FDA CIRCULAR
No. _____

SUBJECT : Further Regulatory Flexibilities for the Implementation of FDA Circular No. 2020-025 "Implementing Guidelines for DOH Administrative Order No. 2019-0019"

I. RATIONALE

On 21 January 2022, the Food and Drug Administration (FDA) issued FDA Circular No. 2021-011-A on the "Extension of Transitory Period and Provision of Interim Guidelines for Product Registration, including the Labeling Requirements, for Household/Urban Hazardous Substances", which established a 2-year transitory period extension until 31 December 2023 for Household/Urban Hazardous Substances (HUHS) product registration in view and consideration of the economic challenges brought about by the COVID-19 pandemic, and in order to assist the HUHS industry as they comply with the registration requirements of FDA Circular No. 2020-025 "Implementing Guidelines for Administrative Order No. 2019-009".

However, appeals had been made by the HUHS industry and other concerned stakeholders to further extend the transitory period to allow compliance with the registration and labeling requirements under FDA Circular No. 2020-025. Further, based on the conducted review of FDA on the registration procedure, there is a gap between the existing number of registered products against the historical market authorizations data, despite an increasing number of licensed establishments since the reinstatement of the licensing and registration guidelines. The FDA thus recognized the need to consider the further extension of the transitory period for the HUHS product registration and labeling requirements. Additionally, with a view of transitioning the licensing process to the updated FDA eServices Portal System, there is a need to consider flexibilities particularly for previously issued licenses to operate which will be expiring before the on-boarding to the said system.

It is in this view that the FDA has considered the regulatory flexibilities announced through FDA Advisory No. 2023-2269, and hereby issues this Circular to assist the HUHS industry in complying with the licensing and registration requirements of FDA Circular No. 2020-025.

II. OBJECTIVES

This Circular aims to:

A. Provide the guidelines for the grant of regulatory flexibilities for HUHS establishments in light of the transition to the FDA eServices Portal System;
B. Establish a one (1)-year transitory period extension for HUHS product registration and labeling requirements; and,

C. Provide the interim guidelines for the implementation of FDA Circular No. 2020-025.

III. SCOPE

This Circular 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.

IV. GUIDELINES

A. License to Operate (LTO) and applicable regulatory flexibilities

1. A License to Operate (LTO) as HUHS establishment shall be mandatory for all establishments engaged or intending to engage in HUHS-related activities, pursuant to Department of Health (DOH) Administrative Order Nos. 2019-0019 and 2020-0017, FDA Circular No. 2020-025, and their future amendments.

2. A pre-licensing inspection upon initial LTO or a major variation application of HUHS manufacturers shall be required before the issuance of the LTO. Other HUHS establishments shall be subjected to post-licensing inspections. HUHS establishments with previously-issued LTOs will be subjected to post-licensing inspection for compliance with existing HUHS standards and regulations.

3. An LTO shall be cancelled if the establishment, upon verification during inspection, is found in violation of relevant rules and regulations, including the absence of a facility. Violations committed while in operation as specified in Book II, Article 1, Section 4.A of the Implementing Rules and Regulations (IRR) of Republic Act (RA) No. 9711 shall likewise be grounds for the disapproval of an application, and suspension or cancellation of the LTO.

4. Until such time that the HUHS Licensing Procedure has been fully on-boarded on to the FDA eServices Portal System, the following procedures shall apply in the filing and submission of HUHS LTO applications:

    a. Initial and variation applications for HUHS LTO shall be lodged and processed in the FDA e-Portal v2 system, following the procedural guidelines in FDA Circular No. 2023-006, and requirements in FDA Circular No. 2020-025 and DOH Administrative Order No. 2020-0017 and their amendments.

    b. For renewal applications, the validity of previously issued HUHS LTOs which will be expiring from 1 November 2023 to 31 March 2024 shall be deemed renewed for an additional three (3) months, provided that:
        - On or before expiry of the previously issued LTO, the HUHS establishment shall submit a notarized letter request and declaration for

renewal to the Food and Drug Action Center (FDAC) which shall be signed by the establishment owner or registered Authorized Representative and Qualified Person, duly acknowledged by the FDA (*Please see Annex A for the procedure and Annex B for the template of Letter Request for LTO Renewal*);

