

11 April 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 23 to 29 March 2024.

Relative thereto, we respectfully invite stakeholders to comment on the five (5) notified draft technical regulations from Brazil and United States:

Document Symbol	Notifying Member	Relevant Dates	Products Covered	Summary
G/TBT/N/BRA/910/Add.8	Brazil	Date of Distribution: 28 March 2024 Deadline for Comments: Not Indicated	Radiopharmaceuticals - Addendum	Resolution 567, 29 September 2021 - previously notified through G/TBT/N/BRA/910/Add.2 -which establishes a list of radiopharmaceuticals to prove the safety and effectiveness, was changed by Resolution 853, 21 March 2024.
G/TBT/N/BRA/1442/Add.1	Brazil	Date of Distribution: 28 March 2024 Deadline for Comments: Not Indicated	Medicines and biological products - Addendum	Draft resolution number 1108, 18 August 2022 - previously notified through G/TBT/N/BRA/1442 - which is regarded to a proposal for a Normative Instruction that establishes the modalities and criteria applied for the optimized analysis procedure, in which the evaluations conducted by the Equivalent Foreign Regulatory Authority (EFRA) are used to analyze the market authorization and post-market authorization petitions of medicines and biological products, and a letter of adequacy of active pharmaceutical ingredient (CADIFA), in national territory, was adopted as Normative Instruction 289, 20 March 2024.
G/TBT/N/BRA/1493/Add.1	Brazil	Date of Distribution: 28 March 2024 Deadline for Comments: Not Indicated	Synthetic and semi-synthetic drugs - Addendum	Draft resolution 1188, 03 August 2023 - previously notified through G/TBT/N/BRA/1493 - which contains provisions on health requirements for safety and efficacy for post-marketing registration alterations of synthetic and semi-synthetic drugs classified as new or innovative, was adopted as Resolution 851, 20 March 2024.
G/TBT/N/BRA/1528	Brazil	Date of Distribution: 27 March 2024	Industrialized medicines for human use	This Draft Resolution contains provisions on the validation of bioanalytical methods and analysis of study samples for regulatory submissions of industrialized medicines for human use.

BUREAU OF PHILIPPINE STANDARDS

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)

		Deadline for Comments: 15 May 2024		The bioanalytical method used to quantify the drug in matrix biological must be described in detail, and Guide n° XX, of XX2024, which deals with the validation of bioanalytical methods and sample analysis study (ICH M10 - Bioanalytical method validation and study sample analysis /ICHM10 - validation of bioanalytical methods and analysis of study samples), and its updates.
G/TBT/N/US/2108	United States	Date of Distribution: 27 March 2024 Deadline for Comments: 28 May 2024	Electrical stimulation devices intended for self-injurious behavior	The Food and Drug Administration (FDA, the Agency, or we) is proposing to ban electrical stimulation devices (ESDs) intended for self-injurious behavior (SIB) or aggressive behavior (AB). FDA has determined these devices present an unreasonable and substantial risk of illness or injury that cannot be corrected or eliminated by labeling. This proposal follows a court decision vacating a prior ban and amendment to the Federal Food, Drug, and Cosmetic Act clarifying our authority to ban a device for one or more intended uses. This action, if finalized, will mean ESDs for SIB and AB are adulterated and not legally marketed.

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