Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA CIRCULAR
No. 2020-025

19 AUG 2020

SUBJECT : **Implementing Guidelines for Administrative Order No. 2019-0019, "Reinstatement of Requirements of Licensing as Importers, Exporters, Manufacturers, Toll Manufacturers, Wholesalers, Distributors, Retailers, or Re-Packers of Those Engaged in Certain Household/Urban Hazardous Substances, and from the Requirement of Prior Registration and/or Notification of Said Products"**

I. RATIONALE

Presidential Decree No. 881 (PD 881) dated 30th January 1976 empowered the Secretary of Health to regulate the labeling, sale and distribution of hazardous substances. Republic Act (RA) No. 3720, as amended by RA 9711, otherwise known as the "FDA Act of 2009" strengthened PD 881, among others, by defining health products as "any food, drugs, cosmetics, devices, biologicals, vaccines, in-vitro diagnostic reagents and household/urban hazardous substances (HUHS) and/or a combination of and/or a derivative thereof. It shall also refer to products that may have an effect on health which require regulations as determined by the FDA." Further, the enactment of RA 11467 imposing for higher excise taxes on certain commodities, and consistent with Executive Order No. 106, the FDA is given the mandate to regulate Novel HUHS Products (Vapor Products) such as Electronic Nicotine and Non-Nicotine Delivery System (ENDS/ENNDS) and Heated Tobacco Products (HTPs).

Considerable developments in chemicals management which affect labeling has lead to the publication in 2003 of the Globally Harmonized System (GHS) of Classification and Labeling of Chemicals which was adopted in the Philippines in 2009 by virtue of Joint DTI-DENR-DA-DOF-DOH-DILG-DOLE-DOTC Administrative Order No. 01 series of 2009.

Finally, Administrative Order (AO) No. 2019-0019 issued on 25 June 2019 reinstated the licensing and registration requirements of certain HUHS products, and mandated the FDA to establish guidelines in relation thereto. Hence, the issuance of this Circular.

II. OBJECTIVE

This Circular aims to:

1. Establish the guidelines for the licensing and inspection of HUHS establishments;

2. Establish the guidelines for registration and other relevant authorizations for HUHS products;
3. Update the categorization of HUHS products;
4. Institutionalize the Globally Harmonized System of Classification and Labeling of Chemicals (GHS) as the new hazard category for labeling of HUHS products; and
5. Ensure compliance of HUHS establishments to FDA regulatory standards, such as but not limited to Good Manufacturing Practice (GMP), Good Distribution Practice (GDP), or Good Storage Practice (GSP); or Good Labeling Practice (GLP).

III. SCOPE

This Circular shall apply to establishments engaged in the manufacture, importation, exportation, distribution, sale, offer for sale, transfer, promotion, advertisement, and/or sponsorship of HUHS products as defined in RA 9711 and Its Implementing Rules and Regulations (IRR), and as categorized herein, intended for consumer and institutional use.

For clarity, while Novel HUHS Products including Vapor Products such as ENDS/ENNDS and HTPs, Toys and Childcare Articles (TCCAs) and Household/Urban Pesticide (HUP) products, are among the categories of HUHS products, licensing of establishments, and registration/notification for these products shall be covered by the existing procedures specific for such categories.

The licensing and registration requirements provided in this Circular, however, shall not apply to the following under Categories III and IV on Section V.2 of this issuance:

1. Establishments engaged in the manufacture, importation, or distribution of raw materials used in the production of HUHS products, and their products;
2. Retailers of HUHS products;
3. HUHS products which are:
    - for donation, in which Administrative Order No. 2020-001 "Guidelines in the Importation, Facilitation and Management of Foreign Donation Involving Health and Health-Related Products" and its future amendments shall apply;
    - imported for personal use, in which Department of Health - Food and Drug Administration – Bureau of Customs (DOH-FDA-BOC) Joint Circular No. 1 "Importation of FDA-DOH Regulated Products for Personal Use" and its future amendments shall apply;
    - intended to be used for exhibits;
    - intended for exclusive use in agricultural setting;
    - intended for other health-related/medical-related use (i.e. disinfectant products under the jurisdiction of Center for Drug Regulation and Research and Center for Device Regulation, Radiation Health and Research);
    - intended to be used for research and development and analysis of HUHS product.

IV. GENERAL GUIDELINES

1. The terms used in this Circular shall have the meaning as defined in RA 9711 and its IRR, and related laws and regulations.
2. HUHS establishments shall continuously comply with existing FDA laws, rules and regulations.
3. HUHS establishments shall be under the supervision of a qualified person with technical knowledge and/or adequate training on HUHS raw material and product safety.
4. HUHS establishments shall secure a License to Operate (LTO) prior to engaging in the manufacture, importation, exportation, sale, offer for sale, distribution, transfer, promotion, advertising, and/or sponsorship of HUHS products.
5. HUHS establishments shall be subject to monitoring and inspection by the FDA Regional Field Offices prior to and/or after the issuance of the LTO.
6. HUHS establishments shall secure the appropriate Certificate of Product Registration (CPR) for HUHS products intended to be manufactured, imported, exported, distributed, sold, offered for sale, transferred, promoted, advertised and/or sponsored. Only FDA-licensed HUHS establishments shall be allowed to apply for a CPR.

V. SPECIFIC GUIDELINES

1. *Classification of HUHS Establishments*

HUHS establishments shall be classified following the definition provided in RA 9711 and its IRR, other related laws and issuances:

1.1 HUHS Manufacturer

1.1.1 HUHS Manufacturer / Toll Manufacturer
1.1.2 HUHS Manufacturer-Packer / Toll Packer
1.1.3 HUHS Manufacturer-Repacker / Toll Repacker
1.1.4 HUHS Manufacturer-Trader

1.2 HUHS Distributor

1.2.1 HUHS Distributor-Exporter
1.2.2 HUHS Distributor-Importer
1.2.3 HUHS Distributor-Wholesaler

2. *Categorization of HUHS Products*

2.1 HUHS products shall be classified into at least the following:

Category I: Novel HUHS Products (Vapor Products)
Category II: Yard and Home Products
Category III: Cleaners, Fresheners and Deodorizers
Category IV: Do-It-Yourself and Hobby Items
Category V: Toys and Childcare Article Products

The product listing per category is identified in *Annex A* of this Circular. This product listing is non-exclusive and may be amended as determined by FDA.

2.2 For purposes of this Circular, HUHS products under Categories III and IV (as applicable) shall be classified further as:

2.2.1 Ready-to-Use – refer to HUHS products that are ready to be used outright of the packaging and for general purposes, which require no further dilution prior to application.

2.2.2 For Professional Use – refer to HUHS products that are highly concentrated requiring further dilution and are restricted only to be applied by a trained personnel.

3. *Application for License to Operate (LTO)*

3.1 HUHS establishments shall abide by the applicable provisions of AO 2020-0017, "Revised Guidelines on the Unified Licensing Requirements and Procedures of the Food and Drug Administration Repealing Administrative Order No. 2016-0003" dated 8 May 2020, or its future amendments, in applying for issuance of LTO.

3.2 All applications for issuance of LTO shall be submitted through the FDA e-Portal System. A Username and Password shall be secured in order to access the FDA e-Portal System as specified in *Annexes B, and B.1.*

3.3 HUHS establishments shall follow the licensing procedure as prescribed in *Annex C* of this Circular.

3.4 All applications shall be deemed filed upon payment of required fees and charges.

4. *Application for Certificate of Product Registration (CPR)*

4.1 All applications for issuance of CPR shall be submitted through the FDA e-Portal System.

4.2 HUHS establishments shall follow the registration procedure as prescribed in *Annex D* of this Circular.

4.3 The evaluation of applications for CPR shall be based on satisfactory compliance to the requirements and appropriate standards.

4.4 HUHS products shall be registered on a per formulation basis.

4.5 HUHS products having the same base formulation but different fragrance or colorant shall be registered as variant.

4.6 For HUHS products that have dual or multiple use (ie. both household and agricultural use), the HUHS establishment shall register the dual or multiple use product with FDA and other concerned regulatory office/s having concurrent jurisdiction thereof.

5. *Application for Issuance of Other Authorizations*

The issuance of sales and promotion permits, Certificate of Free Sale, and other applicable certifications shall comply with the requirements based on existing FDA rules and regulations.

