27 December 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.epingalert.org) from 10 to 16 December 2022.

Relative thereto, we respectfully invite stakeholders to comment on the five (5) notified draft technical regulations from four (4) WTO Members:

Document Symbol	Notifying Member	Relevant Dates	Products Covered	Summary
G/TBT/N/JPN/745/Add.1	Japan	**Date of Distribution**: 12 December 2022 **Deadline for Comments**: Not Indicated	Pharmaceuticals and medical devices - Addendum	Revision to establish, amend and delete articles under Japanese Pharmacopoeia Eighteenth edition notified in G/TBT/N/JPN/745 has been adopted and published on dated 12 December 2022. Supplement to Japanese Pharmacopoeia, Eighteenth edition in English is planned to be published in due course.
G/TBT/N/KEN/1150/Add.1	Kenya	**Date of Distribution**: 16 December 2022 **Deadline for Comments**: Not Indicated	Aquatic spine boards for recovering casualties in controlled aquatic conditions - Addendum	Kenya would like to inform WTO Members that the Kenya Standard KS 2949:2021 Specification for aquatic spine boards for recovering casualties in controlled aquatic conditions; notified in G/TBT/N/KEN/1150 as DKS 2949:2021 was adopted on 26 August 2022 via gazette notice No.10042 dated 26 August 2022. A copy of the document can be obtained via the following link at a basic fee; https://webstore.kebs.org
G/TBT/N/KEN/1218/Add.1	Kenya	**Date of Distribution**: 15 December 2022	Reusable sanitary towels - Addendum	Kenya would like to inform WTO Members that the KS 2925:2021 Textiles — Reusable sanitary towels —

		Deadline for Comments: Not Indicated		Specification; notified in G/TBT/N/KEN/1218 as DKS 2925:2021 was adopted on 13 May 2022 via gazette notice No. 5475 dated 13 May 2022. A copy of the document can be obtained via the following link at a basic fee; https://webstore.kebs.org
G/TBT/N/PHL/296	Philippines	**Date of Distribution**: 12 December 2022 **Deadline for Comments**: 27 December 2022	Food and drug	The FDA, in cognizance of reliance application, shall leverage its review process to accelerate its regulatory decisions of FDA to provide coherence in the FDA's regulatory system for establishments and products under its jurisdiction Effective implementation of reliance will benefit not only the Agency but also the patients/clients, healthcare providers, Marketing Authorization Holders (MAH) and other stakeholders. This will consequently strengthen post-marketing surveillance and promote continuous improvement in building FDA's institutional capacity towards effectively safeguarding public health.
G/TBT/N/USA/1953	United States	**Date of Distribution**: 12 December 2022 **Deadline for Comments**: 09 March 2023	Investigational new drug applications	The Food and Drug Administration (FDA, the Agency, or we) is proposing to amend its regulations on investigational new drug applications (INDs) to exempt from the IND requirements certain clinical investigations of lawfully marketed foods for human consumption (including both conventional foods and dietary supplements) and cosmetics when the product is to be studied to evaluate its use as a drug. Under the proposal, clinical studies to evaluate a

				drug use of such products would not have to be conducted under an IND when, among other things, the study is not intended to support a drug development plan or a labeling change that would cause the lawfully marketed product to become an unlawfully marketed drug, and the study does not present a potential for significant risk to the health, safety, or welfare of subjects. Though exempt from the IND requirements, such investigations would still be subject to other regulations designed to protect the rights and safety of subjects, including requirements for informed consent and review by institutional review boards (IRBs). By exempting from the IND requirements certain clinical investigations of products lawfully marketed as a food or cosmetic, the proposed provisions are intended to reduce the regulatory burden of conducting such studies while retaining protections for human subjects.

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,

Catajay Neil Pinuela

NEIL P. CATAJAY
Director