

Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



19 JAN 2023

FDA ADVISORY No. 2022-0107-A

> TO: CONCERNED STAKEHOLDERS AND THE

> > GENERAL PUBLIC

SUBJECT: Lifting of the FDA Advisory No. 2022-0107 entitled

"Reiteration on Prohibition of Online Selling of FDA Certified COVID-19 Test Kits including Self-Administered COVID-19

Test Kits"

In line with the Department of Health Department Memorandum (DM) No. 2022-0033 entitled "Guidelines on the Use of Self-Administered Antigen Testing for COVID-19, the Food and Drug Administration (FDA) informs all concerned stakeholders and the general public that the provision against the online sale of FDA certified COVID-19 self-administered test kits mentioned in FDA Advisory No. 2022-0107 is hereby lifted.

Thus, online selling of FDA certified COVID-19 self-administered test kits is hereby allowed.

Accordingly, the public is advised to follow the appropriate use and interpretation of results of self-administered antigen test kits provided in DM No. 2022-0033.

The public health warning imposed on the remaining types of FDA certified COVID-19 test kits (RT-PCR, antibody, antigen based) listed in FDA Advisory No. 2022-0107 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 if may deem necessary and appropriate, should there be findings of any violation of the company to the 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.

Dissemination of this advisory to all concerned is hereby requested.

DR. SAMUEL A.

Director Genera

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