6. *Documentary Requirements for the Issuance of LTO, CPR and Other Authorizations*

HUHS establishments shall follow, prepare, and submit the documentary requirements for the issuance of LTO, CPR, and other Authorizations, as prescribed in *Annex E* of this Circular.

7. *Issuance of Emergency Use Permit*

In public health emergency conditions as declared by the Department of Health (DOH) or the respective Local Government Unit (LGU) requiring use of certain HUHS products (ie. surface disinfectants), an emergency use permit may be applied for an unregistered product or for a registered with use different from what has been approved by the FDA.

Application for an emergency use permit shall be evaluated on its merit based on the information submitted following the requirements as prescribed in *Annex F* of this Circular, and shall be granted permission only for the duration of the emergency period.

8. *Decision on Application*

8.1 Grant of Authorization

The appropriate authorization shall be issued upon an application that satisfactorily complied with all applicable requirements and standards.

8.2 Disapproval of Authorization

8.2.1 Applications with incomplete requirements shall automatically be disapproved.

8.2.2 The disapproval of an application is without prejudice to re-application. However, disapproval of application shall mean outright forfeiture of payment.

8.2.3 Any of the following or similar instances shall be a ground for the disapproval of an application, suspension, revocation or cancellation, of an existing LTO, CPR, or any authorization:

8.2.3.1 The application requirements show that the establishment does not meet the required technical requirements or appropriate standards;

8.2.3.2 The applicant made misrepresentations, false entries, or withheld any relevant data contrary to the provisions of the law, existing FDA rules and regulations, or appropriate standards;

8.2.3.3 The holder or owner has violated any of the terms and conditions of its license, registration, or authorization;

8.2.3.4 The label of the health product is false and misleading or does not conform with current labeling requirements;

8.2.3.5 The holder or owner of the CPR/authorization, without legitimate reason, fails to sell the health product or fails to cause it to be marketed during an uninterrupted period of at least three (3) years from date of issuance or renewal of the registration, or the last date of operation or marketing;

8.2.3.6 Such other analogous grounds or causes as determined by the FDA.

8.2.4 Nothing in this section shall restrict the FDA in imposing the penalty of suspension, revocation, or cancellation of license, registration, or authorization for administrative violations of any other relevant laws or their IRR.

9. *Renewal of Authorizations*

9.1 Application for renewal shall be done within three (3) months prior to the validity date of the LTO or CPR. Applications filed after the validity date of the LTO or CPR shall be subject to surcharge as prescribed in RA 9711 and its IRR.

9.2 Application for CPR renewal without changes from the previously approved product information and label, excluding changes requiring initial CPR application, shall be automatically renewed, provided there are no remarks for compliance indicated in the CPR. Otherwise, regular renewal shall apply subject to verification of compliance to requirements indicated in the CPR.

9.3 Applications with variations shall be treated as regular renewal.

10. *Variations to Issued Authorizations*

10.1 The provisions for applying variation/s to LTO as stipulated in AO 2020-0017, "Revised Guidelines on the Unified Licensing Requirements and Procedures of the Food and Drug Administration Repealing Administrative Order No. 2016-0003" dated 8 May 2020, or its future amendments, shall be followed.

10.2 Changes in the circumstances of a registered HUHS product shall either require an initial or variation application, as applicable:

10.2.1 Variations involving change in the address of the manufacturer of the product, and product formulation shall require an initial CPR application.

10.2.2 Other changes in circumstances of the CPR as stipulated in *Annex E* shall require CPR variation application.

11. *Validity of Authorizations*

11.1 Initial LTO issued to HUHS establishments shall be valid for three (3) years. Renewal LTO shall be valid for a maximum period of five (5) years.

11.2 Initial CPR for the registered HUHS product shall be valid for a maximum of three (3) years. Renewal CPR shall be valid for a maximum of five (5) years.

12. *Fees and charges*

Applications shall be charged with the fees pursuant to the schedule of fees stated in AO 50 s. 2001, and its future amendments.

13. *Processing Time*

Applications shall be processed in accordance with the approved FDA Citizen's Charter.

14. *Standards and Specific Requirements Applicable for HUHS Establishments and Products*

14.1 General Provision

The MAH shall ensure compliance to the following adopted standards (as may be applicable), including but not limited to:

- Philippine National Standards (PNS)
- Relevant issuances and standards emanating from laws governing other National Government Agencies having concurrent jurisdiction over chemicals and hazardous substances
- International Conventions, Treaties and Protocols
- Internationally-acceptable Standards

The list of adopted standards for HUHS products are stipulated in *Annex G* of this Circular.

14.2 Specific Requirements for HUHS Establishments

14.2.1 HUHS establishments shall be situated in a commercialized or industrialized area and shall have environmental clearance, as may be necessary.

14.2.2 The Good Manufacturing Practices (GMP) presented in *Annex H* of this Circular shall provide guidelines for HUHS manufacturers to develop their own internal quality management system and procedures, the aim of which is to produce final products that meet the quality standards appropriate to their intended use to assure consumer's health and safety.

14.2.3 No HUHS establishment shall use the FDA logo, the words "Food and Drug Administration" or "Philippine FDA", the initials "FDA", or any imitation of such words, initials, or logo, in the promotional, advertisement, sponsorship, marketing or commercial materials for their HUHS products, pursuant to FDA Memorandum Circular No. 2013-030,

"Guidelines on the Use of the FDA Logo and Name in Promotional, Advertisement, Sponsorship, Marketing or Commercial Materials", and its future amendments.

14.3 Specific Requirements for HUHS Products

14.3.1 A Product Information File (PIF) following the format as specified in *Annex I* shall be prepared and kept by the Marketing Authorization Holder (MAH) and shall be made readily available and easily accessible by the Authorities upon post-registration review of the registered product.

14.3.2 HUHS products shall not be allowed to contain any carcinogenic, mutagenic, reprotoxic (CMR) ingredient, or other unacceptable or banned substances.

14.3.3 HUHS products that have been banned or withdrawn in the country of origin/source or manufacture shall not be permitted to enter the Philippine market.

14.3.4 HUHS products that are already in the market which have been banned or withdrawn in the country of origin/source or manufacture shall be immediately recalled in accordance with the FDA product recall process, or withdrawn from public sale by the MAH in coordination with FDA, and shall be properly disposed of in accordance with the rules and regulations of the Department of Environment and Natural Resources (DENR).

14.3.5 HUHS products determined by FDA to be imminently injurious, unsafe and dangerous shall be immediately recalled in accordance with the FDA product recall process, or withdrawn from public sale by the MAH in coordination with FDA and shall be properly disposed of in accordance with the rules and regulations of the DENR.

14.3.6 The following labeling and packaging requirements for HUHS products shall be complied with:

14.3.6.1 HUHS products shall bear the labeling information and comply with suitable packaging as specified in *Annex J* of this Circular.

14.3.6.2 The GHS shall be used to determine the hazard category of the HUHS product per hazard class.

14.3.6.3 Labels of HUHS products with hazard categories based on GHS shall bear the necessary GHS label components (pictogram, signal word and hazard statement). Label compliance based on the GHS format shall take effect after three (3) years from the issuance of this Circular.

Within the transitory period for compliance to GHS, HUHS labels shall bear appropriate hazard information, as applicable:

- The word "POISON" and the skull and crossbones symbols for any highly toxic substance, and corrosive substance;
- The signal word "DANGER" on substances which are extremely flammable;
- The signal word "WARNING" or "CAUTION" on all other hazardous substances;
- An affirmative statement of the principal hazard or hazards, such as "FLAMMABLE", "VAPOR HARMFUL", "CAUSING BURNS", "HARMFUL OR FATAL IF SWALLOWED", or similar wording to describe the hazard.

14.3.6.4 HUHS labels shall bear the statement "Keep out of reach of children", or its practical equivalent, if the HUHS product is not intended for use by children, with adequate directions for the protection of children from the hazard involved.

For products intended to be used by children (such as coloring materials), a statement indicating the use of the product under adult supervision shall be included in the product label.

14.3.6.5 HUHS products shall not bear unsubstantiated claims, misinformation or misleading information on the label or other information materials, including those contained in brand names or trademarks.

