29 May 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 18 to 24 May 2024.

Relative thereto, we respectfully invite stakeholders to comment on the notified draft technical regulations from Ecuador, Philippines, Brazil, United States, Israel, Russian Federation and United States :

Document Symbol	Notifying Member	Relevant Dates	Products Covered	Summary
G/TBT/N/ECU/513/Add.1	Ecuador	**Date of Distribution:** 24 May 2024 **Deadline for Comments:** Not indicated	Medicines in general - Addendum	New deadline for the period for receiving observations of the Draft Substitute Technical Health Regulations for Obtaining the Health Registration, Control and Surveillance of Medicines in General for human use. In compliance with the provisions of the Agreement on Technical Obstacles to Trade AOTC and the Decision 827 of the Andean Community CAN, the Republic of Ecuador kindly informs that a period is granted for the reception of observations to the Project of Substitute Technical Health Regulations for Obtaining the Health Registration, Control and Surveillance of General Medicines for human use.
G/TBT/N/PHL/271/Rev.1	Philippines	**Date of Distribution:** 24 May 2024 **Deadline for Comments:** 15 June 2024	Drug distributors and drug retail outlets - Revision	These guidelines shall apply to all local drug establishments engaged in distribution, importation, exportation, and retailing of drug products including household remedy, medicinal gas, traditional and herbal medicines, non-sterile and sterile vaccines, biologicals and raw materials used to produce pharmaceutical products for human and animal use. These guidelines shall also apply to Good Distribution and Storage Practices (GDSP) inspectorate service of the FDA's Field Regulatory Operations Office (FROO) for uniformity of regulatory understanding consistent with the provisions of RA No. 3720, as amended by RA No. 9711, RA no. 11032, and relevant national and international standards and policies.
G/TBT/N/BRA/1541	Brazil	**Date of Distribution:** 23 May 2024	Clinical trials with medicines	This Draft Resolution contains provisions on Regulation for carrying out clinical trials with medicines in Brazil.This Draft

		Deadline for Comments: 4 July 2024		Resolution follows guidelines from the International Council for Harmonization (ICH).
G/TBT/N/USA/2105/Add.1	United States	**Date of Distribution:** 23 May 2024 **Deadline for Comments:** 9 August 2024	New animal drugs labeling - Addendum	The Food and Drug Administration (FDA or the Agency) is extending the comment period for the proposed rule entitled "Labeling Requirements for Approved or Conditionally Approved New Animal Drugs" published in the Federal Register of 12 March 2024, by 60 days. The Agency is taking this action in response to a request for an extension to allow interested persons additional time to submit comments.FDA is extending the comment period on the proposed rule published 12 March 2024 (89 FR 18262), by 60 days. Either electronic or written comments must be submitted by 9 August 2024.Title 21 Code of Federal Regulations (CFR) Parts 201500501510514, and 516This extension of comment period and the proposed rule notified as G/TBT/N/USA/2105 are identified by Docket Number FDA-2023-N-5160. The Docket Folder is available on Regulations.gov at https://www.regulations.gov/docket/FDA-2023-N-5160/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. WTO Members and their stakeholders are asked to submit comments to the USA TBT Enquiry Point. Comments received by the USA TBT Enquiry Point from WTO Members and their stakeholders by 4pmEastern Time on 9 August 2024 will be shared with FDA and will also be submitted to the Docket on Regulations.gov if received within the comment period.
G/TBT/N/BRA/1056/Add.1	Brazil	**Date of Distribution:** 22 May 2024 **Deadline for Comments:** Not indicated	Medicinal gases - Addendum	Draft Resolution number 889, 24 July 2020 - previously notified through G/TBT/N/BRA/1056 - which establishes technical requirements for the notification, market authorization, and post market authorization for medicinal gases, was adopted as Normative Instruction 301, 17 May 2024 The final text is available only in Portuguese and can be downloaded at: https://antigo.anvisa.gov.br/documents/10181/3428523/IN_301_2024_.pdf/c49403d9-30b3-4716-ad93-51dd514c34be

