18 October 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) from 30 September to 06 October 2023.

Relative thereto, we respectfully invite stakeholders to comment on the seven (7) notified draft technical regulations from five (5) WTO Members:

Document Symbol	Notifying Member	Relevant Dates	Products Covered	Summary
G/TBT/N/BRA/1504	Brazil	**Date of Distribution**: 05 October 2023 **Deadline for Comments**: 24 November 2023	Biosimilars	This Draft Resolution contains provisions on complementary on the registration of biosimilars through the Comparability Development Pathway
G/TBT/N/BRA/1505	Brazil	**Date of Distribution**: 04 October 2023 **Deadline for Comments**: 24 November 2023	Biological products	This Draft Resolution contains provisions on post-market registration changes and cancellation of market registration of biological products in order to optimize the modification protocol process and its analysis by Anvisa.
G/TBT/N/KOR/1172	Republic of Korea	**Date of Distribution**: 04 October 2023 **Deadline for Comments**: 02 December 2023	Pharmaceuticals	The Ministry of Food and Drug Safety (MFDS) is proposing to amend the "Regulation for Pharmaceutical Approvals, Notifications and Reviews" as follows: A It will be allowed to use food raw materials in enteric nutritional supplements (Article 3 of the Draft) B. Expansion of the scope of minor changes that do not require approval (Article 3-2 of the Draft) C. Clarification of exemption from submission requirement

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)

				of Certificate of Pharmaceutical Product (CPP), deletion of CPP for Common Technical Documents submission requirements (Articles 4, 6, and Annex 3 of the Draft) D. Clarification of approval review data requirements for synthetic peptide drug products (synthetic peptide) that refers to a previously approved peptide drug product of recombinant deoxyribonucleic acid(rDNA) origin(peptide of rDNA origin) (Articles 7, 27, and Appendix 1 of the Draft) E. Exemption from submission of genotoxicity test data if there is no change in the manufacturing process as a drug product already used in Korea (Article 7 of the Draft) F. Acceptance of non-clinical data which utilized appropriate non-clinical data and alternative method instead of animal test as a result of on-site inspection for OECD member countries (Article 7 of the Draft) G. Expansion of the scope of Science Citation Index (SCI) into Science Citation Index Expanded (SCIE) (Articles 7 and 14 of the Draft) H. Establishment of submission standards details for 'Overview of Risk Management Plan' (newly established in Article 7-2 of the Draft and Annex 6-3) I. Expansion of the scope of recognition of multiple specifications for active pharmaceutical ingredients (API) of pharmaceuticals (Article 12 of the Draft) J. Embodying description method of pharmaceuticals

				(Article 13 of the Draft) K. Application to MedDRA to specify precautionary information (Article 17 of the Draft) L. Update of safety and efficacy review standards for injections, ophthalmic solutions, and otic solutions (Articles 25 and 27 of the Draft) M. If a bioequivalence test is not possible or meaningless, it can be replaced with a scientifically valid test (Article 27 of the Draft) N. Update of standards for conducting bioequivalence tests for oral anticancer drugs, etc. (Article 27 of the Draft) O. Exemption from stability data in case of contract manufacture of entire process using the same manufacturing method (Article 28 of the Draft) P. Clarification of documents to be submitted for preliminary review (Newly established in Article 55 of the Draft and Annex 20) Q. Addition of National Essential Medicine (NEM) to expedited review categories (Article 58 of the Draft)
G/TBT/N/KOR/1173	Republic of Korea	**Date of Distribution**: 04 October 2023 **Deadline for Comments**: 02 December 2023	Medical devices	The Ministry of Food and Drug Safety (MFDS) is proposing to amend the "Notification for Placement and Management of Unique Device Identifiers on Medical Devices" as follows: A new UDI-DI (Unique Device Identifiers-Device Identifiers) would not be required if the brand name or model name is changed.
G/TBT/N/NZL/129	New Zealand	**Date of Distribution**: 02 October 2023	Medicinal cannabis	Medicinal cannabis products supplied in New Zealand are required to meet the labelling requirements outlined in regulation 19 of the Misuse of Drugs (Medicinal Cannabis)

		Deadline for Comments: 30 November 2023		Regulations 2019. The Ministry of Health is proposing a technical amendment to regulation 19 to add a reference to the requirement for medicinal cannabis products to display a controlled drug classification statement on the label to align with the labelling of all other controlled drugs supplied as medicines in New Zealand. This requirement is already in place and enforced under the Misuse of Drugs Regulations 1977. The proposed change is a clarifying amendment and not a substantive change in regulation. The technical amendment will reflect the existing guidance issued in Section 3.2.2. of the 'Guideline on the regulation of medicinal cannabis in New Zealand: Part 3' and the 'Guideline on the Regulation of Therapeutic Products in New Zealand Part 5' Section 2.2 and Figure A.
G/TBT/N/THA/685/Add.1	Thailand	**Date of Distribution**: 06 October 2023 **Deadline for Comments**: Not Indicated	Hygienic mask - Addendum	This addendum is to inform that the Notification of the Committee on Labels entitled Determination of Hygienic Mask as Label-Controlled Products entered into force on 8 August 2023.
G/TBT/N/USA/2054	United States	**Date of Distribution**: 04 October 2023 **Deadline for Comments**: 04 December 2023	In vitro diagnostic test systems	The Food and Drug Administration (FDA, the Agency, or we) is proposing to amend its regulations to make explicit that in vitro diagnostic products (IVDs) are devices under the Federal Food, Drug, and Cosmetic Act (FD&C Act) including when the manufacturer of the IVD is a laboratory. In conjunction with this amendment, FDA is proposing a policy under which FDA intends to phase out its general enforcement discretion

				approach for laboratory developed tests (LDTs) so that IVDs manufactured by a laboratory would generally fall under the same enforcement approach as other IVDs. FDA is proposing this phaseout to better protect the public health by helping to assure the safety and effectiveness of LDTs. If finalized, this phaseout may also foster the manufacturing of innovative IVDs for which FDA has determined there is a reasonable assurance of safety and effectiveness.

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