WORLD TRADE ORGANIZATION

G/TBT/N/PHL/305

12 July 2023

(23-4699)

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:** 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 ; cdrr.sds@fda.gov.ph ; bps@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):** Health care technology (ICS code(s): 11); Food technology (ICS code(s): 67); Chemical technology (ICS code(s): 71)
5.	**Title, number of pages and language(s) of the notified document:** Draft Administrative Order "Rules and Regulations on the Issuance of Authorization for Registration Applications of Drug Products and Drug Substances by the Food and Drug Administration"; (22 page(s), in English)
6.	**Description of content:** A. This Administrative Order is issued to provide the guidelines including the rules and regulations on registration applications for the issuance of FDA authorizations and other certifications for drug products and drug substances. B. Specifically, this AO shall provide the regulatory guidelines for the following: 1. Identification of registrable drug products and drug substances; 2. Types of registration applications for drug authorization; 3. Regulatory review implemented by the FDA on the applications and the applicable evaluation routes; and 4. Regulatory decisions on the applications.

7.	**Objective and rationale, including the nature of urgent problems where applicable:** improve efficiency and adopt digitalization in government regulatory services
8.	**Relevant documents:** ● Administrative Order No. 67 s. 1989: Revised Rules and Regulations on Registration of Pharmaceutical Products; ● Administrative Order No. 96 s. 1990: Guidelines on the Registration of Fixed-Dose Combination Drug Products; ● Administrative Order No. 117 s. 1992: Providing for the Classification of Household Remedies; ● Administrative Order No. 23-c s. 2000: Policies and Guidelines on Over-the-Counter (OTC) Drug Products; ● Administrative Order No. 142 s. 2004: Bureau of Food and Drugs (BFAD)'s issuance of Certificate of Product Registration for Foreign Assisted Projects Procurement and Laboratory Testing of Pharmaceutical and Biological products Procured by and/or delivered to the Department of Health; ● Administrative Order No. 172 s. 2004: Guidelines on the Registration of Herbal Medicines; ● Administrative Order No. 184 s. 2004: Guidelines on the Registration of Traditionally-Used Herbal Products; ● Administrative Order No. 2005-0007: Amending Administrative Order No. 142, s. 2004 by providing exemption from the requirement of Certificate of Product Registration for all goods procured through UNICEF, UNDP, WHO, and GDF; ● Administrative Order No. 2005-0030: Guidelines and Procedure for the Automatic Renewal of the Certificate of Product Registration issued by the Bureau of Food and Drugs; ● Administrative Order No. 2005-0031: Guidelines and Procedure for the Issuance of the Principal Certificate of Product Registration and the Listing of Identical Drug Products based on the Identity of Manufacturer and Pharmaceutical Formulation; ● Administrative Order No. 2006-0021: Supplemental Guidelines to Administrative Order (AO) 67 s. 1987, Revised Rules and Regulations on Registration of Pharmaceutical Products and Bureau Circular 05 s. 1997 in evaluating New Drug Applications; ● Administrative Order No. 2016-0008: Revised Rules and Regulations Governing the Generic Labeling Requirements of Drug Products for Human Use; ● Administrative Order No. 2020-0001: Guidelines in the Importation, Facilitation, and Management of Foreign Donations involving Health and Health-Related Products; ● Bureau Circular No. 12 s. 1991: Clarification of New Registration when there is a Change of Manufacturer; ● Bureau Circular No. 5 s. 1997: Revised Checklist of Requirements and the 1997 Guidelines for the Registration of Pharmaceutical Products; and ● FDA Circular No. 2021-020: Revised Post-Marketing Surveillance Requirements for New Drugs under Monitored Release.
9.	**Proposed date of adoption:** To be determined **Proposed date of entry into force:** This Order shall take effect fifteen (15) days after the publication in the Official Gazette or a newspaper of general circulation and filing with the University of the Philippines Office of the National Administrative Register.
10.	**Final date for comments:** 31 July 2023

11. Texts available from: National enquiry point [ ] or address, telephone and fax numbers and email and website addresses, if available, of other body:

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https://www.fda.gov.ph/draft-for-comments-rules-and-regulations-on-the-issuance-of-authorization-for-registration-applications-of-drug-products-and-drug-substances-by-the-food-and-drug-administration/

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