Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 2022-0052-A

15 MAR 2022

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

SUBJECT: **Lifting of the FDA Advisory No. 2022-0052 entitled "Public Health Warning Against the Purchase and Use of the Uncertified COVID-19 Test Kit "HEALGEN® CORONAVIRUS AG RAPID TEST CASSETTE (SWAB)"**

The Food and Drug Administration (FDA) informs all healthcare professionals and the general public that the advisory on **Healgen® Coronavirus Ag Rapid Test Cassette (Swab)** manufactured by Healgen Scientific Limited Liability Company under FDA Advisory No. 2022-0052 dated 24 January 2022 is hereby lifted pursuant to the compliance of the market authorization holder to existing and applicable laws, rules, and regulations.

The FDA issued Special Certification for the above-mentioned product with certificate number SC-2022-055 under company Newlife Pharmaceuticals Inc.

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 existing laws, rules and regulations.

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 uncertified COVID-19 test kits, the online reporting facility, **eReport** can be accessed at **www.fda.gov.ph/ereport**.

Dissemination of this advisory to all concerned is hereby requested.

DR. OSCAR G. GUTIERREZ, JR.
Officer-in-Charge Director General

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