FDA ADVISORY
No. 20241660

13 DEC 2024

TO : **ALL CONCERNED HOUSEHOLD/URBAN HAZARDOUS SUBSTANCES STAKEHOLDERS**

SUBJECT : **Regulatory Updates on the Implementation of Food and Drug Administration (FDA) Circular No. 2020-025**

The Center for Cosmetics and Household/Urban Hazardous Substances Regulation and Research (CCHUHSRR) of the Food and Drug Administration (FDA) hereby informs household/urban hazardous substances (HUHS) stakeholders of the following regulatory updates:

1. **Status of On-boarding of FDA eServices Portal System for the Licensing of HUHS Establishment**

   The FDA is pleased to announce that the on-boarding of FDA eServices system for the licensing of HUHS establishment is in its final stages of testing and is expected to be made available for stakeholder access within the **1st Quarter of 2025.** Once available, all applications pertaining to the issuance of License to Operate (LTO) of HUHS establishments shall be lodged through https://eservices.fda.gov.ph/. To assist stakeholders in lodging their applications through the website, the Center has issued the procedural guidelines provided in FDA Advisory No. 2024-0543 dated 25 March 2024, entitled, "On-Boarding of the Licensing Procedures for Household/Urban Hazardous Substances (HUHS) Establishments on the Food and Drug Administration (FDA) eServices Portal System".

   The FDA hence directs the following HUHS establishments to proceed with the following steps:

   a. All HUHS establishments currently holding an LTO with an automatically extended validity pursuant to the submission of the declaration statement under FDA Advisory No. 2024-0543 are advised to file their renewal applications through the FDA eServices Portal System until **01 April 2025** to avoid incurring penalties and/or surcharges on their renewal applications. After this date, those who fail to lodge their LTO applications shall be subject to the applicable fees and charges, including surcharges, following Administrative Order No. 50 series 2001.

   b. Additionally, to provide ample time for HUHS establishments with expiring LTOs before the availability of the system, such HUHS establishments are advised that they shall be eligible for an automatic extension of the validity of their LTOs until **01 April 2025; Provided, that on or before 15 March 2025** a "Letter of Request and

Declaration Statement" following the format of Annex G of FDA Advisory No. 2024-0543, shall be submitted through the Food and Drug Action Center. After this date, those who fail to lodge their LTO applications shall be subject to the applicable fees and charges, including surcharges, following Administrative Order No. 50 series 2001.

A separate issuance in the form of an FDA Circular shall be released to formalize the regulatory flexibilities above given for the licensing of HUHS establishments.

2. Status of HUHS Product Registration and Labeling Requirements.

In consideration of industry appeals and regulatory challenges seen based on the updated registration review conducted by the Center for the years 2023 through 2024, the FDA hereby announces that further regulatory flexibilities will be granted for the HUHS product registration and labeling requirements under DOH Administrative Order No. 2019-0019 and its implementing guidelines under FDA Circular No. 2020-025. The transitory period provided in DOH Administrative Order No. 2019-0019 will be extended until **30 June 2025** to assist stakeholders to fully comply with the said registration and labeling requirements.

During the extended transitory period, HUHS establishments are allowed to continue the distribution of their HUHS products without a pre-market authorization from the FDA. Additionally, the FDA is taking necessary steps in addressing challenges encountered by the industry during the registration process and will provide further assistance on this matter before the end of the transitory period. Although an extension of the transitory is in place, we enjoin all HUHS establishments with pending registration applications to submit all compliance documents within the prescribed timeline for the issuance of final decisions. The updated regulatory flexibilities mentioned in this Advisory will be formalized through the issuance of the corresponding administrative issuance.

3. Status of HUHS CPR Renewal and Variation Application through e-portal v.2 system

The FDA is pleased to announce that the system for HUHS CPR renewal and variation application, following the implementing guidelines provided in FDA Circular No. 2020-025, is currently in its final stages of development and is expected to be released by **June 2025**. The procedural guidelines for lodging HUHS CPR Renewal and Variation application through the FDA e-Portal System V.2 shall be issued separately.

With the on-going testing of the renewal and variation application process in the FDA e-Portal System V.2, the FDA hereby announces additional regulatory flexibilities:

a. CPR Renewal Applications

All previously-issued Certificate of Product Registration (CPR) which are currently expired will have their validities automatically extended until **30 June 2025 and their surcharges are waived; Provided**, that **prior 15 June 2025** a letter signifying intention to submit a CPR renewal application in the FDA e-Portal System V.2 once available, shall be submitted by the establishment through the Food and Drug Action Center (FDAC). The letter must be in the format of **Annex A**, with complete

information including the declaration statement, and signed by the establishment owner/authorized representative/qualified person. This shall be formalized through the issuance of the aforementioned amended Administrative Order.

b. CPR Variation Applications

All HUHS products with variations on their existing product registration as listed in Annex E of FDA Circular No. 2020-025, shall follow the guidelines provided in Item I, Section IV. Guidelines of FDA Circular No. 2023-006, which state that HUHS establishments must submit a letter of intent to the FDAC, notifying the Center of said change/s in the product's circumstances.