14.3.6.6 HUHS labels shall not bear the words "safe", "non-toxic", "non-hazardous", or other equivalent descriptive words or phrases or modifiers, and shall not be presented in a way that is attractive to children.

14.3.6.7 HUHS products shall be placed suitable packaging, preferably in child-resistant packaging material/s, or containers that will ensure protection of children from undue exposure. HUHS labels shall contain information as to storage conditions of the product so as not to be easily accessed by children.

14.3.6.8 Brand names for HUHS products shall not be allowed to contain names that are identical to those already registered with the FDA in the same product classification, and names that are offensive, obscene, scandalous or otherwise contrary to public morals and policy, pursuant to AO 2005-0016, "General Policies and Guidelines Governing Brand Names of Products for Registration with the Bureau of Food and Drugs", and its future amendments.

14.3.6.9 All label information and statements shall be in English language or its equivalent in Filipino.

14.4 The FDA shall continuously develop, issue and update the standards applicable for HUHS establishments and products.

15. *Postmarketing Surveillance of HUHS Products*

HUHS products shall be subject to regular postmarketing surveillance (PMS) activities of FDA. Applicable administrative regulatory tools shall be implemented to non-compliant establishments and violative products.

16. *Responsibilities of the Marketing Authorization Holder*

16.1 The MAH shall be responsible for ensuring the safety, efficacy and quality of the HUHS products they place in the market, including the monitoring and investigation of adverse events reported by consumers, FDA, health care professionals and other stakeholders.

16.2 The MAH shall report to the FDA any incident that reasonably indicates that said product has caused or contributed to the death, serious illness or serious injury to a consumer, or any person, and coordinate with the national/regional poison center in the event of cases of poisoning involving their HUHS product/s.

16.3 In case the HUHS product has been withdrawn for health and safety reasons, the MAH shall immediately undertake the necessary measures, as well as shoulder incidental costs, in banning its sale, distribution, or its immediate recall, withdrawal or seizure from the market, and its disposal in accordance with the rules and regulations issued by the DENR.

16.4 The MAH shall conduct product information dissemination, appropriate training for product use, consumer awareness campaign, and provide open communication tools, among others, as part of their corporate social responsibility.

VI. IMPLEMENTATION TIMELINE

Consistent with AO 2019-0019, a transitory period of three (3) months from the issuance of this Circular shall be provided to allow all covered establishments to comply with the new licensing and product registration guidelines, with the exception of compliance to GHS labeling requirements which shall take effect three (3) years from the issuance of this Circular. An exhaustion period of six (6) months following the transitory period shall likewise be given for covered HUHS establishments to exhaust their products already existing in the market.

This issuance shall further serve as moratorium period where no other government agency shall require FDA licenses and authorizations from HUHS establishments covered herein while these establishments are in the process of complying with the new guidelines.

In case of public health emergency situation, however, the FDA may further issue interim guidelines covering specific HUHS establishments and products within the transitory period, or as it may deem necessary to address such public health emergency situation.

VII. PENALTY CLAUSE

Administrative and criminal penalties shall be imposed upon those found in violation of the provisions of this Circular.

VIII. REPEALING CLAUSE

All administrative issuances, department circulars and memoranda and other regulations inconsistent with this Circular are hereby withdrawn, repealed and/or revoked accordingly.

IX. SEPARABILITY CLAUSE

If any part, term of provision of this Circular shall be declared invalid or unenforceable, 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 or unenforceable part, term, or provision.

X. EFFECTIVITY DATE

This Circular shall take effect fifteen (15) days following the completion of its publication in two (2) newspapers of general circulation and submission of a copy hereof to the University of the Philippines Office of the National Registry (UP-ONAR), subject to the implementation timeline under Sec. VI of this Circular.

ROLANDO ENRIQUE D. DOMINGO, MD
Director General

DTN: 20191129153810

Annex A
HUHS Product Categorization

1. HUHS products shall be classified into at least the following categories:

   **For clarity, while Novel HUHS Products including Vapor Products such as ENDS/ENNDS and HTPs, TCCA and HUP products, are among the categories of HUHS products, licensing of establishments, and registration/notification for these products shall be covered by the existing procedures specific for such categories.*

   Category I: Novel HUHS Products (Vapor Products)
   - ENDS/ENNDS
   - HTPs

   Category II: Yard and Home Products
   - Household/urban pesticides

   Category III: Cleaners, Fresheners and Deodorizers
   - Bleaches
   - Cleaners (ie. corrosive, multi-purpose, surface, etc.)
   - Deodorizers
   - Dishwashing and laundry detergents/soaps
   - Disinfectants (for surfaces)
   - Fabric conditioners/softeners and ironing aids
   - Fresheners (ie. room, car, etc.), aromatics, diffusers
   - Moisture absorbing agents (ie. dessicant)
   - Polishes
   - Pool chemicals

   Category IV: Do-It-Yourself and Hobby Items
   - Adhesives, glues, and sealants
   - Automotive, furniture and jewelry care, and restoring products
   - Button batteries
   - Coloring materials
   - Fabric dyes, tattoo dyes
   - Paints, varnishes, and thinners
   - Paint stripper
   - Rust remover/degreasers

   Category V: TCCA Products
   - Toys and childcare article products under FDA jurisdiction

2. The above product listings are non-exclusive and may be amended as determined by FDA.

Annex B

General Guidelines in Using the FDA e-Portal System V.2

1. To access the FDA E-Portal, an applicant must appropriately secure a user account through the procedure outlined below:
   1.1 Open the link: **bit.ly/ePortal2** (refer to Annex B.1).
   1.2 Provide all the required information in the user's registration form. **To be accomplished by the Owner of the applicant establishment.*
   1.3 Attach proof of ownership in pdf file format, to the registration form.
   1.4 The User Account credentials shall be sent to the email address provided in the registration form. The User Account credentials is valid for one (1) year.
   1.5 Issuance of the User Account is within three (3) working days upon receipt of the complete and compliant request.

2. Security and integrity of user accounts shall be the responsibility of the regulated establishment. Applicants must ensure only authorized personnel can access their provided user accounts.

3. Applicants shall use their user accounts, in accordance with existing laws, FDA rules and regulations. FDA reserves the right to suspend and cancel user accounts found to be in violation of laws, FDA rules and regulations.

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

5. In the application forms, fields marked with red asterisks (*) are required to be filled-in. Mark required fields with N/A, if not applicable.

6. Documents uploaded to the system must conform to the following specifications:
   6.1 Documents/ files/ information uploaded must be free from bugs, viruses, and the like that may compromise the FDA system.
   6.2 Documents must be scanned and saved in PDF file format at 100-150 dots-per-inch (dpi)
   6.3 Filenames of documents shall be less than 40 characters in length, and shall not contain the following characters: \ ? / : * " > < I."

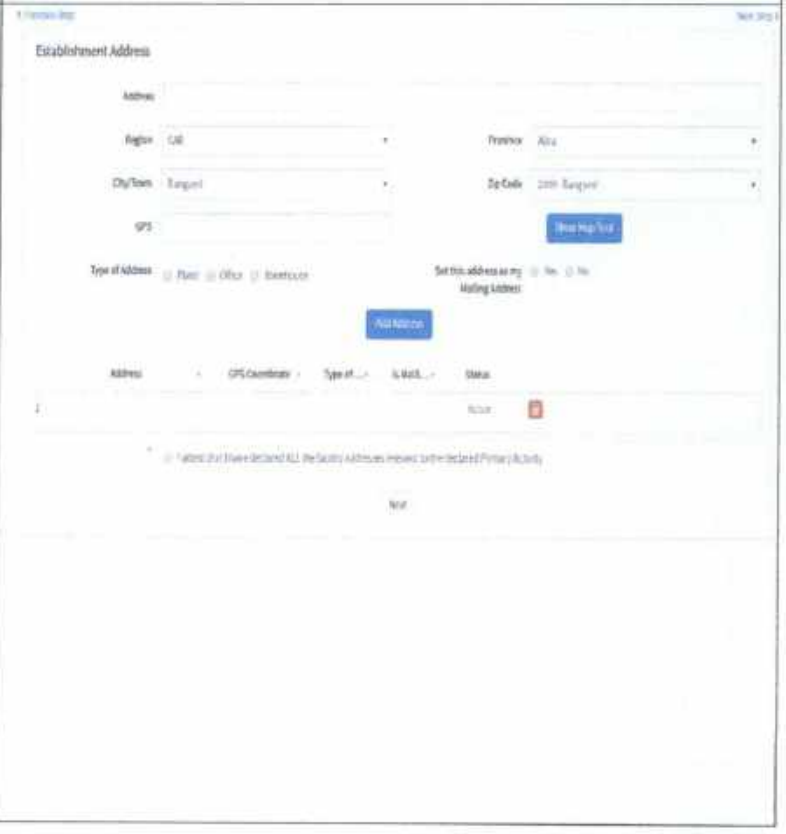
Annex B.1
Online User's Registration Form

