



01 FEB 2023

FDA ADVISORY
No. 20230166

TO: ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

SUBJECT: Public Health Warning Against the Purchase and Use of the Unnotified Medical Device Product “COOLING GEL PATCH (IN FOREIGN CHARACTERS)”

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

The screenshot shows a Shopee product listing for '2pcs Cooling Gel Patch for Fever Headache Relief Cold Sticker for Baby Adult Cool Patch Pad'. The product is priced at P10 and has a 4.8-star rating from 165 reviews, with 1.6K units sold. The listing includes a 'Report' link, shop vouchers for P5 and P7 off, a bundle deal for 2% off on 20 items, and shipping to Binondo, Metro Manila for P38. Color options include watermelon, pineapple, strawberry, and mint patches. The quantity is set to 1, with 2312 pieces available.

Figure 1. Unnotified Cooling Gel Patch (in Foreign Characters) advertised at Shopee.com.ph





Figure 2. Unnotified Cooling Gel Patch (in Foreign Characters) advertised at Shopee.com.ph



Figure 3. Unnotified Cooling Gel Patch (in Foreign Characters) advertised at Shopee.com.ph

The FDA verified through post-marketing surveillance that the abovementioned medical device product is not notified 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 this 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 Notification Certificate is issued, otherwise, regulatory actions and sanctions shall be strictly pursued. Always check if a product has been 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 Notification number on the product label in the form of CMDN-xxx.

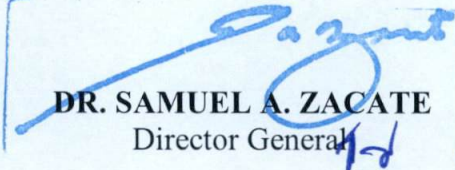
All Law Enforcement Agencies (LEAs) and Local Government Units (LGUs) are requested to ensure that this product is not sold or made available in the market or areas of jurisdiction.

The Bureau of Customs is urged to restrain the entry of this unnotified product.

For more information and inquiries about this advisory, kindly contact the FDA CDRRHR through e-mail at cdrhr@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 medical device, contact the online reporting facility eReport through e-mail at ereport@fda.gov.ph.

Dissemination of this advisory to all concerned is hereby requested.


DR. SAMUEL A. ZACATE
Director General

DTN 20221219074729