FDA ADVISORY
No. 2023-2269

2 0 OCT 2023

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 the implementation of FDA Circular No. 2020-025, in relation to its registration and labeling requirements**

   The FDA has received several appeals from industry associations, marketing authorization holders, and through discussions during the *Kapihan at Talakayan* with HUHS industry stakeholders, to further extend the transitory period to allow compliance with registration and labeling requirements under FDA Circular No. 2020-025. The FDA likewise conducted a review of the registration procedure, wherein it was found that there is a significant gap between the existing number of registered products against historical registration data, despite an increasing number of licensed establishments since the reinstatement of licensing and registration procedures.

   In consideration of such appeals, through this Advisory, the FDA hereby announces that further regulatory flexibilities will be granted in the aspects of securing a Certificate of Product Registration (CPR) and bringing HUHS products into conformity with the labeling requirements under Annex J of the same Circular. The transitory period provided in Item no. 2 of Section IV.A under FDA Circular No. 2021-011-A will be extended until December 2024 to allow affected establishments to comply. A separate FDA Circular will be issued formalizing these arrangements.

2. **On-boarding of the HUHS licensing process on to the FDA e-Services Portal System**

   The FDA is pleased to announce that the on-boarding of the HUHS licensing process on to the FDA e-Services Portal System following Department of Health (DOH) Administrative Order No. 2020-0017 is currently being undertaken through a project by FDA-CCHUHSRR and the Information, Communication and Technology Management Division (ICTMD), with an expected target date early this 1st quarter of 2024. Feedback to the responses received during the recently held consultation period through notice-and-

comment[1] will be published in the coming weeks, thereafter, followed by the issuance of the corresponding FDA Circular.

With a view to transition the licensing process to the updated system, the FDA hereby further announces that it will be providing additional regulatory flexibilities. Previously-issued and qualified Licenses to Operate (LTOs) which will be expiring from 1 November 2023 to 31 March 2024 will have their validities automatically extended for an additional three (3) months or until the renewal process has been fully on-boarded. A separate FDA Circular will be issued formalizing these arrangements, including further details specifying qualifying conditions for such flexibility.

3. Technical assistance of the FDA to the HUHS industry

In the course of implementing FDA Circular No. 2020-025, several industry stakeholders have expressed that they are still in the process of building their capacity in the aspects of classification and labeling of chemicals following the Globally Harmonized System (GHS), risk assessments, generating safety data sheets, among others. To this end, the FDA through CCHUHSRR has launched several initiatives aimed at providing technical assistance to its stakeholders.

a. Technical workshops on HUHS product registration

In 2022-2023, FDA-CCHUHSRR has conducted a series of workshops covering registration applications following FDA Circular No. 2020-025, including GHS. Thirteen (13) workshops were held, and a total of 501 participants attended.

Sustaining its commitment to build the capacity of the industry, FDA-CCHUHSRR, in coordination with the FDA Academy, is currently developing an in-person technical seminar on GHS application in classifying and labelling chemicals. The first series of seminars are expected to be launched by early 1st semester of 2024.

b. HUHS Product Registration Guide Manual

As earlier shared during the *Kapihan at Talakayan* activity in June 2023, FDA-CCHUHSRR has launched an initiative to develop a Guide Manual for the HUHS Industry to assist stakeholders as they comply with FDA regulatory requirements. The first edition of the manual intended for the process covering initial product registration, is at the last stages of development and is slated for publication this quarter.

4. Consumer awareness campaigns on HUHS product safety

Lastly, the FDA is pleased to share its on-going public advocacy campaign intending to raise public awareness concerning the proper and safe use of HUHS products. It includes a social media strategy, entitled, "The Hows of HUHS: Everything you should know about

[1] https://www.fda.gov.ph/draft-for-comments-guidelines-on-the-filing-and-submission-of-applications-for-the-licensing-of-household-urban-hazardous-substances-huhs-establishments-through-the-food-and-drug-administration/

safe handling and use of Household/Urban Hazardous Substances", as well as a project to integrate HUHS licensing and registration information to the FDA Verification Portal (https://verification.fda.gov.ph/).

These initiatives are designed to keep the public well-informed through insightful posts included in the social media strategy and by offering a facility to verify the registration status of HUHS products. Ultimately, the campaign aims to cultivate a safety-conscious society, reducing incidents and the environmental consequences associated with HUHS products.

The FDA emphasizes that regulations are put in place to ensure that HUHS products are safe and effective, when used as directed, and are of standard quality. In promulgating such regulations, the FDA recognizes that its implementation and enforcement must likewise support the economic environment without compromising consumer safety and public health. Thus, while these regulatory flexibilities are further granted, the FDA calls on HUHS industry stakeholders to renew their commitment in pursuit of protecting consumers. Meanwhile, stakeholders and the public may look forward to continuous improvements as the FDA strives towards a more effective and efficient regulatory system.

DR. SAMUEL A. ZACATE
Director General