

11 July 2022

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.tbts.wto.org) from 25 June to 01 July 2022.

Relative thereto, we respectfully invite stakeholders to comment on the six (6) notified draft technical regulations from six (6) WTO Member Countries:

Document Symbol	Notifying Member	Relevant Dates	Products Covered	Summary
G/TBT/N/J/PN/741	Japan	Date of Distribution: 28 June 2022 Deadline for Comments: Not Applicable	Shitei Yakubutsu	Proposal for the additional designation of 3 substances as Shitei Yakubutsu, and their proper uses under the Act
G/TBT/N/PHL/267/Add.1	Philippines	Date of Distribution: 01 July 2022 Deadline for Comments: Not Indicated	Drug products, including vaccines and biologicals - Addendum	Implementation of Abridged and Verification Review Pathways for New Drug, Initial Registration and Post-Approval Changes Applications of Drug Products, including Vaccines and Biologicals
G/TBT/N/SLV/220	El Salvador	Date of Distribution: 28 June 2022 Deadline for Comments: 27 August 2022	Medicines	This Law establishes the prices of the services rendered by the National Directorate of Medicines, which is the national health authority that regulates medicines, medical devices, cosmetics, sanitary and chemical products, including raw materials, and establishments that manufacture, import, export, market or dispense these products
G/TBT/N/TWPKM/496	The Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu	Date of Distribution: 30 June 2022 Deadline for Comments: Not Applicable	Imported COVID-19 antigen home/self tests	To respond to the new coronavirus pandemic and to ensure the quality of medical devices for protecting the safety and well-being of the public, the Food and Drug Administration proposes to conduct inspection and examination for imported COVID-19 Antigen Home/Self Tests

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)

G/TBT/N/U KR/216	Ukraine	Date of Distribution: 01 July 2022 Deadline for Comments: 30 August 2022	Medicines, active pharmaceutical ingredients	The draft Order provides for approval of the the Quality Certification Procedure for medicinal products for international trade and confirmation for exported active pharmaceutical ingredients and aims to remove barriers to medicine quality certification proceedings for international trade and confirmation for exported active pharmaceutical ingredients; to improve and simplify such certification proceedings
G/TBT/N/U SA/1889	United States	Date of Distribution: 29 June 2022 Deadline for Comments: 26 October 2022	Nonprescription drug product with an additional condition for nonprescription use (ACNU)	The Food and Drug Administration (FDA, the Agency, or we) is proposing to establish requirements for a nonprescription drug product with an additional condition for nonprescription use (ACNU)

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 Mrs. Catherine Antonio-Paguinto (CatherineAntonio@dti.gov.ph) and Ms. Jasmin E. Metre (JasminMetre@dti.gov.ph).

Thank you.

Sincerely,

NEIL P. CATAJAY
Director 