- Once the FDA eServices Portal System is available for the HUHS licensing process, the renewal application for the LTO shall be filed within the extended validity, and that the renewal fee and other applicable charges be paid once lodged in the updated system; and,
- No pending case, ruling, or violation that prohibits the company from filing an LTO is found during evaluation, inspection or other related activities conducted by the FDA.

c. Applicants are advised to avoid deferring the filing of renewal applications. It is highly encouraged to file a renewal application as soon as the FDA eServices Portal System is available.

d. For the regulatory flexibilities which will be granted under Item 2.b. of this Section, the LTOs which will be issued following an approved renewal application through the FDA eServices Portal System shall bear a renewed validity date based on the originally issued LTO.

e. Applications filed after the extended validity date shall be subject to penalties relating to the renewal of license stipulated in RA No. 9711 and its IRR.

- LTO renewal applications filed within one-hundred twenty (120) days from the expiry of the extended validity shall remain valid until FDA renders decision on the renewal application, however, it shall be subject to an applicable surcharge based on RA No. 9711 and its IRR.
- LTOs for renewal filed after one-hundred twenty (120) days from the expiry of the extended validity 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 LTO application process, pursuant to RA 9711 and its IRR.
- LTOs due for renewal with no filed applications shall be considered expired and automatically be cancelled after one-hundred twenty (120) days from the expiry of the extended validity.

5. A separate issuance on the implementation, guidelines and procedure for the on-boarding of the HUHS licensing process to the FDA eServices Portal System shall be issued by FDA.

B. Certificate of Product Registration (CPR)

1. **Extended transitory period for registration requirement.** The one (1)-year transitory period shall apply to the registration of HUHS products. Hence, from 01 January to 31 December 2024, HUHS establishments may continue to distribute their HUHS products without a CPR from the FDA. However, effective

01 January 2025, CPR shall be mandatory for all HUHS products distributed in the market.

2. **Labeling requirements including GHS.** The one (1)-year transitory period shall serve as further exhaustion period wherein HUHS establishments may deplete their remaining stocks of HUHS products with non-compliant labels and make necessary plans or preparations to bring their HUHS products into conformity with the labeling requirements under Annex J of the FDA Circular No. 2020-025 including the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) label elements.

3. **Submission of label artworks during transitory period.** During the transitory period, the following must be observed for the submission of product labels for the purposes of product registration applications:

    a. Existing product labels must be submitted and shall be acceptable regardless of their compliance with Annex J of FDA Circular No. 2020-025 for the purposes of product registration, provided that product claims in the provided labels are sufficiently substantiated.
        - In case the provided existing label contains unsubstantiated claims and/or safety claims which are not allowed, an artwork of the proposed label without the unsubstantiated claim and/or safety claim must be submitted during product registration. In lieu of a proposed label, for unallowable safety claims, a letter may be submitted containing a commitment to delete or remove the safety claim from the new HUHS product label.
        - If the existing label does not contain any unsubstantiated product claims and unallowable safety claims, a submission of a proposed artwork is not required for the purposes of product registration.

    b. Any proposed labels submitted during product registration intending to bring a product in conformity with Annex J of FDA Circular No. 2020-025 shall be evaluated for compliance. Placeholders shall be allowed for the purposes of registration.

    c. The submission of final artwork of product labels compliant to Annex J of FDA Circular No. 2020-025 shall be a requirement for renewal and shall be subject for review of its label compliance.

4. **CPR variation application.** For registered HUHS products that have change/s in circumstances as listed in Annex E of FDA Circular No. 2020-025, a letter of intent shall be submitted by the Marketing Authorization Holder to FDAC. This letter shall be signed by the Establishment Owner or company's registered Authorized Representative or Qualified person and shall include the following:
    - Information on the change/s in the product's circumstance/s
    - Commitment that the company shall apply for a CPR variation application once the system is available

The establishment can proceed with the change/s once they have submitted the signed letter of intent and received an acknowledgement/clearance from the FDA.

5. **Notice of Deficiency (NOD).** During the extended transitory period, NODs shall be issued once for HUHS products with minor deficiencies to allow the HUHS establishment to correct and address said deficiencies within fourteen (14) calendar days. Minor deficiencies are those that can be corrected or complied with through the submission of additional supporting documents and do not require revision of the submitted CPR application form. These include but are not limited to the following:
   - Findings that require further clarifications from the HUHS establishment
   - Insufficiently substantiated product claims
   - Presence of unsubstantiated and/or safety claims on the existing product label
   - Minor errors in the submitted documents that will not affect the declared information in the application form
   - Proposed label that is not compliant with Annex J of FC No. 2020-025

   Failure to address all noted deficiencies within this timeline shall result in the disapproval of the CPR application.

