FDA CIRCULAR
No. 2021-011

TO: ALL CONCERNED STAKEHOLDERS


In the interest of the service, and pursuant to Administrative Order No. 30 s. 2020 dated 21 April 2020, directing all government agencies to formulate and issue guidelines on the interruption of periods for the filing of documents for the duration of community quarantine, and in consideration of the public health and economic challenges brought about by the COVID-19 pandemic, the Food and Drug Administration (FDA) hereby announces that the transitory period within which to comply with the licensing and registration requirements for covered Household/Urban Hazardous Substances (HUHS) products and establishments under FDA Circular No. 2020-025, is further extended until 31 December 2021.

Notwithstanding the extended period of compliance, this Office is directing commitment from all covered establishments to proceed with the completion of documentary requirements, lodging of their applications for License to Operate (LTO), and Certificate of Product Registration (CPR), and to adhere to standards in ensuring the safety, quality and efficacy of all HUHS products at all times.

This Office reiterates that an exhaustion period of six (6) months following the transitory period shall be given for covered HUHS establishments to exhaust their products already existing in the market. Further, the extension shall serve as moratorium period where no other government agency shall require FDA licenses and authorizations while covered establishments are in the process of complying with the new guidelines.

Consistent with the provisions of FDA Circular No. 2020-025, the FDA may issue interim guidelines within the transitory period, or as may it be necessary to address public health emergency situation.

This Circular shall take effect immediately and shall be subject to post-implementation review as may be necessary.

For information and guidance.

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Director General