

11 June 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 01 to 07 June 2024.

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

Document Symbol	Notifying Member	Relevant Dates	Products Covered	Summary
G/TBT/N/B RA/1504/A dd.1	Brazil	Date of Distribution: 4 June 2024 Deadline for Comments: Not indicated	Biosimilars - Addendum	Draft resolution 1206, 02 October 2023 - previously notified through G/TBT/N/BRA/1504 - which contains provisions on complementary on the registration of biosimilars through the Comparability Development Pathway, was adopted as Resolution 875, 28 May 2024.
<u>G/TBT/N/U</u> <u>SA/1934/A</u> <u>dd.1</u>	United States	Date of Distribution: 4 June 2024 Deadline for Comments: Not indicated	Medical devices subject to administrativ e destruction - Addendum	The Food and Drug Administration (FDA, Agency, or we) is issuing a regulation to implement our authority to destroy a device valued at \$2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation) that has been refused admission into the United States by providing to the owner or consignee notice and an opportunity to appear and introduce testimony prior to the destruction.

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

. MANFOSTE FERDINAND Officer-in-Chalge

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)