08 October 2024

NOTICE TO RELEVANT STAKEHOLDERS

Dear Sir/Ma'am:

This refers to the draft regulations distributed through the World Trade Organization – Technical Barriers to Trade (WTO-TBT) website (www.epingalert.org) from 21 to 27 September 2024.

Relative thereto, we respectfully invite stakeholders to comment on the notified draft technical regulations from: Israel, United States, Brazil, and Peru.

Document Symbol	Notifying Member	Relevant Dates	Products Covered	Summary
G/TBT/N/ ISR/1287/ Add.1	Israel	**Date of Distribution:** 27 September 2024 **Deadline for Comments:** Not indicated	Ophthalmic optics : single-vision and multifocal lenses - Addendum	The requirements of the Mandatory Standard SI 798 part 1 were declared voluntary.
G/TBT/N/ ISR/1288/ Add.1	Israel	**Date of Distribution:** 27 September 2024 **Deadline for Comments:** Not indicated	Ophthalmic optics : power-variation lenses - Addendum	The requirements of the Mandatory Standard SI 798 part 2 were declared voluntary.
G/TBT/N/ ISR/1289/ Add.1	Israel	**Date of Distribution:** 27 September 2024 **Deadline for Comments:** Not indicated	Ophthalmic optics : uncut finished lenses - Addendum	The requirements of the Mandatory Standard SI 14889 were declared voluntary
G/TBT/N/ USA/1647/ Add.1	United States	**Date of Distribution:** 25 September 2024 **Deadline for Comments:** Not indicated	Cytomegalovirus (CMV) deoxyribonucleic acid (DNA) quantitative assay devices intended for transplant patient management - Addendum	The Food and Drug Administration (FDA or the Agency) is issuing a final order to reclassify cytomegalovirus (CMV) deoxyribonucleic acid (DNA) quantitative assay devices intended for transplant patient management, a post amendments class III device (product code PAB) into class II (general controls and special controls), subject to premarket notification.This order is effective 23 October 2024.89 Federal Register (FR) 77448, Title 21 Code of Federal Regulations (CFR) Part 866 https://www.govinfo.gov/content/pkg/FR-2024-09-23/html/2024-21616.htm https://www.govinfo.gov/content/pkg/FR-2024-09-23/pdf/2024-21616.pdfThis final amendment; final order and the proposed amendment; proposed order notified as

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				G/TBT/N/USA/1647 are identified by Docket Number FDA-2016-N-2880. The Docket Folder is available on Regulations.gov at https://www.regulations.gov/docket/FDA-2016-N-2880/document and provides access to primary and supporting documents as well as comments received. Documents are also accessible from Regulations.gov by searching the Docket Number.
G/TBT/N/BRA/1566	Brazil	**Date of Distribution:** 24 September 2024 **Deadline for Comments:** 13 November 2024	Pharmacovigilance	This Draft Resolution contains provisions on the Good Pharmacovigilance Practices for Medicine Registration Holders for human use, to include the mandatory use of the WHODrug Dictionary to describe medicines when sending notifications.
G/TBT/N/BRA/1567	Brazil	**Date of Distribution:** 24 September 2024 **Deadline for Comments:** 13 November 2024	Medicines and biological products	This Draft Resolution contains provisions on the execution of Terms of Commitment for the purposes of market registration or postmarket registration of medicines and biological products.
G/TBT/N/PER/165	Peru	**Date of Distribution:** 23 September 2024 **Deadline for Comments:** 22 November 2024	In vitro diagnostic medical devices	The purpose of the notified draft Regulations is to establish the regulatory provisions for Law No. 29459 - Law on pharmaceutical products, medical devices and sanitary products - governing the registration, control and sanitary surveillance of in vitro diagnostic medical devices, and accessories thereof, to ensure their safety and performance, with a view to protecting public health.

To access the notification form, right click the document symbol to open the hyperlink. Should you have any queries on this matter or request for full text of draft regulation in English, please do not hesitate to email us at BPS@dti.gov.ph copy bps.smd@dti.gov.ph.

Thank you.

Sincerely,

NEIL P. CATAJAY
Director

BUREAU OF PHILIPPINE STANDARDS

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Membership:
- International Organization for Standardization (ISO)
- International Electrotechnical Commission (IEC)
- World Trade Organization (WTO) Technical Barriers to Trade (TBT)
  - National Enquiry Point (NEP)
  - National Notification Authority (NNA)