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REPUBLIC OF THE PHILIPPINES
DEPARTMENT OF FINANCE
BUREAU OF CUSTOMS
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22 April 2025

CUSTOMS MEMORANDUM CIRCULAR NO. 95 -2025

TO : ASSISTANT COMMISSIONER
ALL DEPUTY COMMISSIONERS
ALL DIRECTORS AND DIVISION CHIEFS
ALL DISTRICT AND SUB-PORT COLLECTORS
ALL OTHERS CONCERNED

SUBJECT : FOOD AND DRUG ADMINISTRATION (FDA) – EXTENSION OF VALIDITY OF LICENSE TO OPERATE (LTO) FOR HOUSEHOLD/URBAN HAZARDOUS SUBSTANCES (HUHS) ESTABLISHMENTS

Pursuant to the attached letter dated 02 April 2025 from Engr. Ana Trinidad F. Rivera, MSc, Director IV, Center for Cosmetics and Household/Urban Hazardous Substances Regulation and Research (CCHUHSRR), FDA is requesting the dissemination of the extension of the LTOs issued to HUHS establishments, i.e., manufacturers, traders, and distributors.

Further, as per the CCHUHSRR, there has been a delay in the implementation of the online application platform for the renewal of LTOs issued to HUHS establishments. As such, the interim guidelines outlined under FDA Advisory No. 2024-1660 shall remain in effect until further notice.

Accordingly, to ensure that the delay does not hamper business operations—including, but not limited to, the release of imported shipments of HUHS products from the Bureau of Customs (BOC)—regulatory flexibilities are extended to the HUHS industry through the automatic extension of the validity of their LTOs, provided that the HUHS establishment holding an expired LTO has successfully submitted to the FDA, through its Food and Drug Action Center, a Letter of Request and Declaration Statement, pursuant to FDA Advisory No. 2024-0543.

In this regard, and in lieu of a valid LTO as HUHS Distributor-Importer, you are hereby directed to accept the following documents as valid documentation to facilitate the release of imported HUHS products intended to be placed in the market:

a. A copy of the expired LTO as HUHS Distributor-Importer; and
b. Acknowledgment Receipt from the FDA for the submitted Letter of Request and Declaration Statement.

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CMC. No. 95 - 2025 p. 2

For records purposes, please disseminate throughout your respective offices and submit the necessary confirmation within fifteen (15) days from receipt hereof.

For your information and reference.

BIENVENIDO Y. RUBIO
Commissioner

08 MAY 2025

CMO No. 95-2025 P.3

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FDA Food and Drug Administration PHILIPPINES

Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

BAGONG PILIPINAS

PORT OPERATIONS COORDINATION DIVISION
AOCG BOC
RECEIVED
10 APR 2025
By: Time:

BUREAU OF CUSTOMS
PORT OPERATIONS SERVICE
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BY: TIME: 2:43

2 April 2025

03-27913

HON. BIENVENIDO Y. RUBIO
Commissioner
Bureau of Customs (BOC)
Office of the Commissioner
G/F OCOM Bldg., 16th Street, South Harbor,
Port Area, Manila

SUBJECT: Extension of LTO Validity for HUHS Establishments

Dear **Commissioner Rubio**,

Greetings!

The Food and Drug Administration (FDA), through the Center for Cosmetics and Household/Urban Hazardous Substances Regulation and Research (CCHUHSRR), respectfully seeks your assistance in disseminating the important information presented below to the relevant divisions, groups, and ports under the Bureau of Customs (BOC).

Due to unforeseen circumstances, there has been a delay in the implementation of the online application platform for the renewal of License to Operate (LTO) issued to Household/Urban Hazardous Substances (HUHS) establishments, i.e. manufacturers, traders, and distributors. As such, the interim guidelines outlined in FDA Advisory No. 2024-1660 will remain in effect **until further notice**.

Accordingly, to ensure that the delay does not hamper business operations including but not limited to the release of imported shipments of HUHS products from the BOC, further regulatory flexibilities are extended to the HUHS industry through the **automatic extension of the validity of their LTOs**, provided that the HUHS establishment holding an expired LTO successfully submits to the FDA, through its Food and Drug Action Center, a Letter of Request and Declaration Statement following FDA Advisory No. 2024-0543.

