Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

Food and Drug Administration PHILIPPINES

24 FEB 2022

FDA CIRCULAR
No. 2021-015-A

SUBJECT : **Extension of FDA Circular No. 2021-015 entitled "Interim Guidelines on the Renewal of Current Good Manufacturing Practice (cGMP) Clearance of Foreign Drug Manufacturers"**

In the interest of service and due to the continuing COVID-19 Pandemic, the effectivity of FDA Circular (FC) No. 2021-015 entitled "Interim Guidelines on the Renewal of Current Good Manufacturing Practice (cGMP) Clearance of Foreign Drug Manufacturers" is hereby extended and made coterminous with the duration of the public health emergency due to COVID-19 as declared in Proclamation No. 922, s. 2020, or the state of national calamity as declared in Proclamation No. 1218, s. 2021, whichever ends later.

It is emphasized, however, that only the effectivity of the interim guidelines is being extended. The validity of the cGMP Clearances issued by the FDA for Foreign Drug Manufacturers of all previously received renewal applications have been extended until 31 December 2021 only. Renewal applications shall follow Section IV.A of FC No. 2021-015 and shall be evaluated based on the submitted acceptable cGMP evidence.

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