

## ANNOUNCEMENT

**TO :** ALL DRUG ESTABLISHMENTS AND THE GENERAL PUBLIC

**SUBJECT :** **DRAFT FOR COMMENTS | Prescribing the Guidelines on Good Manufacturing Practice (GMP) for Drug Manufacturers Repealing AO No. 2013-0022**

**Date :** 15 March 2024

The Food and Drug Administration through the Policy and Planning Service is hereby posting the attached proposed Administrative Order titled, “Prescribing the Guidelines on Good Manufacturing Practice (GMP) for Drug Manufacturers Repealing AO No. 2013-0022” for comments.

The proposed Administrative Order aims to:

- A. Further reengineer the FDA’s process and procedures covering initial and re-issuance applications for Good Manufacturing Practices (GMP) affirming the integration of information and communication technologies (ICT) to maximize a focus on risks, promote coordination and information-sharing, and ensure an optimal use of resources;
- B. Ensure that regulatory rules, including specific requirements, and processes for applications, evaluation, regulatory decisions on inspection are clear, thereby providing coherence in the FDA’s regulatory systems and procedures for pharmaceutical manufacturers and distributors, and that the obligations of the covered pharmaceutical establishments, and their respective qualified officers are clearly articulated; and
- C. Promote transparency and compliance by updating the GMP guidance, list of documentary and technical requirements for GMP applications, specifically for the pharmaceutical industry and because of the recent WHO audit and preparation to other local or international audits.

It is in this view that the FDA respectfully seeks the comments of all covered pharmaceutical establishments including Manufacturers, Importers, and Distributors to the proposed Administrative Order using the “Comment Form Template” attached herein.

All comments are requested to be submitted in MS Word and PDF Format via e-mail to [pfpid@fda.gov.ph](mailto:pfpid@fda.gov.ph) on or before 16 April 2024, otherwise, inputs will no longer be considered.

Thank you very much.



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