Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

Food and Drug Administration PHILIPPINES

FDA ADVISORY
No. 20201599

03 SEP 2020

TO: **ALL CONCERNED STAKEHOLDERS**

SUBJECT: **Implementation of FDA Circular No. 2020-0025, entitled "Implementing Guidelines for Administrative Order No. 2019-0019, "Reinstatement of Requirements of Licensing as Importers, Exporters, Manufacturers, Toll Manufacturers, Wholesalers, Distributors, Retailers, or Re-Packers of Those Engaged in Certain Household/Urban Hazardous Substances, and from the Requirement of Prior Registration and/or Notification of Said Products""**

The Food and Drug Administration (FDA) advises all concerned stakeholders that the "Implementing Guidelines for Administrative Order No. 2019-0019, "Reinstatement of Requirements of Licensing as Importers, Exporters, Manufacturers, Toll Manufacturers, Wholesalers, Distributors, Retailers, or Re-Packers of Those Engaged in Certain Household/Urban Hazardous Substances, and from the Requirement of Prior Registration and/or Notification of Said Products"" has been approved by virtue of FDA Circular No. 2020-0025 issued on 19 August 2020.

For purposes of clarity, this is to reiterate that the guidelines shall take effect fifteen (15) days after the publication requirement, and that all covered establishments shall be given due period of compliance to comply with the licensing, product registration, and labeling requirements as provided in Section VI. Implementation Timeline of FDA Circular No. 2020-0025, to wit:

> *VI. IMPLEMENTATION TIMELINE*
>
> *Consistent with AO 2019-0019, a transitory period of three (3) months from the issuance of this Circular shall be provided to allow all covered establishments to comply with the new licensing and product registration guidelines, with the exception of compliance to GHS labeling requirements which shall take effect three (3) years from the issuance of this Circular. An exhaustion period of six (6) months following the transitory period shall likewise be given for covered HUHS establishments to exhaust their products already existing in the market.*

This issuance shall further serve as moratorium period where no other government agency shall require FDA licenses and authorizations from HUHS establishments covered herein while these establishments are in the process of complying with the new guidelines.

In case of public health emergency situation, however, the FDA may further issue interim guidelines covering specific HUHS establishments and products within the transitory period, or as it may deem necessary to address such public health emergency situation.

In view of the foregoing, all covered establishments are advised to comply with the provisions of FDA Circular No. 2020-0025 accordingly, and to adhere to standards in ensuring the safety, quality and efficacy of your products at all times.

The FDA shall issue an official statement once the implementing guidelines of FDA Circular 2020-0025 become fully implemented. This Office shall no longer issue any other certifications or documentation to individual establishment or company to further clarify the provisions of FDA Circular No. 2020-0025.

For information and guidance. Dissemination of this advisory to all concerned is hereby requested.

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Director General

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