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FDA CIRCULAR
No. 2020-024-A

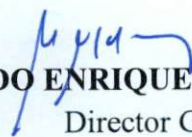
SUBJECT : AMENDMENT TO FDA CIRCULAR NO. 2020-024, ENTITLED, "UPDATED GUIDELINES FOR APPLICATION OF AUTHORIZATIONS WITH THE FOOD AND DRUG ADMINISTRATION IN LIGHT OF THE COMMUNITY QUARANTINE DECLARATIONS"

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.


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