



21 January 2022

(22-0492)

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Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1. Notifying Member: <u>PHILIPPINES</u> If applicable, name of local government involved (Article 3.2 and 7.2):
2. Agency responsible: DR OSCAR G. GUTIERREZ, JR., MPA OIC-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: Irene Florentino-Fariñas, RPh., MD, MNSA OIC-Director, Policy and Planning Service Food and Drug Administration DEPARTMENT OF HEALTH Email: PPS@fda.gov.ph ; iffarinas@fda.gov.ph www.fda.gov.ph
3. Notified under Article 2.9.2 [X], 2.10.1 [], 5.6.2 [], 5.7.1 [], other:
4. Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable): Health products
5. Title, number of pages and language(s) of the notified document: Draft FDA Circular "Categorization of Identified Borderline Health Products under the Jurisdiction of the Food and Drug Administration (FDA)" (30 page(s), in English)
6. Description of content: This Circular aims to provide guidance in the categorization of borderline health products under the jurisdiction of the FDA by: A. Providing the preliminary list of borderline products and their designated product categories; B. Reiterating the considerations in determining product classification; and, C. Providing the appropriate transitory period to allow the proper reclassification of borderline health products.
7. Objective and rationale, including the nature of urgent problems where applicable: Protection of human health or safety
8. Relevant documents: Republic Act (RA) No. 3720, "Food, Drugs and Devices, and Cosmetics Act" as amended by Executive Order (EO) No. 175 and RA 9711

9. Proposed date of adoption: This Circular shall take effect fifteen (15) days following the completion of its publication in a newspaper of general circulation and/or filing of a copy of which to the University of the Philippines Office of the National Register.

Proposed date of entry into force: This Circular shall take effect fifteen (15) days following the completion of its publication in a newspaper of general circulation and/or filing of a copy of which to the University of the Philippines Office of the National Register.

10. Final date for comments: 27 January 2022

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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