WORLD TRADE ORGANIZATION

G/TBT/N/PHL/253/Add.2

17 March 2022

(22-2353)

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Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

Addendum

The following communication, dated 17 March 2022, is being circulated at the request of the delegation of the Philippines.

Title: FDA Circular No._____: Interim Guidelines on the Renewal of Current Good Manufacturing Practice (cGMP) Clearance of Foreign Drug Manufacturers

Reason for Addendum:	
[ ]	Comment period changed - date:
[ ]	Notified measure adopted - date:
[ ]	Notified measure published - date:
[ ]	Notified measure enters into force - date:
[ ]	Text of final measure available from[1]:
[ ]	Notified measure withdrawn or revoked - date: Relevant symbol if measure re-notified:
[ ]	Content or scope of notified measure changed and text available from[1]: New deadline for comments (if applicable):
[ ]	Interpretive guidance issued and text available from[1]:
[X]	Other: https://members.wto.org/crnattachments/2022/TBT/PHL/22_2294_00_e.pdf Effectivity date extended

Description: 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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[1] This information can be provided by including a website address, a pdf attachment, or other information on where the text of the final/modified measure and/or interpretive guidance can be obtained.