Republic of the Philippines
Department of Health
**FOOD AND DRUG ADMINISTRATION**

14 FEB 2019

**FDA CIRCULAR**
**NO. 2019-003**

**Subject: GUIDELINES FOR THE CLASSIFICATION OF DEFICIENCIES OBSERVED DURING INSPECTION OF DRUG MANUFACTURERS**

## I. RATIONALE

Republic Act (RA) No. 3720, as amended by RA No. 9711, declared it a 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 policy, 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, and the registration and monitoring of health products, such as drug products and drug manufacturers, respectively.

Consequently, and in order to achieve the objective of RA No. 9711 of ensuring the FDA's monitoring and regulatory coverage over, and providing coherence in FDA's regulatory system for drug manufacturers and drug products, it is imperative that classification of deficiencies noted during inspection of drug manufacturers is consistent, and drug manufacturers are guided with manufacturing practices considered non-compliant to FDA-implemented rules/ standards in the manufacture 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.

Hence, this Circular is hereby issued.

## II. OBJECTIVE

This Circular is issued to have uniform understanding in the classification of the noted non-conformances during Good Manufacturing Practice (GMP) inspection of drug manufacturers and provide guidelines to the drug manufacturing inspectorate service of the FDA's Field Regulatory Operations Office, as well as drug manufacturers 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.



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## III. SCOPE

These guidelines shall apply to all local and foreign drug GMP inspection, drug GMP inspectorate, and establishments manufacturing drugs including: household remedy, medicinal gas, traditional and herbal medicines, non-sterile, sterile, vaccines and biologicals, radiopharmaceuticals, blood and blood products and active pharmaceutical ingredients for human and animal use.

## IV. GUIDELINES

For uniformity, efficiency and transparency, non-conformances observed during inspections are classified based on the following definitions:

1. **Critical deficiency -** a deficiency which has produced, or may lead to, a significant risk of producing either a product which is harmful to the human or veterinary patient, or a product which could result in a harmful residue in a food producing animal.

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

2. **Major deficiency** –a deficiency which indicates a major deviation from the terms of the marketing authorization/ product registration, PIC/S Good Manufacturing Practice guide and other internationally accepted standard; or which indicates a failure to carry out satisfactory procedures for release of batches of drugs; or

   - a combination of several "other" deficiencies, none of which on their own may be major, but which may together represent a major deficiency and should be explained and reported as such; or repetitive deviation for two or more consecutive inspections.

3. **Others -** a deficiency which cannot be classified as either critical or major, but which indicates a departure from good manufacturing practice. A deficiency may be "other" either because it is judged as minor, or because there is insufficient information to classify it as major or critical.

For reference a list of observations classified according to the above definitions 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.

Deficiencies with upward-arrow marked (↑) are elevated to the next higher level of deficiency for findings noted in a sterile facility.

In case of findings classified as critical deficiency (ies) the establishment is directed to initiate outright, any or all of the following (depending on the assessed degree of risk to patient safety):

a. Temporarily stop production of affected product line/s and further importation (in case of foreign audit findings) and/or distribution;

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

c. Address the deficiencies, including submission of CAPA plan and objective evidence of compliance, not later than thirty (30) calendar days reckoned on the day following the receipt of the inspection report.

   For foreign drug GMP inspections with drug products already available in the Philippine market, submission of CAPA plan and objective evidence does not apply, and non-issuance of appropriate authorization is imperative as per FDA Circular 2014-016.

Apart from the foregoing, critical findings may result in the FDA imposing subsequent regulatory action, including disapproval of application, suspension or revocation of the issued authorization.

In case of major and other deficiencies, the inspector is authorized to direct the establishment to address the deficiencies, including the submission of CAPA Plan and objective evidence of compliance, not later than forty-five (45) calendar days reckoned on the day following the receipt of the inspection report.

## V. REPEALING AND SEPARABILITY CLAUSES

Any provisions of existing FDA-issued Circulars or Memoranda that are inconsistent with this Circular are hereby repealed, withdrawn and/or revoked accordingly.

If any provision of this Circular or application of such provision to any circumstances is held invalid, the validity of the remainder of the provisions hereof not affected shall continue to be in effect.

## VI. EFFECTIVITY

This Circular shall take effect immediately.

**NELA CHARADE G. PUNO, RPh**
Director General