

**FDA ADVISORY**  
No. **2023-2239**

17 OCT 2023

**TO : ALL MARKETING AUTHORIZATION HOLDERS OF DRUG PRODUCTS AND OTHER CONCERNED STAKEHOLDERS**

**SUBJECT : Effectivity of FDA Circular (FC) No. 2023-008, entitled, "Guidelines on the Publishing of Package Insert and Patient Information Leaflet of Registered Drug Products in the Food and Drug Administration (FDA) Verification Portal System"**

This is to inform all Marketing Authorization Holders (MAHs) of drug products and other concerned stakeholders that FDA Circular (FC) No. 2023-008 entitled "*Guidelines on the Publishing of Package Insert and Patient Information Leaflet of Registered Drug Products in the Food and Drug Administration (FDA) Verification Portal System*" was published on a newspaper, *The Manila Times*, on 11 October 2023, thus, shall be effective on **26 October 2023**.

In line with the effectivity of the FC, MAHs of all existing registered drug products shall submit the latest approved facsimile/soft copy of Package Insert (PI) and Patient Information Leaflet (PIL) through email at [cdr.label@fda.gov.ph](mailto:cdr.label@fda.gov.ph), in accordance to the following respective schedules:

<b>Drug Products</b>	<b>Submission Schedule</b>
Monitored Release Status (Chemical/Biological) (including Monitored Release turned Initial status)	26 October 2023- 25 December 2023
Generic Prescription Drug	26 December 2023- 25 June 2024
Biologicals	26 June 2024 - 25 July 2024
Over-the-Counter Drug	26 July 2024 - 25 October 2024
Traditional Medicine/Herbal Medicine/Home Remedy/ Veterinary Drug	26 October 2024 – 25 November 2024

The FDA advises and encourages all stakeholders, healthcare professionals, and the general public to utilize the FDA Verification Portal System to access the list of registered products and the available package inserts and patient information leaflet.

For inquiries or clarification, you may email the Center for Drug Regulation and Research at [cdr.od@fda.gov.ph](mailto:cdr.od@fda.gov.ph).

  
**DR. SAMUEL A. ZACATE**  
Director General

