WORLD TRADE ORGANIZATION

G/TBT/N/PHL/302/Rev.1

3 May 2024

(24-3550)

Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

Revision

The following notification is being circulated in accordance with Article 10.6.

1.	**Notifying Member:** PHILIPPINES **If applicable, name of local government involved (Articles 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):** Pharmaceutics (ICS code(s): 11.120)
5.	**Title, number of pages and language(s) of the notified document:** Draft Food and Drug Administration (FDA) Circular "Guidelines on the Importation and Exportation Notification for Pharmaceutical Products and Raw Materials"; (7 page(s), in English)
6.	**Description of content:** FDA Memorandum Circular (FMC) No. 2013-032, entitled "Requirements for the Immediate Release of Products Covered by the FDA at the Bureau of Customs", was issued, wherein only valid FDA License to Operate (LTO) and Certificate of Product Registration (CPR) were required to be presented to the Bureau of Customs (BOC) for the release of pharmaceutical products. However, there is a need to strengthen market control within the distribution chain through measures to ensure that the public only receives quality-assured pharmaceutical products. The infiltration of substandard and counterfeit pharmaceutical products into the supply system shall be prevented through risk-based surveillance schemes and rigorous control. Therefore, as part of the FDA's powers and functions under RA No. 9711, requiring the concerned pharmaceutical establishments to notify each importation/exportation of pharmaceutical products and raw materials is necessary to strengthen the FDA's overall market surveillance and control

regulatory function.

In the interest of public health, importation and exportation activities relative to pharmaceutical products and raw materials shall be regulated and monitored by the FDA. Hence, issuance of this Circular is imperative in ensuring consistency and effectiveness of these regulatory activities.

7. **Objective and rationale, including the nature of urgent problems where applicable:** Protection of human health or safety

8. **Relevant documents:**

- Implementing Rules and Regulation (IRR) of RA No. 9711: Food and Drug Administration (FDA) Act of 2009
- FDA Memorandum Circular (FMC) No. 2013-032: Requirements for the Immediate Release of Products covered by the FDA at the Bureau of Customs

9. **Proposed date of adoption:** To be determined

Proposed date of entry into force: To be determined

10. **Final date for comments:** 20 May 2024

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

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https://www.fda.gov.ph/draft-for-comments-guidelines-on-the-importation-and-exportation-notification-for-pharmaceutical-products-and-raw-materials/

https://members.wto.org/crnattachments/2024/TBT/PHL/24_02967_00_e.pdf
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