In this regard, this Office would like to inform you that in lieu of a valid LTO as HUHS Distributor-Importer, the HUHS industry has been advised to present the following documents to the BOC as **valid documentation** to facilitate the release of their imported HUHS products intended to be placed in the market from Customs:

(1) A copy of the expired LTO as HUHS Distributor-Importer; AND
(2) Acknowledgment Receipt from the FDA of the submitted Letter of Request and Declaration Statement.

Should there be any concerns related to the subject of this letter, please do not hesitate to contact the HUHS Licensing Section at cchuhsrr.lrd.huhs@fda.gov.ph.

CMC No. 95-2025 P.9 MASTER COPY

We appreciate your support and cooperation.

Very truly yours,

ENGR. ANA TRINIDAD F. RIVERA, MSc
Director IV, Center for Cosmetics and Household/Urban
Hazardous Substances Regulation and Research
DTN: 20250402104459
CCT/jpm

cc: Companies Holding Expired LTO as HUHS Establishment

CMC No. 95-2025 p. 5

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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

CMC NO. 95-2025 p. 9 MASTER COPY

Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

BAGONG PILIPINAS

FDA ADVISORY
No. 20240543

25 MAR 2024

TO : HOUSEHOLD/URBAN HAZARDOUS SUBSTANCES (HUHS) STAKEHOLDERS

SUBJECT : ON-BOARDING OF THE LICENSING PROCEDURES FOR HOUSEHOLD/URBAN HAZARDOUS SUBSTANCES (HUHS) ESTABLISHMENTS ON THE FOOD AND DRUG ADMINISTRATION (FDA) ESERVICES PORTAL SYSTEM

The Food and Drug Administration (FDA) continues its digital system enhancement through the development of online application platforms, particularly, the FDA eServices Portal System. These enhancements aim to further simplify application submissions in alignment with the principles of ease of doing business espoused in Republic Act No. 11032, otherwise known as the "Ease of Doing Business and Efficient Government Service Delivery Act of 2018".

The FDA hereby informs all stakeholders and the general public that the following services in relation to applications for **License to Operate (LTO) for HUHS Establishments** will be on-boarded onto the FDA eServices Portal System:

On-Boarding of FDA eServices Portal System for the Licensing of HUHS Establishments	
Type of LTO Application	1. Initial 2. Renewal 3. Variation
Type of HUHS Establishment	**1. HUHS Manufacturer** a. HUHS Manufacturer / Toll Manufacturer b. HUHS Manufacturer-Packer / Toll Packer c. HUHS Manufacturer-Repacker / Toll Repacker **2. HUHS Distributor** a. HUHS Distributor-Importer b. HUHS Distributor-Exporter c. HUHS Distributor-Wholesaler **3. HUHS Trader**

All applications shall be exclusively filed and accepted through the eServices Portal System at https://eservices.fda.gov.ph beginning on 01 July 2024.

CMC No. 95-2025 p. 10

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Currently, the HUHS licensing module of the eServices Portal System is in the last stages of dry run testing. The FDA will issue a separate announcement once the FDA eServices Portal System is available and ready to receive HUHS LTO applications.

The following guidance documents on the procedure for filing applications are annexed to this Advisory:

1. **Annex A** - LTO Requirements for HUHS Establishments
2. **Annex B** - Procedure in the Submission of an Initial LTO Application
3. **Annex C** - Procedure in the Submission of Renewal LTO Application
4. **Annex D** - Procedure in the Submission of Variation LTO Application
5. **Annex E** - Procedure for Checking the Status of an Application
6. **Annex F** - Procedure for Voluntary Cancellation of an Application
7. **Annex G** – Letter Template for HUHS LTO Renewal

Further, please be clarified on the following arrangements:

1. All initial LTO applications filed via the FDA ePortal v2 System before 01 July 2024 will be processed in accordance with FDA Circular No. 2023-0006, hence, re-application through the FDA eServices Portal System is not necessary. However, should an applicant wish to apply through the new FDA eServices Portal System, the application shall be treated as new, and a separate fee shall be charged.

2. All previously-issued HUHS LTOs expiring before the availability of the system are automatically extended **until 30 June 2024 and their surcharges are waived**; **Provided**, that prior 15 June 2024 a letter signifying intention to submit an LTO renewal application in the FDA eServices Portal System 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 G**, with complete information including the declaration statement, and signed by the establishment owner/authorized representative/qualified person.

For the information and guidance of all concerned.

DR. SAMUEL A. ZACATE
Director General