Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

Food and Drug Administration PHILIPPINES

30 MAR 2023

FDA CIRCULAR
No. 2023-006

SUBJECT : **Updated Guidelines on the Filing and Submission of Applications for the Licensing and Registration of Household/Urban Hazardous Substances (HUHS) Establishments and Products, Respectively, through the FDA E-Portal V.2 System**

I. RATIONALE

Pursuant to DOH Administrative Order No. 2019-0019 and 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) receives and processes application for the licensing and registration of Household/Urban Hazardous Substances (HUHS) establishments and products, respectively, through its online application platform called the FDA Electronic Portal (e-Portal) V.2 System. However, from the issuance of FDA Circular No. 2020-025 on 19 August 2020, changes and updates in the e-Portal V.2 System have been made to incorporate the preliminary assessment (Pre-Assessment) step and update the application forms. This initiative has been made to improve the application process and ensure consistency with Republic Act (RA) No. 11032 or the "Ease of Doing Business and Efficient Government Service Delivery Act of 2018".

In the interest of public service and to further enhance the efficiency of the aforementioned HUHS processes, the updated procedures for the electronic filing and submission of applications for HUHS licensing and registration through FDA e-Portal V.2 System are hereby provided amending Section V, Item nos. 3.2, 3.3, 4.2, and Annexes B, B.1, C. D of FDA Circular No. 2020-025.

II. OBJECTIVE

This Circular aims to provide the updated procedures for the electronic filing and submission of applications for the licensing of HUHS establishments and registration of HUHS products.

III. SCOPE

This Circular covers HUHS manufacturers, traders, distributors including importers, exporters and wholesalers, and HUHS products intended to be placed in the market.

IV. GUIDELINES

A. Applications for licensing and registration shall be lodged and processed through the FDA e-Portal V.2 System.

B. To access the FDA e-Portal V.2 system, a user account must be secured through the procedure outlined in **Annex A**, "Acquiring a User Account for the FDA Electronic Portal V.2 System" amending Section V, Item no. 3.2 and Annexes B, B.1 of FDA Circular No. 2020-025. The user account shall only be issued to the Owner/President/CEO of the establishment upon submission of proof of ownership.

Applications lodged through the FDA e-Portal V.2. system are a responsibility and accountability of the Owner/President/CEO of an establishment, as such only the duly authorized personnel of applicant-establishments and the e-mail address and its password shall be entrusted with FDA applications. For purpose of emphasis, all consultants, liaison officers, or freelancers doing business with FDA or work on a per product registration/notification basis shall not be considered as duly authorized or qualified persons.

C. The security and integrity of user accounts, including the applications filed using such accounts, shall be the responsibility of the regulated establishment. Applicants must ensure only the authorized representative can access their provided user accounts.

D. Applicants shall use their user accounts in accordance with existing laws, and FDA rules and regulations. FDA reserves the right to suspend and cancel user accounts found to be in violation of laws and its rules and regulations. The FDA shall not be liable for any loss, damage, or expenses, howsoever arising, out of or in connection with the use of the application system as a result of negligence, delict, or violations to applicable laws, rules and regulations.

E. The applicant shall follow the updated guidelines and procedures in the submission and filing of applications as specified in the following Annexes, amending Section V, Item nos. 3.2, 3.3, 4.2, and Annexes B, B.1, C. D of FDA Circular No. 2020-025:
    1. **Annex B**, "Procedure in the Submission of an Initial HUHS License to Operate (LTO) Application"
    2. **Annex C**, "Procedure in the Submission of an HUHS LTO Variation Application"
    3. **Annex D**, "Procedure in the Submission of an Initial HUHS Product Registration Application"

F. The applicant shall ensure that the information and documents uploaded to the system and submitted to FDA are true, correct, up to date, and complete.

G. In filling-in of forms and uploading of documents, the following must be observed by the applicant:
    1. In the application forms of the system, fields marked with red asterisks (*) are required to be filled-in. Required fields which are not applicable shall be marked with "Not Applicable" or "N/A".

2. Documents uploaded to the system must conform to the following specifications:
    a. Documents/ files/ information uploaded must be free from bugs, viruses, and the like that may compromise the FDA system.
    b. Documents must be scanned and saved in PDF file format at 100-150 dots-per-inch (dpi). Other documents, such as photos and loose artwork labels of the product/s must be in .png format.
    c. The system allows a maximum file size of 4 megabytes (mb) per document, with a total allowable limit of 20 mb per application filed.
    d. File names of documents shall be less than 40 characters in length, and shall not contain the following characters: \ ? / : * " > < I

H. All HUHS licensing and registration applications shall undergo the pre-assessment step, following RA 11032, which covers the determination of the completeness of information and documents submitted. Incomplete submissions will not be accepted and the application will not proceed to the next step of the process.

I. The feature for the electronic submission of CPR variation application/s in the FDA e-Portal V.2 System is currently under development. Hence, until such time that the system becomes available, all Marketing Authorization Holders whose registered HUHS products have change/s in circumstances as listed in Annex E of FDA Circular No. 2020-025 are instructed to submit to the Food and Drug Action Center (FDAC) a letter of intent, notifying the Center of said change/s in the product 's circumstance/s. The letter shall be signed by the establishment owner or the company's registered Authorized Representative or Qualified Person and shall include a commitment that the company shall apply for a CPR variation application once the system is available. The stakeholder can proceed the change/s once they have submitted the signed letter of intent to FDA. A separate issuance shall be provided with the necessary instructions for CPR variation, once the system is available.

J. The FDA, through CCHUHSRR, shall endeavor to develop and update Information, Education and Communication (IEC) materials to guide the HUHS establishments in navigating the system platform and assist them in their HUHS licensing and registration applications.

V. PENALTY CLAUSE

Any person found in violation of this Circular shall be deemed in violation of Republic Act No. 3720 as amended by Republic Act No. 9711 and shall be penalized accordingly following the Uniform Rules of Procedures laid down under Book III of the Implementing Rules and Regulations of Republic Act No. 9711.

VI. SEPARABILITY CLAUSE

If any part, term of provision of this Circular shall be declared invalid, unenforceable or unconstitutional, the validity or enforceability of the remaining portions or provisions

shall not be affected and this Circular shall be construed as if it did not contain the particular invalid, unenforceable or unconstitutional part, term, or provision.

VII. REPEALING CLAUSE

This Circular hereby repeals Section V, Item nos. 3.2, 3.3, 4.2, and Annexes B, B.1, C, D of FDA Circular No. 2020-025. Other related issuances inconsistent or contrary to the provisions of this Circular are hereby amended or modified accordingly.

VIII. EFFECTIVITY

This Circular shall take effect after fifteen (15) days following the publication in the Official Gazette or in a newspaper of general circulation and filing with the Office of the National Administrative Register of the UP Law Center.

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Director General

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