

## Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



FDA CIRCULAR No. 2021-025-Δ 3 0 SEP 2022

**SUBJECT** 

AMENDMENT OF FDA CIRCULAR NO. 2021-025
ENTITLED "GUIDELINES FOR APPLICATION OF
AUTHORIZATIONS AT THE FOOD AND DRUG
ADMINISTRATION IN LIGHT OF THE EXTENDED STATE OF
PUBLIC HEALTH EMERGENCY", EXTENDING FURTHER

ITS EFFECTIVITY

Proclamation No. 57<sup>1</sup> issued by the Office of the President on 12 September 2022 declares the extension of the State of Calamity throughout the Philippines due to Coronavirus Disease 19 (COVID-19) pandemic effective 13 September 2022 until 31 December 2022, unless earlier lifted or extended as circumstances may warrant. This directs all government agencies and local government units to continue their efforts and appropriate measures to mitigate effects of the COVID-19 pandemic.

In view of the foregoing and in consideration of the economic challenges brought about by the COVID-19 pandemic to our stakeholders, the effectivity of FDA Circular (FC) No. 2021-025 entitled "Guidelines for Application of Authorizations at the Food and Drug Administration in light of the Extended State of Public Health Emergency" is hereby extended from 01 October 2022 until 31 December 2022 with the duration of the State of Calamity declaration in the Philippines due to COVID-19 pandemic.

Existing FDA-issued authorizations enumerated in Section III of FC 2021-025, with validity expiring on 01 January 2022 to 31 December 2022 are automatically extended. An additional four (4) months validity from the original date of expiration of the authorizations shall be given; provided, that a complete application for renewal of the said authorizations have been filed with and duly acknowledged by the FDA within the given extension period, following the provisions of Section IV. A. 2. Renewal Application of FC 2021-025.

As thus amended, all other provisions stipulated in FDA Circular No. 2021-025 dated 09 December 2021, not affected by this amendment shall remain in full force and effect.

This Circular shall take effect immediately.

DR. SAMUEL A. ZACATE
Director General

<sup>&</sup>lt;sup>1</sup> Further Extending the Period of State of Calamity Throughout the Philippines Due to Corona Virus Disease 2019 Declared Under Proclamation No. 929, S. 2020, as Extended Under Proclamation No. 1021, S. 2020, and Proclamation No. 1218, S. 2020

