



FDA CIRCULAR
No. 2020-024-B

22 JUL 2021

SUBJECT : SUPPLEMENTAL GUIDELINES TO FDA CIRCULAR NO. 2020-024 A, ENTITLED, "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"

I. BACKGROUND

The Food and Drug Administration issued 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" on 20 August 2020, to provide its regulated entities an updated guidelines for the application of FDA Authorizations, including stakeholders who are required to submit documents, scheduled to appear at FDA for compliance/meetings, and /or pay appropriate fees and charges.

In addition, an amendment to the said Circular, published as FDA Circular 2020-024A, was issued to extend the validity of FDA authorizations expiring from January to June 2021 and had completed the corresponding renewal application within the said extension period.

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 and its amendment for existing authorizations are hereby applied.

II. OBJECTIVE

This supplemental issuance is provided to give further guidance on the regulatory flexibilities implemented by FDA in light of the continuing COVID-19 pandemic, specifically on the FDA-issued market authorizations.

III. SCOPE

This Circular shall cover the following FDA-issued authorizations:

- Licenses to Operate (LTOs)
- Certificates of Product Registration/Notifications (CPR/Ns)
- Local Good Manufacturing Practice (GMP) Certificates
- Certificate of Compliance (COC) for x-ray facilities under the One-Stop Shop Licensing System of the Department of Health (DOH)



- Certificate of Registration (COR) for Magnetic Resonance Imaging (MRI) facilities to the extension of FDA Circular 2020-024.

IV. GUIDELINES

1. Existing Licenses to Operate (LTOs), Certificates of Product Registration/ Notifications (CPR/Ns), Certificate of Compliance (COC) for x-ray facilities under the One-Stop Shop Licensing System of the Department of Health (DOH), Certificate of Registration (COR) for Magnetic Resonance Imaging (MRI) facilities to the extension of FDA Circular 2020-024, and other clearances/certificates dependent to authorizations, such as local Good Manufacturing Practice (GMP) Certificates, issued by the Food and Drug Administration (FDA), that have a validity expiring on 01 July to 31 December 2021, are automatically extended. An additional four (4) months validity from the original date of expiration of the 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. 2020-024A 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, FC No. 2020-024A, 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.

V. SEPARABILITY CLAUSE

All other provisions of FC No. 2020-024 and FC 2020-0024A unaffected by these changes shall remain in effect.

VI. EFFECTIVITY

This Circular shall take effect immediately until the lifting of the public health emergency declaration by the Office of the President.


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