Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA CIRCULAR No. 2021-025

09 DEC 2021

SUBJECT : **Guidelines for Application of Authorizations at the Food and Drug Administration in Light of the Extended State of Public Health Emergency**

I. BACKGROUND

The Food and Drug Administration (FDA) issued FDA Circular (FC) No. 2020-024 on 20 August 2020 to provide updated guidelines for the application of FDA Authorizations amidst the Coronavirus Disease 2019 (COVID-19) pandemic and congruent with Presidential Proclamation No. 922[1] dated 08 March 2020.

Further amendments to FC No. 2020-024 were issued to extend the validity of certain FDA authorizations expiring from 01 January 2021 in view of the interim changes and restrictions brought about by the pandemic in the FDA and its regulated entities. The extension of regulatory flexibilities is timely as it addresses the continuing impact of COVID-19 disease in the Philippines.

Whereas, on 10 September 2021, Proclamation No. 1218[2] was issued further extending the period of a state of calamity for a period of one (1) year, effective 13 September 2021 to 12 September 2022, unless earlier lifted or extended as circumstances may warrant.

In the interest of the service, this FDA Circular is hereby issued to reinforce the guidelines and ensure the continuity of services while protecting the internal and external stakeholders of the FDA.

II. OBJECTIVE

This FDA Circular is provided to give further guidance on the regulatory flexibilities implemented by the FDA considering the continuing COVID-19 pandemic, specifically on the FDA-issued marketing authorizations.

III. SCOPE

All stakeholders applying for FDA authorizations, and other stakeholders who are required to submit documents, appear at the FDA for compliance/meetings, and/or pay appropriate fees and charges are all covered by this FDA Circular.

[1] Declaring a State of Public Health Emergency Throughout the Philippines
[2] Further Extending the Period of a State of Calamity Throughout the Philippines due to Corona Virus Disease 2019 Declared Under Proclamation No. 1021, S. 2020

The FDA-issued authorizations include but are not limited to the following:

- Licenses to Operate (LTOs)
- Certificates of Product Registration/Certificate of Product Notifications (CPRs/CPNs)
- Local Good Manufacturing Practice (GMP) Certificates
- Certificate of GMP Compliance for Foreign Drug Manufacturer
- Certificates of Compliance (COCs) for x-ray facilities under the One-Stop Shop Licensing System of the Department of Health (DOH)
- Certificates of Registration (CORs) for Magnetic Resonance Imaging (MRI) facilities
- Special Certification for COVID-19 Test Kits

IV. GUIDELINES

A. Application for FDA License to Operate, and Certificate of Product Registration/Certificate of Product Notification

1. Initial Application

a. Initial LTO/CPR/CPN applications shall be processed online through the FDA ePortal System or the FDA eServices Portal System, where applicable. Priority shall be given to establishments with functions intended for use in the diagnosis, cure, mitigation, treatment, prevention, and for personal protective equipment (PPE) for COVID-19, and other essential medicines.

b. Inspection of establishments is based on FDA Circular No. 2020-027 on the Conduct of Risk-Based Local Inspections in Light of the COVID-19 Pandemic and shall be conducted as follows:

i. Initial LTO applications of manufacturers of health products shall await a pre-license inspection schedule in compliance with the community quarantine and imposed Alert Level System[3] of the respective Local Government Units where the establishment is located.

ii. Local inspections[4] shall be conducted in order of prioritization which shall be classified as follows:

(1) For areas under Community Quarantine and imposed Alert Level System: Only high priority inspections[5] shall be scheduled; low priority inspections[6] shall be deferred, unless the safety of the inspector(s) can be assured, and the conduct

---

[3] Executive Order No. 151, "Approving the Nationwide Implementation of the Alert Level System for COVID-19 Response

[4] FDA Circular No. 2020-027, "Conduct of Risk-Based Local Inspections in Light of the COVID-19 Pandemic

[5] High Priority Inspections – pre-license inspections for high priority applications as per FDA Circular No. 2020-006 and its subsequent amendments, products with import and export commitment, and referrals from FDA Centers/Offices

[6] Low Priority Inspections – other pre-license inspections, risk assessment/routine inspections, and post-licensing inspections

of inspection can be justified. A letter of Deferral explaining the reasons for postponement of the inspection shall be issued to applicable establishments.

(2) For areas where community quarantine (under the New Normal) is lifted and there are no imposed Alert Level System yet: Both high priority and low priority inspections shall be scheduled.

Inspectors shall conduct risk-assessment[7] to determine where and when it is safest to conduct inspection. A risk score will be assigned for each scheduled inspection based on the following criteria:

- Community Quarantine classification of the region/city/province/barangay where the establishment is located
- Number of total active cases in the city/province where establishment is located, using data from the Department of Health and/or the Local Government Unit
- Expected duration of inspection

	Inspection Method
High Risk	Remote Inspection OR Combination of remote + on-site inspection under agreed controlled conditions
Low Risk	Combination of remote + On-site inspection under agreed controlled conditions OR On-site inspection under agreed controlled conditions

Remote Inspection

1. The general inspection process shall follow the existing process of the FDA, but remote inspection shall be used in lieu of on-site visit.

