WORLD TRADE ORGANIZATION

G/TBT/N/PHL/323

26 January 2024

(24-0591)

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. SAMUEL A. ZACATE 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:** MS. IRENE V. FLORENTINO-FARIÑAS, RPh., MD, MNSA Director III, Policy and Planning Service Food and Drug Administration DEPARTMENT OF HEALTH Email: pfpid@fda.gov.ph; iffarinas@fda.gov.ph; BPS@dti.gov.ph; BPS.SMD@dti.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):** Domestic safety (ICS code(s): 13.120)
5.	**Title, number of pages and language(s) of the notified document:** Guidelines on the Recall of Health Products Regulated by the Food and Drug Administration; (13 page(s), in English)
6.	**Description of content:** The regulatory landscape of health products has changes significantly that the initially issued Guidelines on Product Recall needs to be revised. This Circular is hereby promulgated to create an updated framework for the recall of products in pursuit of public health and safety.
7.	**Objective and rationale, including the nature of urgent problems where applicable:** This Circular intends to establish a guideline on the recall of health products and effectively contribute in ensuring the safety and protection of the general public which present a substantial risk of injury, illness, and/or gross deception. Specifically, this Circular aims to: A. Strengthen the recall system for health products under the jurisdiction of the FDA; B. Specify the responsibilities and reporting obligations of the MAH in the conduct of product recall; and C. Provide guidance to MAH in conducting effective recalls.; Protection of human health or safety

8.	**Relevant documents:** • Republic Act (RA) No. 9711 or the "Food and Drug Administration Act of 2009" and its Implementing Rules and Regulations (IRR) • FDA Circular (FC) No. 2016-012 or the "Guidelines on Product Recall"
9.	**Proposed date of adoption:** 1 April 2024 **Proposed date of entry into force:** This Circular shall take effect after fifteen (15) days following the publication in the Official Gazette or in a newspaper of general circulation and filing with the Office of the National Administrative Register of the UP Law Center.
10.	**Final date for comments:** 24 February 2024
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://www.fda.gov.ph/draft-for-comments-guidelines-on-the-recall-of-health-products-regulated-by-the-food-and-drug-administration/ https://members.wto.org/crnattachments/2024/TBT/PHL/24_00744_00_e.pdf https://members.wto.org/crnattachments/2024/TBT/PHL/24_00744_01_e.pdf https://members.wto.org/crnattachments/2024/TBT/PHL/24_00744_02_e.pdf https://members.wto.org/crnattachments/2024/TBT/PHL/24_00744_03_e.pdf