



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



FDA ADVISORY

No. ~~2023-0258~~

15 FEB 2023

TO : ALL CONCERNED STAKEHOLDERS

SUBJECT : Implementation of the Pharmaceutical Inspection Cooperation Scheme (PIC/S) Guide for Good Manufacturing Practice (GMP) for Medicinal Products in Compliance with DOH Administrative Order No. 2012-0008

This is in compliance with Administrative Order No. 2012-0008 (AO 2012-0008), or the rules on “Adoption and Implementation of the Pharmaceutical Inspection Cooperation Scheme (PIC/S) Guide for Good Manufacturing Practice (GMP) for Medicinal Products.” According to Section VI of the said Administrative Order, all supplements and revisions related to the PIC/S GMP Guides shall be adopted automatically.

In line with this, the Food and Drug Administration (FDA) reiterates the conformity of all involved stakeholders. Effective 15 January 2023, strict compliance with the PIC/S GMP Guide Version No. PE 009-14 shall be imposed.

Further, involved stakeholders are expected to make the necessary preparation and transition towards the adoption of the PIC/S Guide Version No. PE 009-16 for its implementation as determined by the FDA through a separate issuance of an Advisory.

For everyone’s information, guidance and strict compliance.


DR. SAMUEL A. ZACATE
Director General

