Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 2022-0786

05 APR 2022

TO : **ALL STAKEHOLDERS**

SUBJECT : **Renewal of Current Good Manufacturing Practice (cGMP) Clearance of Foreign Drug Manufacturers under FDA Circular No. 2021-015**

FC No. 2021-015-A or the *Extension of FC No. 2021-015 entitled "Interim Guidelines on the Renewal of Current Good Manufacturing Practice (cGMP) Clearance of Foreign Drug Manufacturers"* states that the effectivity of the interim guidelines of FC No. 2021-015 is being 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 was emphasized in the said amendment, however, that only the effectivity of the interim guidelines is being extended and that the extended validity of the previously received renewal applications remains to be until 31 December 2021 only as per FC No. 2021-015.

On a related note, FC No. 2021-025 or the *Guidelines for Application of Authorizations at the Food and Drug Administration in Light of the Extended State of Public Health Emergency*, provides that existing authorizations enumerated in Section III of said Circular, with validity expiring on 01 January 2022 to 30 September 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.

In this regard, all concerned stakeholders are being informed of the following clarification:

Validity of cGMP Clearances for Foreign Drug Manufacturers as per automatic extension of FC No. 2021-0015	Actual validity of the same based on FC No. 2021-025
31 December 2021	**30 April 2022**

In addition, all concerned stakeholders are hereby reminded to submit renewal applications not later than the extension period to avoid surcharges or penalties as stipulated in Section IV.B. of FC No. 2021-015 and other regulatory actions as warranted.

For the information and guidance of all.

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Officer-in-Charge Director General