AOCG Memo No. 205-2021

MASTER COPY

BUREAU OF CUSTOMS

MAKABAGONG ADUANA, MATATAG NA EKONOMIYA

PROFESSIONALISM INTEGRITY ACCOUNTABILITY

MEMORANDUM

TO : **ALL DISTRICT COLLECTORS**
ALL SUB-PORT COLLECTORS
ALL OTHERS CONCERNED

FROM : **ATTY. EDWARD JAMES A. DY BUCO**
Deputy Commissioner, AOCG

SUBJECT : VALIDITY EXTENSION OF EXISTING LICENSE TO OPERATE (LTO) AND CERTIFICATE OF PRODUCTS REGISTRATION/NOTIFICATIONS (CPR/Ns) ISSUED BY THE FOOD AND DRUG ADMINISTRATION (FDA)

DATE : 14 April 2021

In reference to the letter dated 05 April 2021 from Director General Rolando Enrique D. Domingo, MD, Food and Drug Administration, Department of Health (FDA-DOH), please be informed of the following updated policies being implemented concerning the validity extension of existing FDA LTO and CPR/Ns pursuant to FDA Circular Nos. 2020-024 and 2020-024-A in light of the COVID-19 pandemic:

1. **FDA Authorizations, including Licenses to Operate (LTO), and Certificates of Product Registration/Notifications (CPR/Ns) are granted a four-month validity extension period from the original date of expiration; Provided, that an application for the renewal of the authorization has been successfully submitted to the FDA**

2. **Regulated entities have been advised to attach FC No. 2020-024 and/or FC No. 2020-024-A, with supporting documents, when transacting with the Bureau of Customs (BOC).**

Copies of FDA Circular Nos. 2020-024 and 2020-024-A are hereto attached for your ready reference.

Please be guided accordingly.

AOCG Memo No. 205 - 2021

MASTER COPY

Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

05 April 2021

REY LEONARDO GUERRERO
Commissioner
Bureau of Customs (BOC)
Port Area, Manila

Subject: Validity Extension of Existing LTO/CPR/Notifications issued by the Food and Drug Administration

Dear **Commissioner Guerrero:**

Greetings!

In keeping with the spirit of the previously enacted *Bayanihan* laws in light of the COVID-19 pandemic, the Food and Drug Administration (FDA) has been implementing regulatory flexibilities to involved stakeholders. Relative thereto, we are respectfully updating your good Office with the following policies, for your information and guidance:

1. FDA Authorizations, including Licenses to Operate (LTO), and Certificates of Product Registration/Notifications (CPR/Ns) are granted a four-month validity extension period from the original date of expiration; Provided, that an application for the renewal of the authorization has been successfully submitted to the FDA. (FDA Circular No. 2020-024 and 2020-024-A)

2. Following Item No. 1, regulated entities have been advised to attach FC No. 2020-024 and/or FC No. 2020-024-A, with supporting documents, when transacting with the Bureau of Customs (BOC).

Enclosed are copies of the aforementioned issuances for your reference.

Rest assured that the FDA fully supports the mandate of the BOC as we mutually endeavor to facilitate trade, while securing the borders from all unauthorized entry of prohibited imported goods in the Philippine market.

Should you have clarifications or questions, you may reach us at pps@fda.gov.ph.

Thank you very much.

Very truly yours,

ROLANDO ENRIQUE D. DOMINGO, MD
Director General

DTN #20210331162407

AOCG Memo No. 205 - 2021

MASTER COPY

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.

ROLANDO ENRIQUE D. DOMINGO, MD
Director General

AOCG Memo No. 205-2021

MASTER COPY

Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

18 FEB 2021

FDA CIRCULAR
No. 2020-024-A

SUBJECT : AMENDMENT TO FDA CIRCULAR NO. 2020-024, ENTITLED, "UPDATED GUIDELINES FOR APPLICATION OF AUTHORIZATIONS WITH THE FOOD AND DRUG ADMINISTRATION IN LIGHT OF THE COMMUNITY QUARANTINE DECLARATIONS"

In the interest of service and due to the continuing Coronavirus Disease 2019 (COVID-19) pandemic, the extension of the following regulatory flexibilities introduced in FDA Circular (FC) No. 2020-024 for existing authorizations are hereby applied –

1. Existing Licenses to Operate (LTOs), and Certificates of Product Registration/ Notifications (CPR/Ns) issued by the Food and Drug Administration (FDA), that have a validity expiring on 01 January to 30 June 2021, are automatically extended. An additional four (4) months validity from the original date of expiration of the market authorization shall be given; Provided, that a complete application for renewal of the said authorizations have been filed with the FDA within the given extension period.

2. Failure to successfully submit the appropriate renewal applications for expiring LTOs and CPR/Ns within the 4-month validity extension but has done so within one hundred twenty (120) days from the extended validity date will incur surcharges on top of the renewal application fees, as prescribed in the Implementing Rules and Regulations (IRR) of Republic Act (RA) No. 9711 and relevant FDA issuances.

3. Thereafter, failure to apply shall render the authorizations expired and shall be subject to the initial filing of application procedures, subject to the applicable initial application fees and surcharges as prescribed in the IRR of RA 9711 and relevant FDA issuances.

4. Extensions of the validity granted through FC No. 2020-024 and this amendment are non-cumulative, such that the four-month extension shall only be granted once to existing authorizations, subject to the conditions granted in Items 1 through 3 as stated above.

5. Regulated entities are further advised to attach FC No. 2020-024 and this amendment, the acknowledgment receipt, and official receipt of the renewal application, in transactions with the Bureau of Customs, in support of authorizations which have expired during the said period.

All other provisions of FC No. 2020-024 unaffected by these changes shall remain in effect. This Circular shall take effect immediately until the lifting of the public health emergency declaration by the Office of the President.

ROLANDO ENRIQUE D. DOMINGO, MD
Director General

DTN 20201228090428