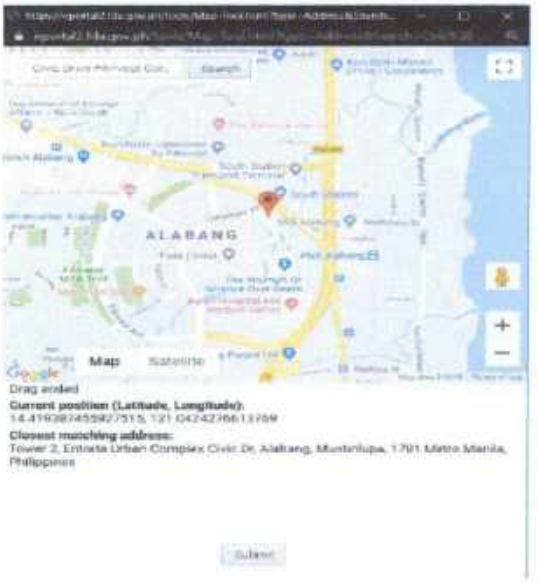
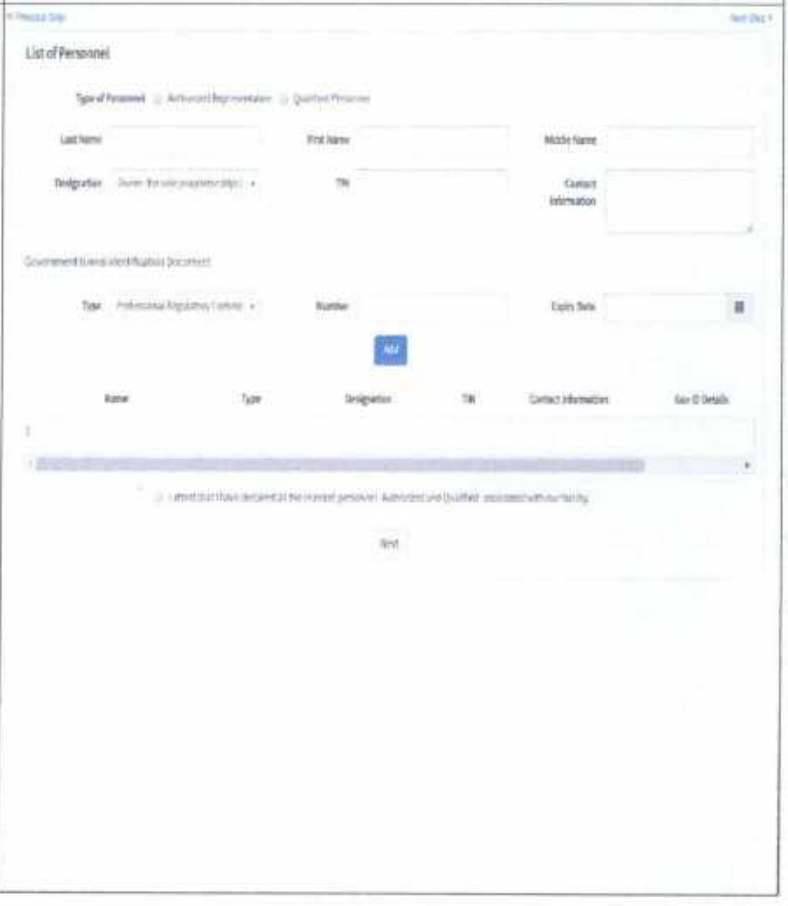
The Form can be accessed thru the link below:
bit.ly/ePortal2

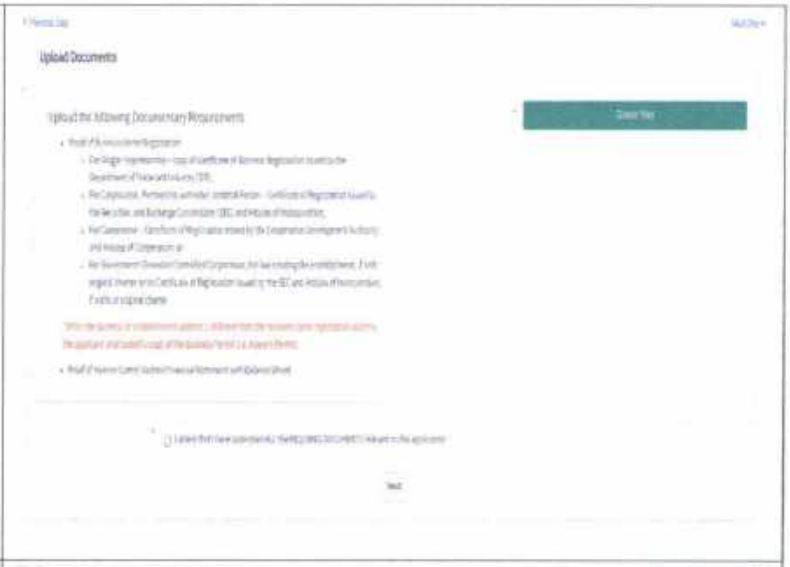
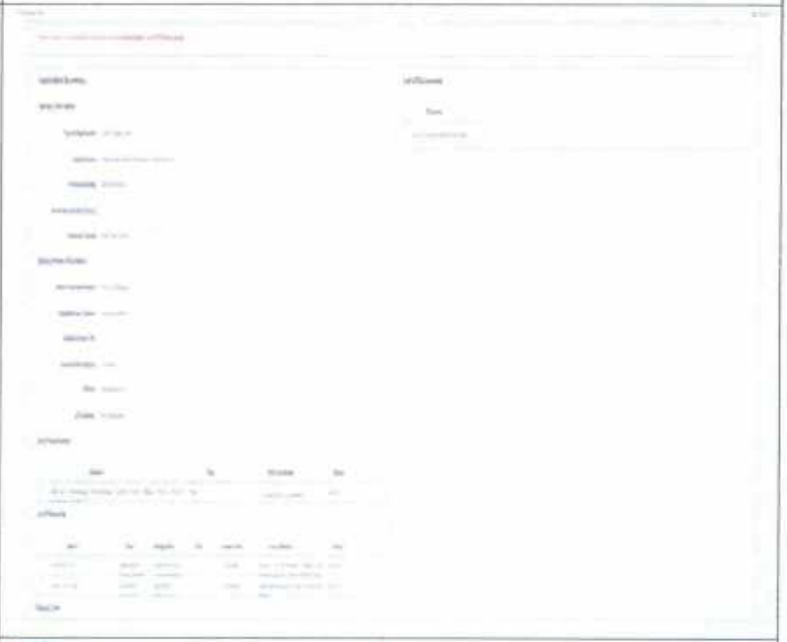
Annex C

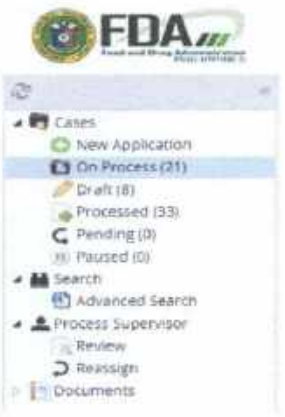
Submission of LTO Application Thru the FDA e-Portal V.2

1. Access the FDA e-Portal V.2 at https://eportal2.fda.gov.ph 2. Log-in by entering the issued username and password.	
3. In the HOME tab, select New Application in the navigation pane and click e-License to Operate (Initial Application) to proceed to the LTO application form.	
4. Accomplish the application form as provided in parts by the application wizard. Fill-in the fields as completely as possible. Fields marked with a red asterisk (*) are required to be filled-in. Mark required fields with N/A, if not applicable. • Declaration - Proceed with the application by selecting your response using the drop-down list and click 'Next'.	

