Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA CIRCULAR
No. 2020-024

20 AUG 2020

SUBJECT: **UPDATED GUIDELINES FOR APPLICATION OF AUTHORIZATIONS AT THE FOOD AND DRUG ADMINISTRATION IN LIGHT OF THE COMMUNITY QUARANTINE DECLARATIONS**

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 amendments, Circular No. 2020-006-A on 2 April 2020 and Circular No. 2020-006-B on 17 July 2020 as the Agency's response to the Community Quarantine declaration.

In view of the interim changes brought about by the COVID-19 pandemic in the agency and its regulated entities, this Circular is hereby issued to reinforce the guidelines and ensure the continuity of services while protecting the internal and external stakeholders of FDA.

II. SCOPE AND COVERAGE

This Circular shall cover the general public, 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.

For purposes of these Guideline, "Community Quarantine" shall mean the Enhanced Community Quarantine (ECQ), the Modified Enhanced Community Quarantine (MECQ), the General Community Quarantine (GCQ), and local community quarantines declared in accordance with IATF Guidelines.

III. GUIDELINES

A. Application for License to Operate

1. Initial Application

a. Initial LTO application shall be processed online through the FDA ePortal System. Priority shall be given to establishment with function intended for use in the diagnosis, cure, mitigation, treatment, prevention, and personal protective equipment (PPE) of COVID-19, and essential medicine.

b. Initial LTO applications of manufacturers of health products shall await pre-license inspection schedule as soon as the community quarantine of the respective Local Government Unit of the establishment is lifted. Exemption to this shall be given to establishment with health products intended for use in the diagnosis, cure, mitigation, treatment, prevention, and personal protective equipment (PPE) of COVID-19, and essential medicines.

c. The conduct of all foreign inspections for the Year 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.

2. LTO Renewal Application

a. LTO expiring on 01 July 2020 to 31 December 2020 shall be given additional four (4) months validity extension from the date of expiration of the market authorization. The applicant shall still apply for the renewal application within the given validity extension period without surcharge.

b. Renewal application received beyond the 4-month validity extension up to a maximum of one hundred twenty (120) days shall be subject to surcharge as prescribed in the Republic Act (RA) No. 9711 Implementing Rules and Regulations (IRR) and FDA issuances.

c. Any application for renewal received thereafter shall be considered expired and the application shall undergo initial filing and evaluation procedure, subject to applicable fees as prescribed in the RA NO. 9711 IRR and FDA issuances.

d. For transactions with the Bureau of Customs, this Circular shall be attached in support to the authorization which expired during the mentioned period.

B. Application for Certificate of Product Registration/Notification (CPR/CPN)

1. Initial Application

Initial CPR/CPN application shall be processed online through the FDA ePortal System, as applicable. Priority shall be given to health products intended for use in the diagnosis, cure, mitigation, treatment, prevention, and PPE of COVID-19, and essential medicine.

2. Renewal Application

a. CPR/CPN expiring on 01 July 2020 to 31 December shall be given additional four (4) months validity extension from the date of expiration of the market authorization. These applicants, however, shall apply for renewal within the given extension period.

b. Renewal application received beyond the 4-month validity extension up to a maximum of one hundred twenty (120) days shall be subject to surcharge as

prescribed in the Republic Act (RA) No. 9711 Implementing Rules and Regulations (IRR) and FDA issuances.

c. Any application for renewal received thereafter shall be considered expired and the application shall undergo initial filing and evaluation procedure, subject to applicable fees as prescribed in the RA NO. 9711 IRR and FDA issuances.

d. The automatic validity extension shall not preclude the FDA from revoking the relevant market authorization if the evaluation of the application so warrants.

e. For transactions with the Bureau of Customs, this Circular shall be attached in support to the authorization which expired during the mentioned period.

Specific guidelines on initial and renewal CPR applications applicable on health product category and/or their Center of jurisdiction shall be issued on a separate issuance.

C. Application for other Market Authorizations/Certificates/Permits

Application for other Market Authorizations shall be done electronically, as applicable. Specific guidelines on filing of applications shall be issued on a separate issuance.

D. Payment of Fees and Charges

1. Over-the-counter payments shall be suspended during the community quarantine period.
2. Payment of fees as indicated in the Order of Payment (OP) maybe done thru On-Coll payment at Land Bank of the Philippines (LBP) branches, or online payment thru Bancnet Online Payment Facility (including LBP bills payment).

E. Release of FDA Market Authorizations and Certificates

1. Results of applications and scanned copy of FDA market authorizations and certificates shall be sent to the registered email of the company's authorized representative.

2. For clients within the National Capital Region (NCR), authorizations shall mailed thru courier to the registered mailing address of the Company.

3. 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.

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. REPEALING CLAUSE

Provisions of FDA Circular No. 2020-006, its amendment, and other previous issuances inconsistent with this Circular are hereby repealed, rescinded and modified accordingly.

VI. EFFECTIVITY

This Circular shall take effect immediately. The provisions stated herein, as well as those stated in FDA Circular No. 2020-006, FDA Circular No. 2020-006-A, and FDA Circular 2020-006-B 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