

FDA ADVISORY
No. ~~2025-0030~~

15 JAN 2025

TO : ALL FDA-LICENSED DRUG MANUFACTURERS, TRADERS, DISTRIBUTORS, AND OTHER CONCERNED STAKEHOLDERS

SUBJECT : Effectivity of Administrative Order No. 2024-0013 entitled "General Rules and Regulations on the Registration of Pharmaceutical Products and Active Pharmaceutical Ingredients Intended for Human Use"

Notice is hereby given to all FDA-licensed drug establishments and concerned stakeholders of pharmaceutical products and active pharmaceutical ingredients (APIs) for human use that Administrative Order (AO) No. 2024-0013 was published in the newspaper, *The Manila Times*, on 26 November 2024 and made effective on **11 December 2024**.

The signed copy of the AO and its annexes may be accessed from the FDA Website at <https://www.fda.gov.ph/administrative-order-no-2024-0013-general-rules-and-regulations-pharmaceutical-products-and-ingredients-intended-for-human-use-on-the-registration-of-active-pharmaceutical/>

All current Certificate of Product Registration (CPR) holders of pharmaceutical products and foreign donations approved under the previously existing guidelines shall be valid until expiration. Renewal and variation applications shall follow and be covered by the rules of AO No. 2024-0013 through its implementing guidelines.

Pending the issuance of the implementing guidelines, the existing regulations shall continue to be followed.

For inquiries or clarification, you may email the Center for Drug Regulation and Research at cdrr.od@fda.gov.ph

Dissemination of this Advisory to all concerned is hereby requested.

DR. SAMUEL A. ZACATE
Director General

