NOTIFICATION

Addendum

The following communication, dated 8 March 2022, is being circulated at the request of the delegation of the Philippines.

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**Title:** Draft FDA Circular entitled "Specific List of Registrable In Vitro Diagnostic Medical Devices (IVDs) and Revised Technical Requirements for Registration of COVID-19 Test Kits"

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| **Reason for Addendum:** |
| [X] | Comment period changed - date: 11 April 2022 |
| [  ] | Notified measure adopted - date:  |
| [  ] | Notified measure published - date:  |
| [  ] | Notified measure enters into force - date:  |
| [  ] | Text of final measure available from[[1]](#footnote-1):  |
| [  ] | Notified measure withdrawn or revoked - date: Relevant symbol if measure re-notified:  |
| [  ] | Content or scope of notified measure changed and text available from1: New deadline for comments (if applicable):  |
| [  ] | Interpretive guidance issued and text available from1:  |
| [  ] | Other:  |

**Description:** This notification provides additional time for Members to provide comments to the draft Circular which can be accessed at <https://www.fda.gov.ph/wp-content/uploads/2022/02/Specific-List-of-Registrable-In-Vitro-Diagnostic-Medical-Devices-IVDs-and-Revis.pdf>.

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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. [↑](#footnote-ref-1)