



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



28 DEC 2021

FDA CIRCULAR

No. 2021-023-A

SUBJECT : Amendment to FDA Circular No. 2021-023 Re: Extension of Validity of Selected Special Certification for COVID-19 Test Kits Under FDA Memorandum No. 2020-006 entitled "Issuance of Special Certification for Imported Test Kits of COVID-19"

In the interest of service and to ensure the availability of COVID-19 test kits during the continuing pandemic due to COVID-19, FDA Circular No. 2021-023 re: Extension of Validity of Selected Special Certification for COVID-19 Test Kits Under FDA Memorandum No. 2020-006 entitled "Issuance of Special Certification for Imported Test Kits of COVID-19" is hereby amended to change the date of extension of validity of Special Certification for COVID-19 test kits under FDA Memorandum No. 2020-006 whose Market Authorization Holders filed for the re-issuance of the said authorization following FDA Memorandum No. 2021-009 entitled "Minimum Performance Requirements for COVID-19 Test Kits Used for SARS-CoV-2 Infection" on or before 23 September 2021 and are waiting for the result of the performance validation conducted by the Research Institute for Tropical Medicine from 31 December 2021 to **31 January 2022** subject to FDA regulatory and enforcement actions as may be warranted.

In case of circumstances warranting further extension of the abovementioned Special Certification, said extension may be issued through an FDA Advisory.

All other provisions of FDA Circular No. 2021-023 not affected by this Circular shall remain in effect.

This Circular shall take effect immediately and shall remain valid unless otherwise revoked, repealed, or rescinded.


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Director General

DTN: 20211210133717

