (02) 8857-1900 loc. 8301.

To report any sale or distribution of unregistered/unnotified 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.

ROLANDO ENRIQUE D. DOMINGO, MD
Director General

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