Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

11 MAR 2021

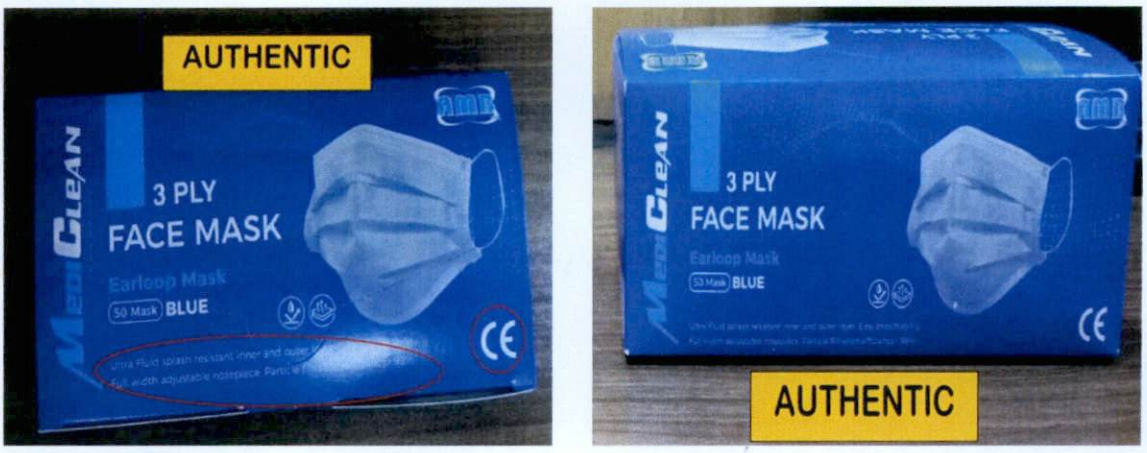
FDA ADVISORY
No. 2021-0524

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

SUBJECT: **Public Health Warning Against the Purchase and Use of Counterfeit Medical Device Product "Mediclean Face Mask"**

The Food and Drug Administration (FDA) advises the public from purchasing and using the counterfeit medical device:

AUTHENTIC



COUNTERFEIT

Counterfeit – No specifications in the label, bigger box size, without CE mark and manufactured reflected: Hefei Mlush Sanitary Products CO., LTD

Figure 1. Comparison between the Authentic and Counterfeit Mediclean Face Mask

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Figure 2. Comparison between the Authentic and Counterfeit Mediclean Face Mask

The FDA has coordinated with the Market Authorization Holder (MAH), AMB HK Enterprises Inc., and has verified that the aforementioned medical device is **COUNTERFEIT**. The MAH stated that they are not responsible for the importation and distribution of the above-mentioned counterfeit medical device product.

Counterfeit products did not go through the required safety assessment and the FDA verification process. These products pose potential health hazards to the consuming public since their safety and purity cannot be guaranteed.

In light of the foregoing, the public is advised not to purchase the aforementioned violative products.

All concerned establishments are warned not to distribute counterfeit medical device.

All FDA Regional Field Offices and Regulatory Enforcement Units, in coordination with law enforcement agencies and Local Government Units, are requested to ensure that violative products are not sold or made available in the market or areas of jurisdiction.

For more information and inquiries, kindly contact the FDA Center for Device Regulation, Radiation Health, and Research through e-mail at **cdrrhr@fda.gov.ph**, or call **(02) 8857-1900 loc. 8301.**

To report any sale or distribution of 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.

ROLANDO ENRIQUE D. DOMINGO, MD
Director General

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