WORLD TRADE ORGANIZATION

G/TBT/N/PHL/302

26 May 2023

(23-3618)

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):** 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 for the Importation and Exportation of Finished Drug Products and Raw Materials"; (6 page(s), in English)
6.	**Description of content:** The proposed policy aims to provide detailed guidelines and clear procedures in the issuance of Clearance for Customs Release (CFCR) for finished drug products and raw materials and to conduct inspections of entry/exit ports authorized by the Bureau of Customs (BOC) for finished drug products and raw materials. This proposed policy shall apply to all FDA-licensed drug establishments [Manufacturer/Trader/Distributor (Importer/Exporter)] involved in the manufacture, importation, and exportation of finished drug products and raw materials intended for distribution. However, it shall not cover drug products and raw materials used in clinical trials/product development/research, drug products for personal use, donations, and under Compassionate Special Permit, and shall be processed based on existing rules and regulations.

7. Objective and rationale, including the nature of urgent problems where applicable:

Republic Act (RA) No. 9711, otherwise known as the "Food and Drug Administration (FDA) Act of 2009", mandates the FDA to regulate and subsequently issue appropriate authorizations to establishments engaged in the manufacture, distribution, importation, exportation and retailing of health products, among others.

Article I Section 6 (Requirements for Every Incoming Shipment of Health Products) of the Book II of the Implementing Rules and Regulation (IRR) of RA No. 9711, states that "*The FDA in coordination with the Bureau of Customs, Bureau of Quarantine and other concerned agencies is mandated to undertake and adopt measures relating to importation of health products such as, but not limited to, sampling and examination, in accordance with relevant existing laws and regulations, of every incoming shipment of health products".* The FDA hereby issued FDA Memorandum Circular (FMC) No. 2013-032 wherein a valid License to Operate (LTO) and Certificate of Product Registration (CPR) are required for the release of drug products. However, there is a need to strengthen market control within the distribution chain through additional measures to ensure that the public only receive quality-assured drug products. The infiltration of substandard and falsified drug products into the supply system shall be prevented through risk-based surveillance scheme and rigorous control. Therefore, as part of the FDA's powers and functions under RA No. 9711, issuance of appropriate authorization such as import/export clearance is necessary to strengthen the FDA's overall market surveillance and control regulatory function.

In the interest of public health, import/export activities related to drug products need to be controlled and under the proper oversight of the FDA. Issuance of this guidelines is imperative to ensure the consistency and effectiveness of these regulatory activities.

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: 23 June 2023

11. Texts available from: National enquiry point [X] 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-guidelines-for-the-importation-and-exportation-of-finished-drug-products-and-raw-materials/

https://members.wto.org/crnattachments/2023/TBT/PHL/23_09836_00_e.pdf
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