4. Technical Assistance Conducted for the HUHS Industry

As contribution to the capacity building and good submission practice of the HUHS industry in compliance with the HUHS licensing, registration and labeling requirements of FDA Circular No. 2020-025, the FDA through CCHUHSRR, in coordination with FDA Academy, has released several initiatives that aimed to provide technical assistance to HUHS industry.

a. Licensing and Product Registration Seminars

In 2024, a total of two (2) free webinars on licensing of HUHS establishments were held separately on 24 February and 28 June. Likewise, a two (2) day seminar on technical requirements and procedures for CPR applications was held on 09-10 October. Through these initiatives, the administration ensures that the HUHS industry can comply with the regulatory and technical requirements of the FDA.

b. Seminar on Globally Harmonized System of Classification and Labeling of Chemicals (GHS)

On July and September 2024, the FDA officially launched its five (5) day training on Globally Harmonized System of Classification and Labeling of Chemicals (GHS), where the GHS subject matter experts from the CCHUHSRR acted as the resource speakers. The seminar was able to equip the HUHS industry with the knowledge to classify and label HUHS products in relation to their physical, health and environmental hazards. The knowledge gained through this seminar is considered crucial in the industry compliance with safety data sheet and GHS labelling requirement of the FDA Circular No. 2020-025 and can better ensure the safety of their HUHS product for consumer and institutional use. With the success of the seminars conducted and the administration's commitment to capacitate industry stakeholders, it is expected that the seminar on GHS will be held again in the coming years.

5. Information, Education and Communication (IEC) Materials Released

Finally, the FDA is pleased to share the release of the IEC material entitled "**Hows of HUHS: Mga Button Batteries ay Itago, Para Bata ay Ligtas / Hows of HUHS: Keep**

Button Batteries Away, Keep Kids Safe All the Way" as part of public advocacy campaign aimed to raise awareness on safe handling and use of HUHS products. This part of the How of HUHS campaign series ultimately aimed to contribute to increasing consumer awareness of the dangers of common household items such as button batteries, which may pose greater risk to vulnerable populations, especially babies and children, if proper handling and storage are not in place.

The FDA wishes to emphasize its commitment to safeguard public health and safety by ensuring health products, especially HUHS products, are considered safe, effective, and of standard quality. In pursuit of such commitment, the FDA regulates HUHS products consistent with sound chemical management while considering industry concerns and challenges in compliance with the regulation. It is within this reasoning that regulatory flexibilities are further granted, provided that the HUHS industry renews their commitments to actively protect consumers of their HUHS products. The FDA likewise wishes to inform the industry and the public that further improvements in the regulatory processes and systems are continuously being made to increase the administration's productivity, efficiency, and effectiveness.

DR. SAMUEL A. ZACATE
Director General

ANNEX A
Letter Template for HUHS CPR Renewal

Letter of Request and Declaration Statement

(Date)
Food and Drug Administration
Civic Drive, Filinvest Corporate City
Alabang, Muntinlupa City

Attention : **Center for Cosmetics and Household/Urban Hazardous Substances Regulation and Research**

Purpose statement:

This letter serves as this company's request for the renewal of the Certificate of Product Registration (CPR) with the following details:

CPR No.: _____
Product Name: _____
Product Brand Name: _____
Name of Market Authorization Holder (MAH) : _____
LTO No. of MAH: _____
Validity: _____

This signifies this company's intention and commitment to submit an application for the renewal of CPR of the HUHS product with the above provided details on or before the expiry of the extended validity through the FDA System for the Renewal of HUHS CPR once available; and to pay the renewal fee and other applicable charges once lodged in the updated system, pursuant to DOH Administrative Order No. 2020-0017, FDA Circular 2020-025 and their future amendments.

Declaration statement:

1. This company understands and agrees with the following conditions on the renewal of an HUHS CPR from FDA:
   - That if the company fails to fulfil the conditions, including failure to file an application through the FDA system system once available within the extended validity and/or payment of applicable fees and charges, the CPR shall be rendered invalid and shall be treated as if its validity was not extended; unless an application is filed within one-hundred twenty (120) days after the extended validity date which will be subject to applicable fees and surcharges in accordance with Republic Act (RA) No. 9711 and its Implementing Rules and Regulations (IRR);
   - That if the company was found during evaluation, inspection, or other regulatory activities to have committed violations against applicable laws, rules, and regulations, the CPR shall be disapproved, suspended, revoked or cancelled after due process; and,
   - That if the company applies for CPR renewal after one-hundred twenty (120) days from the expiry of the extended validity, the CPR shall be considered expired and the

application shall be subject to a fee equivalent to the total surcharge or penalty plus the initial filing fee; and shall undergo the initial CPR application process, pursuant to RA 9711 and its IRR.

2. The applicant hereby declares on behalf of the company that the information provided in this application are true and correct, and the documents supplied are authentic or true copies.

Contact information:

This submission is made on behalf of **(Name of establishment)** and any concerns/clarifications may be addressed to:

Name of Qualified Person: _____
Designation: _____
E-mail Address: _____
Mobile Number: _____
Telephone Number: _____

_____
Name and Signature of Owner/Authorized Person