WORLD TRADE ORGANIZATION

G/TBT/N/PHL/289

1 June 2022

(22-4141)

Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1.	**Notifying Member:** PHILIPPINES **If applicable, name of local government involved (Article 3.2 and 7.2):**
2.	**Agency responsible:** DR. OSCAR G. GUTIERREZ, JR., MPA Officer-in-Charge Director General Food and Drug Administration DEPARTMENT OF HEALTH **Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above:** Jesusa Joyce N. Cirunay, RPh Director IV Center for Drug Regulation and Research Food and Drug Administration DEPARTMENT OF HEALTH Email: cdrr.od@fda.gov.ph www.fda.gov.ph
3.	**Notified under Article 2.9.2 [X], 2.10.1 [ ], 5.6.2 [ ], 5.7.1 [ ], 3.2 [ ], 7.2 [ ], other:**
4.	**Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** Investigational products used in clinical trials for public health emergency, rare disease, cancer HIV/AIDS and emerging and re-emerging infectious disease of public health threats
5.	**Title, number of pages and language(s) of the notified document:** Guidelines on Regulatory Reliance on the Conduct of Clinical Trials in the Philippines; (6 page(s), in English)
6.	**Description of content:** The proposed issuance aims to provide guidelines on reliance for approval of clinical trials and to promote a more efficient and effective approach to the regulations in the oversight of the conduct of clinical trials in the Philippines.
7.	**Objective and rationale, including the nature of urgent problems where applicable:** The FDA recognizes that reliance will further streamline the review process and accelerate the conduct of clinical trials in the country. Streamlined processes will boost local competitiveness and attract more local and foreign sponsors. This will facilitate the evaluation and improve access of investigational drug products for public health emergency, rare disease, cancer HIV/AIDS and emerging and re-emerging infectious disease of public health threats

8.	**Relevant documents:** • Republic Act No. 9711 "Food and Drug Administration (FDA) Act of 2009" • Administrative Order No. 2020-0010 "Regulations on the Conduct of Clinical Trials for Investigational Products" • World Health Organization (WHO) Technical Report Series, No. 1033, 2021 (annex 10, Good reliance practices in the regulation of medical products: high level principles and considerations) • International Council for Harmonization (ICH) Guidelines E6 (R2): Good Clinical Practice • International Council for Harmonization (ICH) Guidelines E17: General Principles for Planning and Design of Multi-Regional Clinical Trials
9.	**Proposed date of adoption:** This Circular shall take effect fifteen (15) calendar days after publication in one (1) newspaper of general circulation and upon filing with the University of the Philippines, Office of the National Administrative Register (ONAR) **Proposed date of entry into force:** Upon effectivity
10.	**Final date for comments:** 3 June 2022
11.	**Texts available from: National enquiry point [X] or address, telephone and fax numbers and email and website addresses, if available, of other body:** Mr. Neil P. Catajay Director Bureau of Philippine Standards Department of Trade and Industry 3F Trade and Industry Building 361 Sen. Gil Puyat Avenue Makati City Philippines Tel: (632) 751 4700; (632) 7913128 Email: bps@dti.gov.ph Website: http://www.bps.dti.gov.ph https://members.wto.org/crnattachments/2022/TBT/PHL/22_3815_00_e.pdf https://members.wto.org/crnattachments/2022/TBT/PHL/22_3815_01_e.pdf https://members.wto.org/crnattachments/2022/TBT/PHL/22_3815_02_e.pdf https://members.wto.org/crnattachments/2022/TBT/PHL/22_3815_03_e.pdf