Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

24 SEP 2021

FDA ADVISORY
No. 20212362

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

SUBJECT: **Public Health Warning Against the Purchase and Use of the Unnotified Medical Device Product "JAPAN QUALITY FACE MASK"**

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

Figure 1. Unnotified Japan Quality Face Mask

The FDA verified through post-marketing surveillance that the above mentioned 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 the evaluation process of the FDA, the agency cannot assure its quality and safety.

Furthermore, the FDA reiterates the provisions of FDA Memorandum Circular No. 2013-030 entitled "Guidelines on the Use of the FDA Logo and Name in Promotional, Advertisement, Sponsorship, Marketing or Commercial Materials" wherein it states that "No person, establishment or organization, shall use the FDA logo, the words "Food and Drug Administration" or "Philippine FDA", the initials "FDA", or any imitation of such words, initials, or logo in print and other forms of broadcast media, including the internet, in connection with any health product, merchandise, impersonation, solicitation, or commercial activity in a manner that convey that such use is approval, endorsement, or authorization by the FDA unless with written permission from the agency".

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 **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 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

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