• General Information - Select the applicable product classification and primary activity of the applicant establishment. Tick the secondary activity and select the declared capital. These shall be based on the selected product classification and primary activity. To continue to the next step, tick the box to certify all information is true and correct, then 'Next'.	
• Establishment Information - Fill-in the necessary information. All provided information shall be reflected also on the submitted Proof of Business Name Registration. Tick the box to certify all information is true and correct, then 'Next'.	
• Establishment Addresses – Declare all the addresses of the applicant establishment by ticking the type of address applicable. The applicant may simultaneously tick the plant, office, and warehouse if all three have the same address. Utilize the dropdown list when selecting the region, province, city and zip code. Click Show Map Tool and a separate window will appear showing the GPS map of the address. Move the arrow to the exact location of the establishment. Click 'Submit'. The GPS coordinates will be	

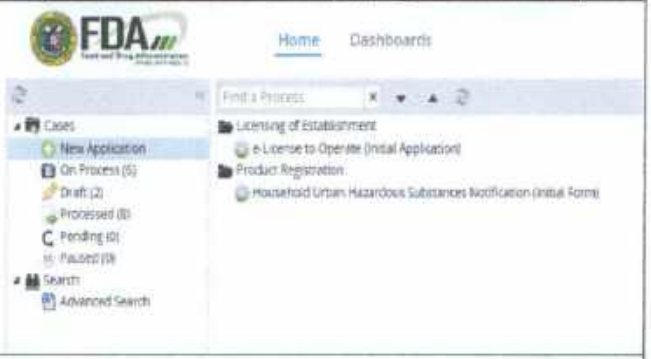
automatically updated when you move the arrow, then click 'Submit'. Select the desired mailing address by clicking "Set this address as my mailing address" and then click 'Add Address'. For manufacturers, please provide one (1) plant address. Submission is limited to one (1) plant address per manufacturer only. Tick the box to certify all information is true and correct, then 'Next'.	
• Product Line (For Manufacturer Only) – Select the applicable product line from the dropdown list and click 'Add'. Tick the box to certify all information is true and correct, then 'Next'.	
▪ List of Personnel – Declare the Authorized and Qualified personnel. Select the Type of Personnel and provide the required information. An establishment may add only one (1) Authorized Person and one (1) or more Qualified Person/s. The Authorized Representative should be the owner of the establishment while the Qualified Person must be the technical personnel with technical knowledge and/or adequate training on HUHS product safety. Click 'Add' after every submission of personnel. Tick the box to certify all information is true and correct, then 'Next'.	

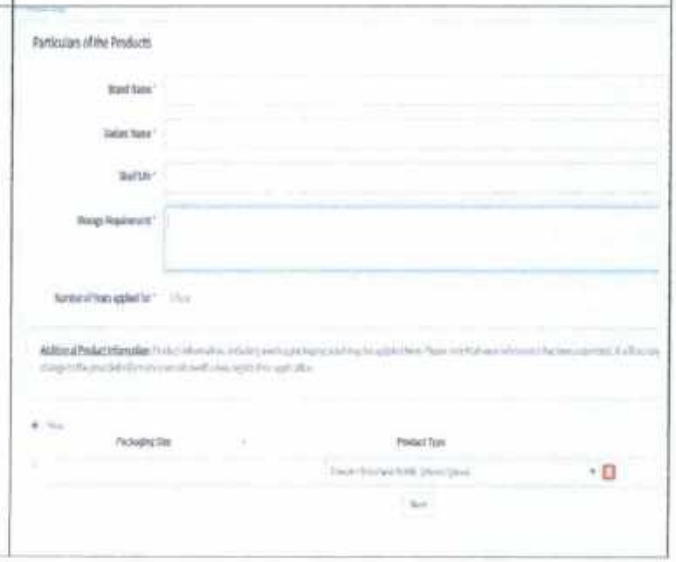
▪ Upload Documents – Upload the required document/s in PDF format: ▪ Proof of Business Name Registration, Proof of Income. Tick the box to certify all information is true and correct, then 'Next'. ▪ Applicants may upload documents simultaneously.	
• Application Summary – It reflects all the declared information and uploaded documents. The applicant establishment may review and recheck the information. If there are corrections to be made, the applicant may revisit the pages of the application form by clicking 'Previous Steps'. The applicant establishment may also view the attached document by clicking its file name.	
• Order of payment – A computer generated document will appear reflecting the appropriate fees and charges. The applicant establishment should save and print a copy of the document as reference for payment. Click 'Next' to continue and delegate the application to payment verification.	

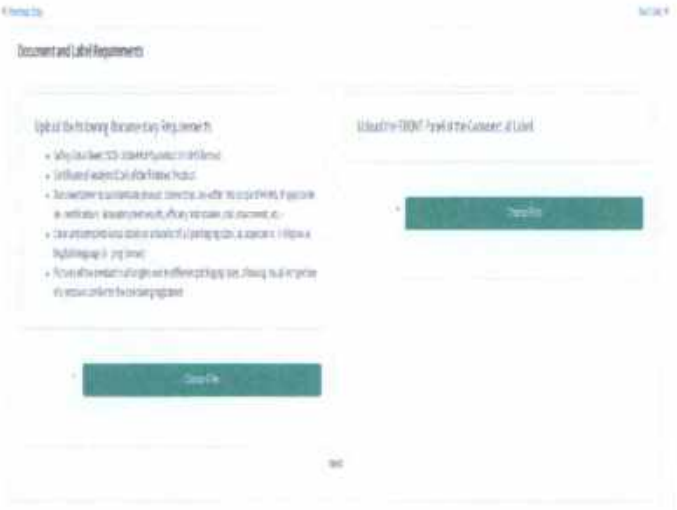
5. The application will undergo the licensing evaluation process accordingly. The application may either be approved or disapproved. The result may be downloaded through the On-Process folder of the applicant establishment. Download and print the document and click 'Next' to end the task.	

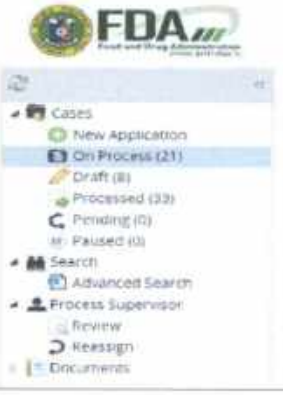
Annex D

Submission of Product Registration Application Thru the FDA e-Portal V.2

1. Access the FDA e-Portal V.2 at https://eportal2.fda.gov.ph 2. Log-in by entering the issued username and password.	
3. In the HOME tab, select New Application in the navigation pane and click HUHS Product Registration (Initial Form) to proceed to the application form.	
4. Accomplish the application form as provided in parts by the application wizard. Fill-in the fields as completely as possible. Fields marked with a red asterisk (*) are required to be filled-in. Mark required fields with N/A, if not applicable. • Declaration - Proceed with the application by selecting your response using the drop-down list and click 'Next'.	

• Local Company Responsible for Placing the Product in the Market - Select the LTO number specific for the HUHS application. All relevant information about the applicant establishment will automatically be reflected. Click 'Next' button.	
• Product Source - Fill-in the necessary information. Click 'Next' button.	
• Particulars of the Product – Provide the required information. Please note that once information has been submitted, it will no longer be modifiable. Hence, any change to the provided information would merit a new registration application. Click 'Next' button.	

• Ingredient List – provide the full ingredient listing with function and amount in percentage of each ingredient. Click 'New' to add new ingredient to the list. Click 'Next' button.	
• Upload Documents – Upload the required document/s in PDF format: 1.1 Safety Data Sheet (SDS) in GHS format, Certificate of Analysis of the Finished Product, Documentation to substantiate product claims that are within the scope of HUHS, if applicable, Clear and complete loose labels or artworks of all packaging sizes, as applicable, in Filipino or English language (in .png format), Pictures of the product in all angles and in different packaging sizes, allowing visual recognition of a product similar to the one being registered ▪ Applicants may upload documents simultaneously.	

