

Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



FDA ADVISORY

0 3 NOV 2020

No. 20202035

TO:

ALL CONCERNED STAKEHOLDERS

SUBJECT:

"Update on the 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""

Pursuant to the requisite in the completion of its publication requirement, the Food and Drug Administration (FDA) advises all concerned stakeholders that the 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", has commenced on 30 October 2020.

Administrative Order No. 30 s. 2020 dated 21 April 2020 was issued 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. Pursuant thereto, and in consideration of the industry's appeal for longer transitory period and phase implementation of FDA Circular No. 2020-0025 due to the public health and economic challenges brought about by the COVID-19 pandemic, this Office hereby sets forth for the extension of the transitory period to six (6) months from effectivity date of the issuance, within which to comply with the licensing and registration requirements to allow affected stakeholders to comply with the documentary requirements, and applicable standards stipulated in FDA Circular No. 2020-0025.

The timelines for implementation shall be as follows:

Date	Activity	Remarks
30 October 2020	Launch of the HUHS e-Portal System* *link to request for User Account	Acceptance of requests for User Account and processing of requests thereafter
2-13 November 2020	Uploading of User's Guide/video tutorial on the use of HUHS e-Portal in the FDA website	Cascading materials for reference of stakeholders
16 November 2020	Launch of the Licensing Application Form in the HUHS e-Portal	Acceptance of licensing applications and processing of applications thereafter



1 February 2021	Launch of the Registration Application Form in the HUHS e-Portal	Acceptance of product registration applications and processing of applications thereafter
		*Full compliance to the new labeling requirements shall be made mandatory upon renewal of the product registration.

All previous applications and requests that are not in accordance with the above timelines shall not be processed.

For HUHS Manufacturers, all applications shall be processed accordingly. However, due to existing community quarantine, site inspection shall be done as a post-licensing activity and subject to local quarantine conditions.

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

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.

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

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

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Director General

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