

20 July 2023

### 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](http://www.epingalert.org)) from 08 to 14 July 2023.

Relative thereto, we respectfully invite stakeholders to comment on the six (6) notified draft technical regulations from four (4) WTO Members:

Document Symbol	Notifying Member	Relevant Dates	Products Covered	Summary
<a href="#">G/TBT/N/AR/M/96</a>	Argentina	<p><b>Date of Distribution:</b> 10 July 2023</p> <p><b>Deadline for Comments:</b> 22 August 2023</p>	Veterinary medicines	The draft provides for the possibility of simplifying the procedure for bringing the registration dossier of veterinary medicinal products in line with the requirements of the Rules for certain groups of veterinary medicinal products. The draft also contains technical amendments.
<a href="#">G/TBT/N/ID/N/157</a>	Indonesia	<p><b>Date of Distribution:</b> 11 July 2023</p> <p><b>Deadline for Comments:</b> 08 September 2023</p>	Medicines, biological products and medical devices	Presidential Decree Number 6 of 2023 is a mandate of Government Regulation No. 39 of 2021 regarding Implementation of Halal Product Assurance, article 142 paragraph (4). Government Regulation No. 39 of 2021 regulates the obligations for products that entering, circulating, and traded in the territory of Indonesia is required to have a halal certificate issued by Halal Product Assurance Organizing Agency (BPJPH), Ministry of Religious Affairs. The products regulated by the halal obligations including medicines, biological products and medical

### 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)

				devices that must be halal certified.
<a href="#">G/TBT/N/ISR/1287</a>	Israel	<b>Date of Distribution:</b> 14 July 2023  <b>Deadline for Comments:</b> 11 September 2023	Ophthalmic optics : single-vision and multifocal lenses	The existing Mandatory Standard, SI 798 part 1, dealing with single-vision and multifocal lenses, shall be declared voluntary. This declaration aims to remove unnecessary obstacles to trade and lower trade barriers.
<a href="#">G/TBT/N/ISR/1288</a>	Israel	<b>Date of Distribution:</b> 14 July 2023  <b>Deadline for Comments:</b> 11 September 2023	Ophthalmic optics : power-variation lenses	The existing Mandatory Standard, SI 798 part 2, dealing with power-variation spectacle lenses, shall be declared voluntary. This declaration aims to remove unnecessary obstacles to trade and lower trade barriers.
<a href="#">G/TBT/N/ISR/1289</a>	Israel	<b>Date of Distribution:</b> 14 July 2023  <b>Deadline for Comments:</b> 11 September 2023	Ophthalmic optics : uncut finished lenses	The existing Mandatory Standard, SI 14889, dealing with uncut finished lenses, shall be declared voluntary. This declaration aims to remove unnecessary obstacles to trade and lower trade barriers.
<a href="#">G/TBT/N/PHL/305</a>	Philippines	<b>Date of Distribution:</b> 12 July 2023  <b>Deadline for Comments:</b> 31 July 2023	Drug products and drug substances	A. This Administrative Order is issued to provide the guidelines including the rules and regulations on registration applications for the issuance of FDA authorizations and other certifications for drug products and drug substances. B. Specifically, this AO shall provide the regulatory guidelines for the following: 1. Identification of registrable drug products and drug substances;

				2. Types of registration applications for drug authorization; 3. Regulatory review implemented by the FDA on the applications and the applicable evaluation routes; and 4. Regulatory decisions on the applications.
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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](mailto:BPS@dti.gov.ph) copy [bps.smd@dti.gov.ph](mailto:bps.smd@dti.gov.ph).

Thank you.

Sincerely,

**NEIL P. CATAJAY**  
Director