• Application Summary – It reflects all the declared information and uploaded documents. The applicant establishment may review and recheck the information. If there are corrections to be made, the applicant may revisit the pages of the application form by clicking 'Previous Steps'. The applicant establishment may also view the attached document by clicking its file name.	
• Order of payment – A computer generated document will appear reflecting the appropriate fees and charges. The applicant establishment should save and print a copy of the document as reference for payment. Click 'Next' to continue and delegate the application to payment verification.	
5. The application will undergo the product notification process accordingly. The application may either be approved or disapproved. The result may be downloaded through the On-Process folder of the applicant establishment. Download and print the document and click 'Next' to end the task.	

Annex E

Documentary Requirements for the Issuance of Authorizations

I. License to Operate

1. Initial LTO

1.1 Declaration and Oath of Undertaking

1.2 Accomplished Application Form

1.3 Proof of Business Name Registration

1.3.1 For Single Proprietorship – copy of Certificate of Business Registration issued by the Department of Trade and Industry (DTI);

1.3.2 For Corporation, Partnership and other Juridical Person – Certificate of Registration issued by the Securities and Exchange Commission (SEC) and Articles of Incorporation;

1.3.3 For Cooperative – Certificate of Registration issued by the Cooperative Development Authority and Articles of Cooperation; or

1.3.4 For Government-Owned or Controlled Corporation, the law creating the establishment, if with original charter, or its Certificate of Registration issued by the SEC and Articles of Incorporation, if without original charter.

*When the business or establishment address is different from the business name registration address, the applicant shall submit a copy of the Business Permit (i.e. Mayor's Permit).

1.4 Proof of Income (Latest Audited Financial Statement with Balance Sheet)

1.5 Credentials of the Qualified Person

1.5.1 PRC ID issued for professions with Board/Licensure Examination, or Diploma for profession without Board/Licensure Examination

1.5.2 Certificate of Attendance to seminars, training, learning and development activities on HUHS safety, quality, and use

1.6 Risk Management Plan and Site Master File, if HUHS Manufacturer

**Requirements 1.5 and 1.6 shall be presented to the FDA inspector for examination or review, when required.*

1.7 Payment of fees

2. Renewal

2.1 Declaration and Oath of Undertaking

2.2 Accomplished Application Form

2.3 Payment of fees

3. Variation

3.1 Declaration and Oath of Undertaking

3.2 Accomplished Application Form

3.3 Specific Documentary Requirements (please see below)

3.4 Payment of fees

A. Major Variation

Type of Variation	Documentary Requirement/s
Transfer of Location of Manufacturing Plant - Physical transfer of the establishment (and may entail changes in the previously approved address)	a. Business permit reflecting the new address b. Updated Site Master File to be presented upon inspection
Expansion of Manufacturer and/or Additional Product Line; or Change of Manufacturing Activity - Expansion shall refer to expansion made which is adjacent to the existing location of the establishment - Additional product line shall refer to additional type or class of products produced within the same manufacturing site - Change in manufacturing activity shall refer to an additional activity that a manufacturer engage in (e.g. LTO as Manufacturer with additional activity as Repacker)	Updated Site Master File to be presented upon inspection

B. Minor Variation

Transfer of Location of Offices - Physical transfer of the office of the establishment (which may also entail changes in the previously approved address)	Business permit reflecting new location office
Change of Distributor Activity - Shall refer to an addition/deletion of/change in activity that the distributor engage in	Contract Agreements showing change in activity
Transfer/Addition of Warehouse - Physical transfer and addition of the warehouse of the establishment (which may also entail changes in the previously approved address)	Business permit reflecting new warehouse
Expansion of Office Establishments - Shall refer to expansion made which is adjacent to the existing location of the establishment	Expansion floor plan
Change of Ownership - Change in ownership of the licensed establishment	a. Business name registration reflecting new ownership b. Any proof on the transfer of ownership such as any of the following: i. Deed of sale or assignment or transfer of rights/ownership; ii. Memorandum of Agreement; or iii. Notarized Affidavit of

	the owner, proprietor, Chairman or CEO of the establishment validating the transfer
Change of Business Name - Change only in the business name of the establishment	Business permit reflecting the new name
Zonal Change in Address - Change of the name/number of the street/building without physical transfer of the establishment	Certificate of Zonal Change
Change of Authorized Person - Change in the authorized person initially registered with the FDA	a. Name of new authorized person b. Updated contact details
Change of Qualified Person - Change in the identified qualified person initially registered with the FDA	a. Name of new qualified person b. Applicable requirements as specified above

II. Certificate of Product Registration

1. Initial
   - 1.1 Declaration and Oath of Undertaking
   - 1.2 Accomplished Application Form
   - 1.3 Safety Data Sheet (SDS) of the HUHS product (in GHS format)
   - 1.4 Certificate of Analysis (CoA) of the Finished Product
   - 1.5 Documentation to substantiate product claims that are within the scope of HUHS, if applicable (ie. certifications, laboratory test results, efficacy test studies, risk assessment, etc.)
   - 1.6 Clear and complete loose labels or artworks of all packaging sizes, as applicable, in Filipino or English language (in .png format)
   - 1.7 Pictures of the product in all angles and in different packaging sizes, allowing visual recognition of a product similar to the one being registered
   - 1.8 Payment of fees

2. Renewal
   - 2.1 Automatic
     - 2.1.1 Declaration and Oath of Undertaking
     - 2.1.2 Accomplished Application Form
     - 2.1.3 Payment of Fees
   - 2.2 Regular
     - 2.2.1 Declaration and Oath of Undertaking
     - 2.2.2 Accomplished Application Form
     - 2.2.3 Documentary requirements for the variations included in the renewal application (refer to variation requirements)
     - 2.2.4 Payment of Fees

3. Variation
    3.1 Declaration and Oath of Undertaking
    3.2 Accomplished Application Form
    3.3 Copy of old/existing product label
    3.4 Specific Documentary Requirements (please see below)
    3.5 Payment of fees

Type of Variation	Documentary Requirement/s
Change in Product / Brand / Variant Name	Copy of the complete labeling materials reflecting the change in product/brand/variant name
	Authority from the foreign source (if product is imported)
Change in Labeling/Packaging Design	Copy of the complete labeling materials reflecting the change in labeling/packaging design
Change in / Additional Packaging Size	Copy of the complete labeling materials reflecting the change in packaging size
Change in / Additional Packaging Type or Packaging Material	Proof of suitability of packaging type or material, including stability of the product in the new packaging
	Copy of the complete labeling materials reflecting the change in packaging type or packaging material
Change in / Additional Product Claim	Documentation to substantiate new product claim
	Copy of the complete labeling materials reflecting the new product claim
Change in / Extension/ Reduction of Shelf-life	Stability Study (Accelerated or Real-time) to support change of shelf-life
	Copy of the complete labeling materials reflecting the change in shelf-life
Change in Business Name and/or Address* of the MAH *(*) excluding plant sites of manufacturers*	Copy of valid LTO reflecting the change in business name and/or address
	Copy of the complete labeling materials reflecting the change in business name and/or address
Change in Product Ownership	Copy of Termination Contract/Deed of Assignment
	Copy of Agreement / Appointment Letter
	Copy of the complete labeling materials reflecting the change in ownership
Change in / Additional Safety Data Sheet Information	Copy of the old Safety Data Sheet
	Copy of the new Safety Data Sheet
	Documentation supporting the new SDS information

Change in GHS Hazard Categorization in any of the Physical, Chemical or Environmental Hazard Class	Copy of the old Safety Data Sheet
	Copy of the new Safety Data Sheet
	Copy of the complete labeling materials reflecting the change in GHS information
	Documentation supporting the new GHS information

III. Requirements During Inspection

During inspection, the HUHS establishment shall be required to present the following documents, as applicable:

1. Organizational Chart of the Establishment
2. 201 Personnel of Technical Personnel (including Job Description)
3. Signed Duties and Responsibilities of Technical Personnel
4. Training Certificate of Key Personnel
5. Health Certificate of Employees
6. Pest Control and Cleaning Records
7. Technical Specifications of Raw Materials
8. Certificate of Analysis of Finished Products
9. Master Formula
10. Batch Manufacturing Records
11. Standard Operating Procedures (SOPs) for the following:
    - Receiving of Starting Materials and Dispatch of Finished Goods
    - Training of Personnel
    - Cleaning and Sanitation for Premises and Equipment
    - Preventive Maintenance for Premises and Equipment
    - Pest Control Activities
    - Manufacturing Process
    - Batch Coding System
    - Quality Control Process
    - Reprocessing / Reworking (if applicable)
    - Handling of Product Complaints
    - Handling of Product Recall
    - Handling of Product Disposal
    - Other SOPs related to manufacturing of HUHS
12. Environmental Clearance Certificate
13. Contract Agreements (including Tripartite Agreement, as applicable)
14. Product Information File (Post-Market Review)
    - *Please refer to Annex I for specific documents*

