Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

14 OCT 2021

FDA CIRCULAR
No. 2021-023

SUBJECT : **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"**

I. RATIONALE

On 12 March 2020, the Food and Drug Administration (FDA) issued FDA Memorandum No. 2020-006 entitled "Issuance of Special Certification for Imported Test Kits of COVID-19" to provide guidelines for the issuance of special certification for imported in-vitro diagnostic (IVD) test kits used for diagnosis and screening of COVID-19.

Subsequently, FDA Memorandum No. 2021-009 entitled "Minimum Performance Requirements for COVID-19 Test Kits Used for Screening of SARS-CoV-2 Infection" was issued on 23 March 2021 to set the minimum performance requirements for COVID-19 test kits and to provide specific guidelines on the re-evaluation of product performance of COVID-19 test kits with Special Certification by the FDA. In addition, FDA Memorandum No. 2021-009 also provides for the validity of all issued Special Certification under FDA Memorandum No. 2020-006. Section III (C) of FDA Memorandum No. 2021-009 stipulates that "All issued Special Certification under FDA Memorandum No. 2020-006 shall be valid for a period of six (6) months from date of this guidelines unless otherwise revoked earlier". Thus, as per stated provision, all issued Special Certification under FDA Memorandum No. 2020-006 shall expire on 23 September 2021.

In the interest of service and to ensure the availability of COVID-19 test kits during the continuing pandemic, this Circular is hereby issued.

II. OBJECTIVE

This supplemental Circular is issued to provide guidance on the regulatory flexibility implemented by the FDA in light of the COVID-19 pandemic specifically on the issued Special Certification for COVID-19 test kits under FDA Memorandum No. 2020-006.

III. SCOPE

This issuance shall apply to manufacturers, traders, and distributors (importers, exporters and wholesalers) of COVID19 test kits to be used for the diagnosis and screening of SARS-CoV-2 infection that are for re-issuance of Special Certification issued under FDA Memorandum No. 2020-006.

IV. GUIDELINES

A. All Special Certifications for COVID-19 test kits under FDA Memorandum No. 2020-006 whose Market Authorization Holders (MAH) filed for the re-issuance of the said authorization following FDA Memorandum No. 2021-009 on or before 23 September 2021 and are waiting for the result of the performance validation conducted by the Research Institute for Tropical Medicine are hereby extended until 31 December 2021 subject to FDA regulatory and enforcement actions as may be warranted.

B. On the other hand, all other Special Certifications issued under FDA Memorandum No. 2020-006 whose MAH did not file for the re-issuance of the said authorization in accordance with FDA Memorandum No. 2021-009 are hereby deemed revoked or cancelled.

V. SEPARABILITY CLAUSE

All other provisions of FDA Memorandum No. 2021-009 unaffected by the provisions of this Circular shall remain in effect. Furthermore, in the event that any provision or part of this Circular is declared invalid, the other provisions hereof shall not be affected.

VI. EFFECTIVITY

This Circular shall take effect fifteen (15) days following its publication in a newspaper of general circulation and upon filing three (3) certified copies with the University of the Philippines Law Center.

ROLANDO ENRIQUE D. DOMINGO, MD
Director General

DTN: 20210914124040

ANNEX A

References

Congress of the Philippines. (2009). R.A. 9711 entitled "Food and Drug Administration (FDA) Act of 2009". Philippines: Congress of the Philippines

Food and Drug Administration. (2021). FDA Memorandum No. 2021-009 entitled "Minimum Performance Requirements for COVID-19 Test Kits Used for SARS-CoV-2 Infection". Philippines: FDA

Food and Drug Administration. (2020). FDA Memorandum No. 2020-006 entitled "Issuance of Special Certification for Imported Test Kits of COVID-19". Philippines: FDA