Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA CIRCULAR
No. 2020-006-B

17 JUL 2020

SUBJECT: FURTHER AMENDMENT TO FDA CIRCULAR NOS. 2020-006 and 2020-006-A ENTITLED "GUIDANCE FOR APPLICATIONS AND TRANSACTIONS AT THE FOOD AND DRUG ADMINISTRATION IN LIGHT OF THE COMMUNITY QUARANTINE DECLARATIONS" ISSUED ON 17 MARCH 2020 AND ITS AMENDMENT ISSUED ON 2 APRIL 2020.

I. RATIONALE

The Food and Drug Administration (FDA) issued Circular No. 2020-006 entitled "Guidance for Applications and Transactions at the Food and Drug Administration in Light of the Community Quarantine Declaration on 17 March 2020 and its amendment, Circular No. 2020-006-A on 2 April 2020 as the Agency's response to the community Quarantine declaration.

On 21 April 2020, Administrative Order (A.O.) No. 30 was issued by the Office of the President directing all heads of departments, agencies, offices, and instrumentalities of the government including Government-Owned or -Controlled Corporations (GOCCs), Government Financial Institutions (GFIs), State Universities and Colleges (SUCs), and LGUs to formulate and issue rules or guidelines on the implementation of Section 4(z) of Republic Act (RA) No. 11469, otherwise known as the "Bayanihan to Heal as One Act".

This Circular is hereby issued to provide supplemental guidance on the interruption of reglementary periods for the commencement of action and claims, filing of pleadings, appearances, motions, notices, and all other papers, and the rendition of judgments, resolutions, and orders for the duration of the community quarantine; cancellation of proceedings and the rescheduling thereof after the lifting of community quarantine; suspension of deadlines for the payment of fees and other charges related to the services and processes of the Food and Drug Administration and other monetary obligations and/or submission of documents, for the duration of community quarantine

II. SCOPE AND COVERAGE

This Circular shall cover all stakeholders applying for FDA authorizations and other stakeholders who are required to submit documents, scheduled to appear at FDA for compliance/meetings, and/or pay appropriate fees and charges.

Likewise covered by this Circular is the commencement of administrative actions including administrative cases pending evaluation, proceedings, or for decisions involving violations of R.A. No. 3720, as amended by R.A. No. 9711 and other FDA-implemented laws rules and regulations.

This Circular does not cover the proceedings and running of reglementary periods for urgent cases which are necessary to enable the FDA to act expeditiously on matters affecting the current public health emergency, such as any coronavirus disease 2019 (COVID-19) related cases (e.g. violations of the imposed price freeze or ceiling on covered products or those cases pertaining to activities or products regulated by FDA without prior authorization intended for or claiming to address the COVID-19).

For purposes of these Guidelines, community quarantine shall mean the Enhanced Community Quarantine, the General Community Quarantine, and local community quarantines declared in accordance with IATF Guidelines.

III. GUIDELINES

A. Matters Pertaining to Payment of Fees, Schedule of Document Submission and Appearance

1. Payment of fees as indicated in the Order of Payment (OP) maybe done thru Over-the Counter payment at FDAC, ON-Coll payment at Land Bank of the Philippines (LBP) branches, or online payment thru Bancnet Online Payment Facility (including LBP bills payment).

   Bancnet Online Payment Facility is available for ePortal applications with FDA-generated Order of Payment only, as stated in FDA Circular No. 2017-010.

2. Extension of submission of relevant documents in compliance with the Notice of Deficiency issued by FDA during facility inspection whose compliance periods will end during the community quarantine shall be within three (3) months from the end of their compliance period. Corrective and Preventive Action (CAPA) Report may be submitted to fdac.letters@fda.gov.ph.

3. Clients who are scheduled to appear at the Food and Drug Action Center (FDAC) during the community quarantine period may do so within three (3) months from their original schedule, provided that the client shall notify the FDAC at least **seven (7) working days** before their desired schedule for proper coordination and arrangement of appearance.

4. Face-to-face interactions, including but not limited to meetings, public consultations, public hearings, and Kapihan shall be rescheduled after the community quarantine or as may be allowed by the existing rules.

5. The use of video conferencing and online meeting applications is encouraged for urgent discussions.

B. Matters Pertaining to Regulatory, Enforcement and Quasi-Judicial Actions

1. The FDA shall continue conducting regulatory actions and enforcement to ensure safety and quality of health products during the community quarantine. This includes but not limited to posting of health advisories for violative products, safety updates, recall for public information.

2. The conduct of all foreign inspections for 2020 shall be deferred until further notice pending the lifting of the travel restrictions being imposed in the Philippines and the other countries concerned. A separate issuance shall be issued for this matter.

3. The reglementary period for filing before the FDA - Legal Service Support Center of complaints, pleadings, appearances, motions, notices and all other papers shall be interrupted for the duration of the community quarantine.

   All concerned parties are given fifteen (15) calendar days from the lifting of the community quarantine to file their respective complaints, pleadings and other papers.

4. The rendition of judgments, resolutions or orders, including the service/execution thereof shall be suspended during the community quarantine and rescheduled once lifted or as may be allowed by the existing rules. However, the preparation or drafting of judgments, resolutions or orders shall proceed as applicable.

5. The foregoing provisions shall not be applicable to urgent cases which are necessary to enable FDA to act expeditiously on matters affecting the current public health emergency like violations of COVID-19-related rules and regulations, including but not limited to: misleading, deceptive, and false claims of health products on the treatment and prevention of COVID-19, selling of essential emergency medical supplies and medicines beyond the price ceiling, and selling, distribution, and use of COVID-19 testing kit without FDA authorization.

C. Release of FDA Market Authorizations and Certificates

1. For Clients within the National Capital Region (NCR), Authorizations may be picked up at FDAC following the Advisory dated July 30, 2019 in Releasing of FDA Authorizations. However, if after ten (10) working days and the Authorization is not yet picked up, this will be mailed thru courier to the registered mailing address of the Company.

2. For Clients outside of the NCR, Authorizations will be mailed thru courier to the respective Regional Field Office (RFO) which has jurisdiction over the concerned Company.

3. Request for scanned copy of LTOs and CPRs and sending the same thru email will no longer be facilitated. NCR Clients can secure the copies of their authorizations at FDAC.

D. Matters Pertaining to Procurement

1. Expiring lease of contracts for Regional Offices may be extended by the Bids and Awards Committee (BAC) upon the recommendation of the Cluster Director. All necessary documents would be submitted to the BAC immediately upon lifting of the community quarantine.

2. All Covid-19 related procurements shall follow the existing Joint Memorandum Circular issued by the Government Procurement Policy Board (GPPB) and the Commission on Audit (COA).

IV. SEPARABILITY CLAUSE

If any provision or part of this Circular or the application of such provision to any individual or entity is declared invalid or unconstitutional by the proper authorities, the remaining provisions not affected by such declaration shall remain in effect.

All directives previously released or implemented by FDA pertaining to the extension, interruption or movement of the periods and timelines set by law, rules and regulations for the filing of documents, conduct of proceedings, payment of fees and other charges are hereby adopted insofar as they are consistent with the guidelines set forth by the IATF and the directives of the Office of the President.

V. EFFECTIVITY

This Circular shall take effect immediately. The provisions stated herein, as well as those stated in FDA Circular No. 2020-006 and FDA Circular No. 2020-006-A shall remain in effect until the lifting of the Public Health Emergency declaration in the Philippines or as recommended by the IATF.

For compliance.

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Director General

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