IV. Other Authorizations

1. Certificate of Free Sale (CFS)

1.1 Letter of Intent reflecting country of exportation
1.2 Copy of Valid LTO for Manufacturers and Traders
- For distributors, valid LTO reflecting the exporting activity

1.3 Copy of Valid Product Registration
1.4 Payment of fees

2. Sales Promotion Permit

2.1 Duly Accomplished Application Form
2.2 Duly Accomplished Information Sheet
2.3 Copy of Valid Product Registration
**Tabulated copy with the format (Product Name – Registration – Validity)*
2.4 Layout of Promo Materials
2.5 Payment of fees

Annex F

Requirements for Emergency Use Permit for Surface Disinfectants

1. For Registered Product

1.1 Application Form / Letter of Request

1.2 Information required for public health exemption:

1.2.1 The name of the microorganism to be controlled including the description of the disease expected to arise

1.2.2 A discussion of the magnitude of the health problems which are expected to occur without the possible use.

1.3 Description of the product:

1.3.1 Full (100%) ingredient listing of the formulated finished product including the functions and GHS classification

1.3.2 SDS of the HUHS product (GHS format)

1.3.3 Complete labeling to be used in connection with the proposed exemption use (GHS compliant)

1.3.4 Trade name of the product

1.3.5 The complete name and address of the company responsible for placing the product in the market (MAH)

1.3.6 Copy of manufacturing license of the manufacturer

1.3.7 Copy of product approval from the country of origin

1.4 Description of the proposed use:

1.4.1 Target species, intended use, and effectiveness

1.4.2 Purpose of use and users

1.4.3 The method of application

1.4.4 The dose or rate of application in terms of active ingredient and product

1.4.5 The maximum number of applications;

1.4.6 The total amount of product proposed to be used if dilution or combination with other products

1.4.7 All applicable restrictions and requirements concerning the proposed use which may not appear on labelling

1.4.8 The duration of the proposed use

1.4.9 Health and safety precautions

1.4.10 Environmental concerns and disposal considerations

1.4.11 Risk management measures for various exposure scenarios

1.4.12 Proposed packaging size and materials

1.5 Justification for the EUP application

1.5.1 A detailed explanation of the purpose for the application. The submission must be supported by scientific data or studies by qualified experts, academe, professional medical organizations, or other infection control experts on the feasibility of the use of the active ingredient.

1.5.2 Cost-benefit or feasibility study to show that the product is more advantageous and economical to use.

1.6 Discussion of the effectiveness of proposed use

1.7 Discussion of risk information

2. For Unregistered Product

2.1 Application Form / Letter of request
2.2 Safety Data Sheet (SDS) of the HUHS product following the Globally Harmonized System for Classification and Labeling of Chemicals (GHS) format
2.3 Certificate of Analysis (CoA) of the Finished Product
2.4 Documentation to substantiate product claims that are within the scope of HUHS, if applicable (ie. certifications, laboratory test results, efficacy test studies, risk assessment, etc.)
2.5 Clear and complete loose labels or artworks of all packaging sizes, as applicable, in Filipino or English language (in .png format)
2.6 Pictures of the product in all angles and in different packaging sizes, allowing visual recognition of a product similar to the one being registered
2.7 Requirements 1.2 to 1.7 (under Registered Product)
2.8 Payment of fees

Annex G
List of HUHS Product Standards

1. The MAH shall ensure compliance to the following adopted standards and their future amendments or updates (as may be applicable), including but not limited to:

    1.1 Philippine National Standards (PNS)
    - *PNS 461:1991* Paints and Varnishes – Reflectorized Traffic Paint (White and Yellow Premixed) – Specification
    - *PNS 562:1992* Flor Wax – Water Emulsion – Specification
    - *PNS 48:1994* Scouring Powder – Specifications
    - *PNS 10:2002* Surface Active Agents – Laundry Soap – Specification
    - *PNS 2044:2005* Adhesives for Wall and Ceiling Boards – Specifications
      PNS ASTM D 2022-2007 Standard Test Methods of Sampling and Chemical Analysis of Chlorine Containing Bleaches
    - *PNS ASTM C 1311:2011* Standard Specification for Solvent Release Sealants
    - *PNS 1994:2012* Adhesives for Floor and Wall Applications – Resilient Vinyl; Linoleum, and Rubber Sheet and Tiles – Interior and Exterior Use – Specification

    1.2 Relevant issuances and standards emanating from laws governing other National Government Agencies having concurrent jurisdiction over chemicals and hazardous substances
    - PD 442 or the "Labor Code of the Philippines"
    - RA 6969, otherwise known as the "Toxic Substances and Hazardous and Nuclear Wastes Act of 1990"
    - RA 7394, otherwise known as the "Consumer Act of the Philippines"
    - RA 8970, "An Act Prohibiting the Manufacture, Importation, Distribution and Sale of Laundry and Industrial Detergents Containing Hard Surfactants and Providing Penalties for Violation Thereof"
    - RA 9165, otherwise known as the "Comprehensive Dangerous Drug Act of 2002"
    - RA 9514, otherwise known as the "Fire Code of the Philippines of 2008"
    - Joint DTI-DENR-DA-DOF-DILG-DOLE-DOTC Administrative Order No. 01 series of 2009, "The Adoption and Implementation of the Globally Harmonized System of Classification and Labeling of Chemicals (GHS)"

    1.3 International Conventions, Treaties and Protocols
    - Montreal Protocol on Substances That Deplete the Ozone Layer
    - Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal
    - Chemical Weapons Convention
    - Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade
    - Stockholm Convention on Persistent Organic Pollutants

- Minamata Convention on Mercury

1.4 Internationally-acceptable Standards based on:

- Association of Southeast Asian Nations (ASEAN)
- European Union (EU)
- Food and Agriculture Organization of the United Nations
- International Agency for Research on Cancer (IARC)
- International Organization for Standardization (ISO)
- Organization for Economic Co-operation and Development (OECD)
- U.S. Consumer Product Safety Commission
- U.S. Environmental Protection Agency
- World Health Organization (WHO)

2. The FDA shall continuously develop, issue and update the standards applicable for HUHS products.

Annex H

Guidelines for Good Manufacturing Practices (GMP) for HUHS Manufacturers

1. Quality Management System

A quality system should be developed, established and implemented as a means by which stated policies and objectives will be achieved. It should define the organizational structure, functions, responsibilities, procedures, instructions, processes and resources for implementing the quality management.

2. Personnel

There should be an adequate number of personnel having knowledge, experience, skill and capabilities relevant to their assigned function. They should be in good health and capable of handling the duties assigned to them.

All personnel should be appropriately trained in manufacturing operations in accordance to GMP principles. Training in GMP should be conducted on a continuous basis and records of training should be maintained and its effectiveness assessed periodically.

3. Premises

The premises should be suitably located, designed, constructed and maintained:

- Effective measures should be taken to avoid any product mix-up, and contamination from the surrounding environment and from pests.
- The site should be of adequate size to allow defined areas be provided for, wherever possible and applicable.
- The site should be adequately lit, properly ventilated, and easy to clean and sanitize or disinfect.

4. Equipment

Equipment should be designed and located to suit the manufacturing of the HUHS product:

- The equipment surfaces coming into contact with the HUHS product should not react with or adsorb the product being processed.
- Equipment should be easily cleaned.
- Equipment should be located to avoid congestion and should be properly identified to assure that product do not become admixed or confused with one another.
- Weighing, measuring, testing, and recording, wherever applicable, should be serviced and calibrated regularly. All records should be maintained.

5. Sanitation and Hygiene

Sanitation and hygiene should be practiced to avoid contamination of the HUHS products. It should cover personnel, premises, equipment and production materials and containers.

