Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

21 JAN 2022

FDA CIRCULAR
No. 2021-011-A

SUBJECT : **Extension of Transitory Period and Provision of Interim Guidelines for Product Registration, including the Labeling Requirements, for Household Urban/Hazardous Substances**

I. RATIONALE

On 24 May 2021, the Food and Drug Administration (FDA) issued FDA Circular No. 2021-011 with subject, Extension of Transitory Period for the Implementation of FDA Circular No. 2020-025, "Implementing Guidelines for Administrative Order No. 2019-0019" wherein the Household/Urban Hazardous Substances (HUHS) industry was given until 31 December 2021 to comply with the new licensing and registration requirements for covered HUHS establishments and products, respectively. However, as the current transitory period draws to an end, appeals had been made by the HUHS industry and other concerned stakeholders for the FDA to give them a longer compliance period within which the covered HUHS establishments can secure the appropriate marketing authorization for their HUHS products as required by FDA Circular No. 2020-025.

In view of the foregoing and in consideration of the economic challenges brought about by the current state of calamity in the country due to COVID-19, the FDA recognizes the need to extend the current transitory period and assist the HUHS industry as they comply with the registration requirements of FDA Circular No. 2020-025.

II. OBJECTIVES

This Circular aims to:

A. Establish a 2-year transitory period extension for HUHS product registration; and,
B. Establish an interim guideline for product registration as well as product labeling during the transitory period.

III. SCOPE

This issuance shall apply to products classified as Categories III and IV of HUHS as defined in Republic Act No. 9711 and categorized in FDA Circular No. 2020-025, and the establishments engaged or intending to engage in their manufacture, importation, exportation, distribution, sale, offer for sale, transfer, promotion, advertising and/or sponsorship. The covered Categories III and IV HUHS products shall be those intended for consumer or institutional use only and shall not covered those intended for industrial use.

IV. GUIDELINES

A. Two (2) - Year Transitory Period Extension

The 2-year transitory period extension shall start on 01 January 2022 and end on 31 December 2023.

1. License to Operate (LTO)

The 2-year transitory period extension shall not apply to the licensing of HUHS establishments. Hence, effective 01 January 2022, a LTO as HUHS establishment shall be mandatory for all establishments engaged or intending to engage in HUHS-related activities.

2. Certificate of Product Registration (CPR)

The 2-year transitory period extension shall apply to the registration of HUHS products. Hence, from 01 January 2022 to 31 December 2023, HUHS establishments may continue to distribute their HUHS products without a CPR from the FDA. However, effective 01 January 2024, a CPR shall be mandatory for all HUHS products distributed in the market.

Further, the 2-year transitory period extension shall serve as the exhaustion period within which the HUHS establishments may deplete the remaining stocks of HUHS products with labels that are not compliant with the labeling requirements set forth in Annex J of FDA Circular No. 2020-025 including the GHS label elements.

As such, for the purposes of HUHS product registration, the FDA shall accept complete, loose artwork of existing labels of all packaging sizes of the product, as applicable, regardless of compliance to Annex J of FDA Circular No. 2020-025 as this shall be the basis for the additional conditions that the HUHS establishment must comply with at the end of the transitory period upon implementation of the full labeling requirements. Notwithstanding the acceptance of loose artwork of existing HUHS product labels, all product claims reflected on said labels shall be substantiated by sufficient documentation during product registration.

3. Other authorizations including Customs Clearances, Sales and Promo Permit and Certificate of Free Sale (CFS)

Securing Sales and Promo Permits for products covered by this Circular are not mandatory, including Customs Clearances as the issuance of the said permits require a valid CPR. For the purposes of conducting advertising and sales promotions activities and customs-related concerns, a copy of this Circular together with a copy of the valid LTO of the HUHS establishment may be presented to government and non-government entities in lieu of a valid FDA-issued CPR.

B. Post-Marketing Surveillance (PMS) of HUHS Products

PMS shall be in accordance with FDA Circular No. 2020-025 during and after the transitory period extension. This does not preclude this Office from issuing subsequent orders it may deem necessary and appropriate, particularly on labeling to ensure consumer protection and prevent misleading claims on labeling and should there be findings of any violation of the company to the existing laws, rules, and regulations.

C. Reiteration/Adoption of Other Provisions in FDA Circular No. 2020-025

The Responsibilities of Marketing Authorization Holder (MAH) including all other clauses or parts stipulated in FDA Circular No. 2020-025 remains valid and shall be enforced.

D. After the 2-Year Transitory Period Extension

1. CPR shall be mandatory for all HUHS products distributed in the market.
2. Sales and Promo Permit shall be mandatory for all companies conducting promotional activities with participating HUHS products.
3. Labels of HUHS products shall be fully compliant with Annex J of FDA Circular No. 2020-025, including the GHS Label Elements.
4. Any requests for exhaustion of remaining stocks of non-compliant labels or HUHS products with non-compliant labels shall no longer be granted.

V. REPEALING CLAUSE

This Circular hereby amends relevant provisions in FDA Circular Nos. 2020-025 and 2021-011.

VI. SEPARABILITY CLAUSE

The provisions of this Circular are hereby declared separable and in the event of any such provision/s is/are declared invalid or unenforceable, the validity of enforceability of the remaining portions or provisions which are not affected, shall remain in full force and in effect.

VII. EFFECTIVITY

This Circular shall take effect fifteen (15) days following the completion of the publication in a newspaper of general circulation and filing with the University of the Philippines Law Center Office of the National Administrative Register.

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Secretary of Health