   For further guidance, please refer to the *Annex D.II.D.2 of FDA Circular No. 2023-006* and *Part II.A. Initial HUHS Product Registration Process, Items (4) Evaluation (page 60) and (6) NOD (page 61) of the Guide for the Industry on the Initial Product Registration of Household/Urban Hazardous Substances (HUHS) Products through FDA Advisory No. 2023-2268* for the detailed guidelines and procedure for the issuance of and/or compliance to NODs.

6. **FDA e-Portal v2 System for HUHS CPR.** Applications for registration of HUHS products shall be lodged in the FDA e-Portal v2 system following the updated procedural guidelines in the FDA Circular No. 2023-006 and requirements in FDA Circular No. 2020-025.

7. **HUHS products solely for export and re-export.** The HUHS products solely for export and re-export shall not be required to secure a CPR, however an LTO for the exporter activity shall be required following DOH AO No. 2020-0017 and FDA Circular No. 2020-025. Further, establishments exporting and/or re-exporting such HUHS products shall bear the overall responsibility for the safety, efficacy and quality of their products. Furthermore, such establishments shall be responsible for any necessary compliance with the standards and regulations of the receiving country or state.

C. **Other Authorizations**

Applications for other authorizations shall be processed in accordance with the fees following AO No. 50 s. 2001 and its future amendments, and the procedures specified in the FDA Citizen's Charter.

1. **Sales and Promo Permits and Customs-related concerns.** Securing other authorizations including Sales and Promo Permit and clearance for customs-related concerns for products covered by this Circular are not mandatory, as the issuance of permits require a valid CPR. During the transitory period, for the purpose 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.

2. **Certificate of Free Sale (CFS).** CFS applications may only be accepted for products with a valid CPR. Establishments requiring a CFS for their own purposes must register their products with the FDA following FDA Circular No. 2020-025 or its amendments, wherein a CPR must be secured first before submitting an application for CFS.

3. **Good Manufacturing Practice (GMP) Certificate.** If applied whether subsequent to an initial, or simultaneous to renewal of LTO, a Certificate of GMP Compliance shall only be issued upon demonstration of satisfactory compliance with existing GMP standards stipulated in Annex H of FDA Circular No. 2020-025, rules and regulations. The validity of the Certificate of GMP Compliance shall be congruent with the validity of the current LTO of the HUHS manufacturer.

D. Postmarketing surveillance (PMS) Activities

PMS activities shall be in accordance with FDA Circular No. 2020-025 or its amendments during and after the transitory period extension. This does not preclude FDA from issuing subsequent orders and perform regulatory actions it may deem necessary and appropriate to protect public health and safety, including, warnings for labeling and advertisements to prevent misleading claims, alerts on safety concerns, and other regulatory actions for unlicensed establishments conducting activities and other violations covered by existing laws, rules, and regulations.

E. Responsibilities of the Marketing Authorization Holder (MAH)

The responsibilities of the MAH, including all other clauses or parts stipulated in FDA Circular No. 2020-025 remain valid and shall be enforced.

F. Full implementation of FDA Circular No. 2020-025 beginning 1 January 2025

1. The CPR requirement shall be mandatory for all HUHS products distributed in the market.

2. Labels of HUHS products shall be fully compliant with Annex J of FDA Circular No. 2020-025 and its amendments, including GHS label elements.

3. A 6-month transitory period shall be given to the sales promotion requirement to provide the industry with sufficient time in the preparation of necessary promotional materials once CPRs are secured. On 01 July 2025, the Sales and

Promo Permit shall be mandatory for all companies conducting promotional activities with participating HUHS products.

4. HUHS establishments and their products shall be subject to regular postmarketing surveillance (PMS) activities of FDA. Appropriate regulatory actions shall be imposed to establishments with HUHS products monitored and collected through PMS activities without proper authorizations and/or with non-compliance to the requirements under FDA Circular 2020-025 and its amendments, and relevant laws, rules and regulations.

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 amends relevant provisions in FDA Circular Nos. 2021-011-A 2020-025 and 2023-006, and FDA Advisory No. 2020-2035. 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.

DR. SAMUEL A. ZACATE
Director General