NOTICE OF VIRTUAL PUBLIC HEARING

As part of the mandate of the Food and Drug Administration (FDA) to protect public health and safety through regulation of health products including in vitro diagnostic medical devices (IVDs) and in adherence to the provisions of the ASEAN Medical Device Directive, the FDA through the Center for Device Regulation, Radiation Health and Research (CDRRHR) is in the process of developing guidelines on the regulation of IVDs.

The CDRRHR has finalized the draft guidelines & policies related to IVD registration processes as follows:

1. Specific List of Registrable In Vitro Diagnostic Medical Devices (IVDs) and Revised Technical Requirements for Registration of COVID-19 Test Kits
2. Rules and Regulations Governing the Issuance of an Authorization for an In-Vitro Diagnostic Medical Device (IVD)

In the interest of service and to seek the comments of the stakeholders that will be affected by the proposed policies, the FDA is inviting representatives from the IVD industry to attend the **Virtual Public Hearing** on **28 February 2021** via Google Meet. Eighty (80) slots have been allotted for those interested to attend the said activity. One (1) representative per company shall be accommodated.

To register and confirm your attendance, you may send an email to the CDRRHR – Product Research and Standards Development Division at cdrrhr-prsdd@fda.gov.ph. Kindly send the following information when you register:

1. Name of company
2. Name of participant
3. Designation/Position of participant
4. Email address of participant

Thank you.