Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA CIRCULAR
No. 2021-006

18 FEB 2021

SUBJECT: **Interim Guidelines on the Issuance of Certificate of Accreditation and Inspection of Bioequivalence (BE) Testing Centers**

I. RATIONALE/BACKGROUND

Pursuant to Republic Act (RA) No. 9711 and its Implementing Rules and Regulations (IRR), the Food and Drug Administration (FDA) is responsible for the oversight and/or inspection of facilities that conduct BE studies for drug products to ensure compliance with the principles of Good Clinical Practice (GCP) and Good Laboratory Practice (GLP).

In March 2020, the World Health Organization (WHO) declared COVID-19 a global pandemic. The FDA Philippines recognizes that this ongoing pandemic is not only affecting public health, but also posing a crisis in the pharmaceutical sector. Furthermore, this Public Health Emergency of International Concern imposes operational challenges and limitations and renders BE inspections not feasible. Conducting on-site inspections on BE testing facilities located within hospital premises poses a clear health risk to the FDA BE inspectorate.

In light of the current situation, this Circular is hereby issued to provide the interim guidelines on the issuance of a Certificate of Accreditation and inspection of BE testing centers to ensure the safety, efficacy, and quality of generic drug products.

II. OBJECTIVES

Considering the COVID-19 pandemic, this Circular is being issued to provide the interim guidelines on the processing of applications for the accreditation and inspection of BE testing facilities.

III. SCOPE

This Circular shall apply to all incoming and pending initial and renewal accreditation applications of local BE testing facilities.

IV. GUIDELINES

1. The conduct of on-site inspections of BE testing centers is temporarily suspended for a period of one (1) year from the date of effectivity of this issuance, unless sooner revoked. Actual on-site inspections shall be conducted as soon as the declared public health emergency is lifted.
2. In lieu of on-site inspections, remote/virtual inspections shall be conducted using video conferencing platforms (e.g., Google Meet, Zoom) for the following:
   a. Initial applications
   b. Transfer of locations
   c. Renewal applications which may require verification of documents after desktop review
3. Virtual meetings shall be recorded.
4. Applicants shall follow the process of submission provided in the FDA Circular No. 2020-026, *Subject: Food and Drug Action Center (FDAC) New Normal Operational Guidelines of the Food and Drug Administration (FDA).*
5. Applicants are required to submit electronic copies of the following facility- and study-based documents to confirm compliance with GCP and GLP:
   a. Organizational Chart
   b. Certificates of Accreditation and Licenses-to-Operate from relevant agencies
   c. Quality Manual
   d. Personnel Record including curriculum vitae and training records demonstrating sufficient qualifications based on educational background, training, and work experience
   e. Standard Operating Procedures (SOPs), Work Instructions, and forms of all critical processes and activities including interim activities during the COVID-19 pandemic
   f. Records/logbook of instrument and equipment usage, maintenance, calibration, and standardization
   g. Records of environmental monitoring and control (e.g., temperature, relative humidity, pests, microbes)
   h. Memoranda of Understanding/Contracts of Agreements between the Bioavailability Unit and:
      - Duly licensed/accredited 3rd party Screening Laboratory (for hematology, urinalysis, X-ray, ECG, drug testing, etc.)
      - Duly licensed/accredited 3rd party Bioanalytical Facility
      - Other relevant parties involved in biological sample transport, waste disposal, instrument calibration, maintenance, and standardization

      The FDA may require additional documents or evidence to ascertain GCP and GLP compliance.

6. All applications covered by this Circular shall be issued with a Certificate of Accreditation valid for three (3) years pursuant to Administrative Order (AO) No. 2012-0024.

7. Any violation shall be a ground for filing appropriate administrative charges and/or imposition of administrative sanctions such as, but not limited to, imposition of fines, suspension, cancellation, or revocation of the BE accreditation certificate.

V. REPEALING AND SEPARABILITY CLAUSE

Provisions in previous circulars and memoranda that are inconsistent with this Circular are hereby withdrawn, repealed and/or revoked accordingly.

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

VI. EFFECTIVITY

This Circular is an interim guideline during the COVID-19 pandemic in the Philippines and shall take effect immediately, unless otherwise revoked.

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Director General