G/TBT/N/BRA/1057/Add.1	Brazil	**Date of Distribution:** 22 May 2024 **Deadline for Comments:** Not indicated	Medicinal gases - Addendum	Draft Resolution 890, 24 July 2020 - previously notified through G/TBT/N/BRA/1057 - which establishes the lists of medicinal gases subject to notification, was adopted as Resolution 870, 17 May 2024.The final text is available only in Portuguese and can be downloaded at: https://antigo.anvisa.gov.br/documents/10181/3428523/RDC_870_2024_.pdf/f56f27f3-87be-43c0-ac3d-6393ffa4735a
G/TBT/N/ISR/1293/Rev.1	Israel	**Date of Distribution:** 22 May 2024 **Deadline for Comments:** 21 July 2024	Medical electrical equipment - Revision	Revision of the Mandatory Standard SI 60601 part 1, dealing with medical electrical equipment. This draft standard revision adopts the International Standard IEC 60601-1 – Edition 3.2: 2020-08 with a few changes in the normative references that appear in the standard's Hebrew section. The major differences between the old version and this new revised draft standard are an outcome of adopting Amendment 2 to the International Standard. Both the old standard and the new proposed standard will apply from the entry into force of this revision for a transition period of 1 year. During this time, medical electrical equipment may be tested according to any of these standards.
G/TBT/N/RUS/160	Russian Federation	**Date of Distribution:** 22 May 2024 **Deadline for Comments:** 16 June 2024	Medicinal products	The draft amendment to the Decision of the Council of the Eurasian Economic Commission №. 83 of November 3, 2016 envisages the establishment of uniform approaches to the procedures for conducting pharmaceutical inspections of research organizations (testing centers, testing laboratories) for compliance with the requirements of the Rules of Good Laboratory Practice of the Eurasian Economic Union in circulation of medicines.
G/TBT/N/USA/1412/Add.1	United States	**Date of Distribution:** 22 May 2024 **Deadline for Comments:** Not indicated	Ultrasound cyclodestructive device - Addendum	The Food and Drug Administration (FDA, the Agency, or we) is issuing a final order reclassifying the ultrasound cyclodestructive device, a postamendments class III device (product code LZR), into class II (special controls), subject to premarket notification. FDA is also establishing special controls that are necessary to provide a reasonable assurance of safety and effectiveness of the device. FDA is finalizing this reclassification on its own initiative based on valid scientific evidence. For this class II device, instead of a premarket approval

				application, manufacturers may submit a premarket notification, i.e., a 510(k) submission, and obtain FDA clearance of the device before marketing it.This order is effective 20 June 2024.Title 21 Code of Federal Regulations (CFR) Part 886This final amendment; final order and the proposed order notified as G/TBT/N/USA/1412 are identified by Docket Number FDA-2018-N-3074. The docket, which provides access to primary and supporting documents as well as comments received, should be accessible from Regulations.gov at https://www.regulations.gov/docket/FDA-2018-N-3074/document. Documents are also accessible from Regulations.gov by searching the Docket Number.
G/TBT/N/ISR/1343	Israel	**Date of Distribution**: 21 May 2024 **Deadline for Comments:** 20 July 2024	Power-operated lifting platforms	Revision of the Mandatory Standard SI 2252 part 2, dealing with power-operated lifting platforms for persons with impaired mobility. This proposed standard revision adopts the International Standard ISO 9386-2 – First edition: 2000-11-01, with a few changes that appear in the standard's Hebrew section. The major differences between the old version and this new revised draft standard are as follows:Edits the national deviations appear in the standard's Hebrew part;Amend the national normative references that appear in Section 2.Both the old and the new revised standards will apply from entry into force of this revision for 12 months. During this time, products may be tested according to the old or the new revised standard.

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,

Digitally signed by
Catajay Neil Pinuela

NEIL P. CATAJAY
Director