



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



23 APR 2021

FDA ADVISORY

No. 2020-2043-A

TO: ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

SUBJECT: Lifting of the Advisory No. 2020-2043 entitled "Public Health Warning Against the Purchase and Use of the Unnotified Medical Device Product "ZHONGKA FACE MASK"

The Food and Drug Administration (FDA) informs all healthcare professional and the general public that the medical device product Zhongka Face Mask, has been notified by the Market Authorization Holder (MAH), ZhongKa Corporation, in accordance to existing FDA rules and regulations.


Accordingly, the warning against the purchase and use of the product as mentioned in FDA Advisory No. 2020-2043 is hereby lifted.

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

To report any sale or distribution of unregistered medical device products, the online reporting facility, eReport can be accessed at www.fda.gov.ph/ereport.

The issuance of this advisory shall not in any manner preclude this Office from issuing subsequent orders it may deem necessary and appropriate, should there be findings of any violation of the company to the existing laws, rules, and regulations.

Dissemination of this advisory to all concerned is hereby requested.


ROLANDO ENRIQUE D. DOMINGO, MD
Director General

DTN: 20200925113255

