Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 2023-0771

05 MAY 2023

TO : **ALL MANUFACTURERS, TRADERS AND DISTRIBUTORS OF BIOSIMILAR PRODUCTS AND CONCERNED STAKEHOLDERS**

SUBJECT : **Adoption of the World Health Organization Updated Guidelines on the Evaluation of Similar Biotherapeutic Products (SBPs) in Compliance with Administrative Order No. 2014-0016**

This is to inform concerned stakeholders of the compliance to Administrative Order (AO) No. 2014-0016 entitled Adoption of the World Health Organization, "Guidelines on Evaluation of Similar Biotherapeutic Products (SBPs)" for the Registration of Biosimilar Products which directs all manufacturers, traders and distributors (exporters, importer, wholesaler) of biosimilar products to adopt the current version of the WHO "Guidelines on Evaluation of Biosimilars" (2022).

Likewise, Section V.1 of the said AO states that all supplements and revisions related to the WHO "Guidelines on Evaluation of Similar Biotherapeutic Products (SBPs)" shall be adopted automatically.

To provide updated globally acceptable principles for the licensing of biological products that are similar to biological products of assured quality, safety and efficacy, the WHO Expert Committee on Biological Standardization on its seventy-fifth meeting on 4-8 April 2022 adopted the new guidelines on evaluation of biosimilars as replacement to the Annex 2 of WHO Technical Report Series No. 977.

This Advisory is being issued to provide guidance on the strict compliance with AO No. 2014-0016. The updated WHO *"Guidelines on Evaluation of Biosimilars"* dated 22 April 2022, can be accessed at the FDA official website through this link: https://www.fda.gov.ph/wp-content/uploads/2023/03/WHO-Guidelines-on-SBPs-Annex-3.pdf

Dissemination of this advisory to all concerned is hereby requested.

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