Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

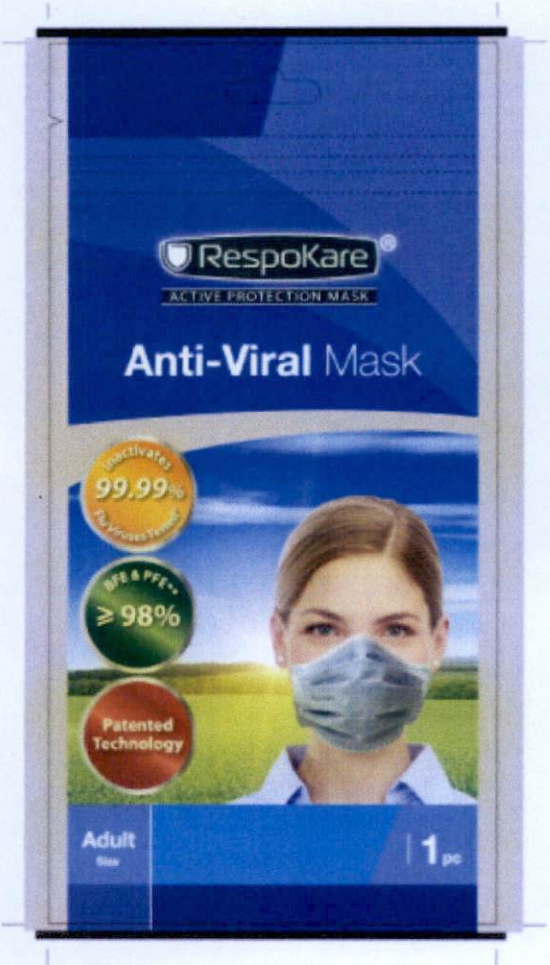
06 AUG 2021

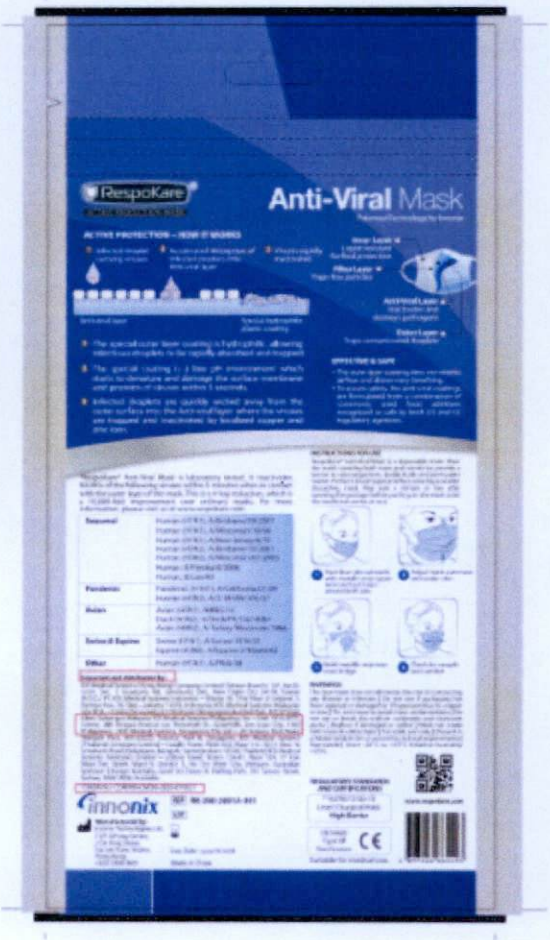
FDA ADVISORY
No. 2020-782-A

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

SUBJECT : **Lifting the Advisory of the Notified Medical Device under FDA Advisory No. 2020-782 entitled Public Health Warning Against the Unapproved and Misleading Health Claims of Medical Devices that Decreases the Risk for Coronavirus Disease (COVID-19) Infection**

The Food and Drug Administration (FDA) informs all healthcare professionals and the public that the medical device product "Respokare® Active Protection Mask Anti-Viral Mask" has been notified by the Market Authorization Holder (MAH), IDS Medical System Philippines Inc., with FDA notification number CDRRHR-CMDN-2020-670621 in accordance to FDA rules and regulations. Below is the approved label for the product:





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Accordingly, the warning against the purchase and use of the product as mentioned in FDA Advisory No. 2020-782 is hereby lifted.

For more information and inquiries, kindly contact the FDA Center for Device Regulation, Radiation Health, and Research through email at **cdrrhr@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 public health warning imposed on the remaining product listed in FDA Advisory No. 2020-782 shall remain to be upheld and shall not be affected by the issuance of this advisory. Furthermore, 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: 20210802094051