FDA CIRCULAR
No:_____

Subject: **Guidelines on the Classification of Deficiencies Observed During Inspection of Drug Distributors, Drugstores, Hospital Pharmacies and Retail Outlet for Non-Prescription Drugs (RONPD)**

I. RATIONALE

Republic Act (RA) No. 3720 or the Food, Drug, and Cosmetic Act, as amended by Executive Order No. 175, s. 1987 and RA No. 9711 or the Food and Drug Administration (FDA) Act of 2009, declared that it is within the policy of the State to adopt, support, establish, institutionalize, improve and maintain structures, processes, mechanisms, and initiatives that are aimed, directed and designed to help establish and maintain an effective health products regulatory system. Pursuant to the foregoing laws, the State, through the Food and Drug Administration, must enhance its regulatory capacity and strengthen its capability with regard to the inspection, licensing, and monitoring of establishments, as well as registration and monitoring of health products.

In order to align with the international level of standard for Good Distribution and Storage Practice, Administrative Order no. 2013-0027 "Adoption and Implementation of World Health Organization Good Distribution and Storage Practice for Pharmaceutical Products" and FDA Circular 2021-003 "Revised Guidelines on the Cold Chain Management of Pharmaceutical Products and Establishments" were issued.

Consequently, to achieve the objectives of RA No. 9711 of ensuring the FDA's monitoring and regulatory coverage over, and providing coherence in the FDA's regulatory system, it is imperative that the classification of deficiencies noted during inspection of drug distributors, drugstores, hospital pharmacies and retail outlets for non-prescription drugs are consistent and guided with distribution and storage practices considered non-compliant with FDA-implemented rules/standards in the distribution of drug products.

Finally, in compliance with the declared policy of the State laid down in Republic Act No. 11032 or the Ease of Doing Business and Efficient Government Service Delivery Act of 2018 to promote integrity, accountability, establish effective practices, aimed at efficient turnaround of the delivery of government services and the prevention of graft and corruption in government, the FDA is committed to take appropriate measures to promote transparency.

II. OBJECTIVE

This Circular is issued to provide uniform understanding in the classification of noted non-conformances during inspection of Drug Distributors, Drugstore, Hospital Pharmacies and Retail Outlets for Non-Prescription Drugs and to guide the drug distributors and retail outlets

on Good Distribution and Storage Practices (GDSP) inspection being performed by the inspectorate service of FDA's Field Regulatory Operations Office.

III. SCOPE

These guidelines shall apply to all local drug establishments engaged in distribution, importation, exportation, and retailing of drug products including household remedy, medicinal gas, traditional and herbal medicines, non-sterile and sterile vaccines, biologicals and raw materials used to produce pharmaceutical products for human and animal use.

These guidelines shall also apply to Good Distribution and Storage Practices (GDSP) inspectorate service of the FDA's Field Regulatory Operations Office (FROO) for uniformity of regulatory understanding consistent with the provisions of RA No. 3720, as amended by RA No. 9711, RA no. 11032, and relevant national and international standards and policies.

IV. DEFINITION OF TERMS

A. **Deficiency** – failure to meet with the standards set for GDSP and other related laws, rules and regulation due to lacking requirements and/or non-conformances observed during inspections of Drug Distributors, Drugstore, Hospital Pharmacies and Retail Outlets for Non-Prescription Drugs (RONPD).

B. **Critical deficiency** - is a departure from the Good Distribution and Storage Practices (GDSP) Guide that led or may lead to a significant risk of causing a pharmaceutical product to be harmful to human or animal patients or public health.

It also covers findings of the establishment's or its agent's commission of fraud, misrepresentation or falsification of products, records or data, or withhold any relevant data contrary to the provision of law, rules and regulations or appropriate standards.

C. **Major deficiency** – this indicates a major deviation from Good Distribution and Storage Practices that has a direct impact on the quality/ efficacy of pharmaceutical products.

A combination of several "other" deficiencies, none of which may be major, but which together present a major deficiency and should be explained and reported as such.

D. **Others** - a deficiency that is not classified as either "Critical" or "Major", but indicates a deviation from GDSP or a deficiency may be judged as "Other" because there is insufficient information to classify it as "Critical" or "Major".

V. GUIDELINES

A. Deficiencies and non-conformances observed during inspections shall be classified whether critical, major or others based on the above definitions.

B. For reference, a list of classified observations is attached as **ANNEX A.** The list is non-exhaustive and other observations may be added, removed, or re-classified as appropriate, subject to notice to the concerned stakeholders.

C. Upon findings of deficiency classified as critical during inspection, the establishment shall be directed to outright initiate any or all (depending on the assessed degree of risk to patient safety) of the following:

1. Temporarily stop distribution of affected products.

2. Undertake or cause company-initiated recall of affected batches following existing FDA rules and procedure for product recall.

3. Address the deficiencies, including submission of Corrective Action and Preventive Action (CAPA) plan and objective evidence of compliance, not later than fifteen (15) working days reckoned on the day following the receipt of the inspection report.

D. Apart from the foregoing, critical findings shall result in the FDA imposing subsequent regulatory action, including disapproval of the application, or, after notice and hearing, suspension, or revocation of the issued authorization.

E. In case of major and other deficiencies, the inspector shall be authorized to direct the establishment to address the deficiencies, including the submission of CAPA Plan and objective evidence of compliance, not later than fifteen (15) working days reckoned on the day following the receipt of the inspection report.

F. CAPA Plan and objective evidence of compliance shall be submitted to the current/existing FDA's external communication channel/platform.

G. Non-submission of the required CAPA or non-implementation of the FDA-accepted CAPA within the approved timeline shall be dealt with appropriate regulatory actions.

VI. SEPARABILITY CLAUSE

If any portion or provision of this Circular is declared invalid, unenforceable, or unconstitutional, the validity or enforceability of the remaining portions or provisions shall not be affected, and this Circular shall be construed as if it did not contain the particular invalid or unenforceable or unconstitutional portion or provision

VII. REPEALING CLAUSE

All previous issuances which are inconsistent with the provisions of this Circular are hereby repealed, amended or modified accordingly.

VIII. EFFECTIVITY

This Circular shall take effect fifteen (15) days after completion of publication in the Official Gazette or a newspaper of general circulation, upon filing with the University of the Philippines Office of the National Administrative Register.

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Director General