2. Communication with the establishment shall be done online through e-mail and/or phone call.

3. Virtual meeting conferencing platforms (e.g., Google Meet) shall be used if possible. Virtual meetings shall be documented and/or recorded with permission from the establishment.

4. Documents for inspection shall be transmitted via a file-sharing platform (e.g., Google Drive) and shall be subjected to desktop review.

[7] Section IV.B, FDA Circular No. 2020-027, "Conduct of Risk-Based Local Inspections in Light of the COVID-19 Pandemic"

5. Photos or videos shall be used to tour the facility and/or obtain proof of compliance.

6. Collection of samples, if necessary, shall be coordinated with the establishment.

On-site Inspection under Agreed Controlled Conditions

1. The existing inspection process of the FDA shall be followed with additional measures taken to protect both parties from infection.

2. Focal person(s) from the establishment who shall interact with the inspector(s) shall be limited to 1-2.

3. The duration of the inspection shall be minimized as much as possible without compromising the inspection agenda.

4. FDA inspectors shall inspect establishments within the vicinity of their municipality or city of residence including nearby and accessible areas, as determined by the Management.

(3) The conduct of foreign inspections for the year 2022 shall be deferred until further notice pending the lifting of the travel restrictions being imposed on the Philippines and the other countries concerned. A separate issuance shall be provided for this requirement.

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

2. Renewal Application

a. Existing authorizations enumerated in Section III of this FDA Circular, with validity expiring on 01 January 2022 to 30 September 2022, are automatically extended. An additional four (4) months validity from the original date of expiration of the authorizations shall be given; provided, that a complete application for renewal of the said authorizations have been filed with and duly acknowledged by the FDA within the given extension period.

b. Failure to successfully submit the appropriate renewal applications for expiring LTOs and CPRs/CPNs within the 4-month validity date shall incur surcharges on top of the renewal application fees, as prescribed in the Implementing Rules and Regulations (IRR) of Republic Act No. 9711[8] and relevant FDA issuances.

c. Thereafter, failure to apply shall render the authorizations expired and shall be subjected to the initial filing of application procedures, subject to the

[8] The Rules and Regulations Implementing Republic Act No. 9711 – The Food and Drug Administration Act of 2009

applicable initial application fees and surcharges as prescribed in the IRR of RA 9711 and relevant FDA issuances.

d. For CPRs/CPNs, the automatic validity extension shall not preclude the FDA from revoking the relevant market authorization if the evaluation of the application so warrants.

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

f. Extensions of the validity granted through all amendments to FC No. 2020-024 and this FDA Circular are non-cumulative, such that the four-month extension shall only be granted once to existing authorizations, subject to the conditions granted in Section IV.A.2 as stated above.

g. For transactions with the Bureau of Customs, this FDA Circular, the acknowledgement receipt, and official receipt of the renewal application shall be attached in support to the authorization which expired during the mentioned period.

B. Application for other FDA Certificates and Permits

Application for other FDA Certificates and Permits shall be done electronically, as applicable. Specific guidelines on filing of applications, where applicable shall be provided on a separate issuance. Existing guidelines in filing of application for FDA authorizations remain valid.

C. Payment of Fees and Charges

1. Over-the-counter payments shall be suspended during the state of public health emergency unless earlier lifted or may be extended if the situation warrants.

2. Payment of fees as indicated in the Order of Payment maybe done through On-coll payment at Land Bank of the Philippines (LBP) branches, or online payment through Bancnet Online Payment Facility (including LBP payment) and LBP Linkbiz Portal.

D. Release of FDA Marketing Authorizations and Certificates

1. Results of applications and scanned copy of the FDA marketing authorizations and certificates shall be sent to the registered e-mail address of the company's authorized representative.

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

3. For clients outside of the NCR, the authorizations shall be mailed through courier to the respective FDA Regional Field Offices, which have jurisdiction over the concerned Company.

V. SEPARABILITY CLAUSE

If any provision or part of this FDA 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.

VI. REPEALING CLAUSE

FC No. 2020-024 and its amendments, and other previous issuances inconsistent with this FDA Circular are hereby repealed, rescinded, and modified accordingly.

VII. EFFECTIVITY

This FDA Circular shall take effect fifteen (15) days following its publication in a newspaper of general circulation and upon filing three (3) certified true copies with the University of the Philippines – Office of the National Administrative Register (UP-ONAR). The provisions stipulated in this FDA Circular shall remain in effect until the lifting of the Public Health Emergency declaration in the Philippines.

ROLANDO ENRIQUE D. DOMINGO, MD
Director General

DTN #20211024140501