6. Production

HUHS products should be manufactured in accordance with approved specifications and procedures. HUHS products should be produced in such a way as to protect such from microbial and other contamination.

Every finished product should bear a production identification number for traceability purposes. A batch numbering system should be specific for the product and a particular batch number should not be repeated for the same product in order to avoid confusion. Whenever possible, the batch number should be printed on the immediate container of the bulk product. Records of the batch number should be maintained.

7. Quality Control

Quality control (QC) shall be observed in all manufacturing activities such as sampling, inspecting and testing of starting materials, in process, intermediate, bulk, and finished products. It also includes where applicable, environmental monitoring programs, review of batch documentation, sample retention program, stability studies and maintaining correct specifications of materials and products.

8. Documentation

All documents related to the manufacture and operations from raw materials, packaging materials, master production and control, batch production, laboratory control and batch production record review should be prepared, reviewed, approved and distributed according to written procedures.

9. Internal Audits

An internal audit consists of an examination and assessment of all or part of a quality system with the specific purpose of improving it. An internal audit may be conducted by outside or independent specialists or a team designated by the management for this purposes. Such internal audits may also be extended to suppliers and contractors, if necessary. A report should be made at the completion of each internal audit.

10. Storage

Storage areas should be of sufficient capacity to allow orderly storage of the various categories of materials and products, and should be designed to ensure good storage conditions.

Incoming delivery of bulk products should be checked against relevant documentation and physically verified by label description, type and quantity. Records should be retained for each delivery.

11. Contract Manufacturing and Analysis

There should be a written contract between the principal and the contract manufacturer to clearly establish the duties and responsibilities of each party.

12. Complaints

There should be a system for handling complaints. A person for handling complaints and deciding the measures to be taken should be designated. There should be written procedures describing the action to be taken, including the need to consider a recall, in the case of a complaint involving a possible product defect.

Complaint records should be maintained, appropriately referenced to corresponding batch records, and where applicable, regularly reviewed for an indication of specific or recurring manufacturing issues or problems.

The FDA should be informed if the manufacturer is considering action following possibly faulty manufacture and product deterioration, which may lead to serious safety issues.

13. Product Recalls

There should be a system of recall from the market of products known or suspected to be defective.

A person responsible for the execution and co-ordination of recalls should be designated. Written procedures for recall should be established and regularly reviewed. Recall operations should be capable of being initiated promptly.

The recall process should be recorded and a final report issued, including reconciliation between the delivered and recovered quantities of the products.

Annex I
Product Information File

I. General Provisions

1. The MAH responsible for placing the HUHS product (with the exception of products intended for children) in the market shall keep an updated Product Information File (PIF) for each registered product.
2. The PIF shall be readily accessible at the address of the MAH that is consistent with the address declared in the CPR and indicated in the product label.
3. The PIF shall be kept in either electronic and/or printed copies, and shall be made readily available and easily accessible upon post-registration review of the registered product.
4. The PIF shall be kept for a minimum of three (3) years after the HUHS product is last placed in the market.
5. PIF audits shall be conducted within the validity period of the CPR. A Notice of Audit (NoA) shall be sent to the MAH accordingly.
6. The MAH with incomplete PIF shall be given sufficient amount of time to provide their corrective action report (CAR) and other supporting documents as required after the audit.
7. Failure of the MAH to present the PIF or to comply within the agreed timeline of submission of supporting documents shall be ground for imposition of appropriate regulatory action.
8. When actual conduct of audit is not feasible, PIF shall be submitted to the Authority, as deemed necessary.

II. Documentary Requirements

The PIF shall contain the following documentary requirements:

1. Part I - Administrative Documents and Product Summary
   1.1 Administrative Documents
      1.1.1 Copy of valid LTO of the MAH
      1.1.2 Copy of valid Distribution Agreement
         1.1.2.1 If MAH sources the products locally:
            1.1.2.1.1 Copy of valid LTO of the local supplier
            1.1.2.1.2 Copy of valid Distribution Agreement between MAH and the local supplier
         1.1.2.2 If MAH sources the products from foreign supplier:
            1.1.2.2.1 If the foreign supplier is the manufacturer of the HUHS product, Foreign Agency Agreement (FAA) or Letter of Authorization from the foreign supplier
            1.1.2.2.2 If the foreign supplier is not the manufacturer of the HUHS product:
               1.1.2.2.2.1 FAA or Letter of Authorization from the foreign supplier and copy of the valid Supply Agreement between the

foreign supplier and the manufacturer; or

1.1.2.2.2.2 Copy of valid Tripartite Agreement between the MAH, foreign supplier and the manufacturer

1.1.3 Copy of the valid CPR

1.2 Qualitative and Quantitative Formula of the HUHS Product

1.2.1 Full ingredient list of the HUHS product with their corresponding function and percentage (%) content. Ingredients shall be named using the nomenclatures from approved references (ie. Chemical Abstract Service, or International Pharmacopeias).

1.2.2 For HUHS products containing fragrance materials, the name, code number of the composition, and the identity of the supplier of the fragrance material shall be indicated.

1.3 Product Presentation

1.3.1 Actual commercial sample of the HUHS product.

1.3.2 In case when the actual commercial sample is unavailable, facsimile samples of the immediate and/or secondary packaging and other informative materials that are used may be presented.

1.4 Manufacturing Statement

1.4.1 For locally manufactured HUHS products, any of the following may be presented:

1.4.1.1 Copy of the valid GMP Certificate of the local manufacturer

1.4.1.2 Self-declaration of compliance to GMP by the local manufacturer

1.4.2 For imported HUHS products, any of the following may be presented:

1.4.2.1 Certificate of Free Sale (CFS) issued by the National Regulatory Authority (NRA) of the country of origin

1.4.2.2. GMP Certificate of the foreign manufacturer/source

1.4.2.3. Manufacturing License of the foreign manufacturer/ source

1.4.3. Copy of batch coding system / key of the HUHS product

1.5 Summary of the Safety Assessment of the HUHS Product

1.5.1 Signed summary of the safety assessment

1.5.2 Name and qualifications of the safety assessor or his/her curriculum vitae

1.6 Summary of the Confirmed Undesirable Effects on Human Health

1.6.1 Updated summary of confirmed undesirable effects on human health

1.6.2 SOP on Receiving and Processing of Consumer Complaints

1.7 Summary of the substantiation/justification to support product claims

1.7.1 Literature review of published data on the properties of the ingredients contained in the HUHS product
1.7.2 Literature review of published data on the benefits of HUHS product with similar formulation
1.7.3 Actual tests performed which can either be in vitro or in vivo.

2. Part II – Quality of Raw Material
   2.1 Specification and Test Methods of Raw Materials
      2.1.1 Technical specifications of each ingredient including water
      2.1.2 Method of analysis corresponding to the technical specifications for each ingredient
      2.1.3 Signed Certification of Analysis (CoA) for each ingredient corresponding to its technical specifications
      2.1.4 In case of fragrance materials, the name, code number of the composition, and the identity of the supplier of the fragrance material, certificate of compliance with the latest International Fragrance Association (IFRA) guidelines

   2.2 Safety Data of the ingredients, taken from any of the following:
      2.2.1 Safety Data Sheet (SDS) of each ingredient
      2.2.2 Published literature and databases of ingredients
      2.2.3 Reports from Scientific Committees

3. Part III – Quality Data of Finished Product
   3.1 Qualitative and Quantitative Formula of the HUHS Product
      3.1.1 Full ingredient list of the HUHS product with their corresponding function and percentage (%) content. Ingredients shall be named using the nomenclatures from approved references (ie. Chemical Abstract Service, or International Pharmacopeias).
      3.1.2 For HUHS products containing fragrance materials, the name, code number of the composition, and the identity of the supplier of the fragrance material shall be indicated.

   3.2 Manufacturing details
      3.2.1 Details of the HUHS manufacturer including the company name, complete address and contact information.
      3.2.2 Details of the secondary assembler (repacker) of the HUHS product including the company name, complete address and contact information, if applicable.
      3.2.3 Summary of the manufacturing process or batch manufacturing method

   3.3 Technical specifications of the finished HUHS product and their corresponding test methods
      3.3.1 Technical specifications of the finished HUHS product.
      3.3.2 Test methods used corresponding to the technical specifications of the finished HUHS product.
      3.3.3 Signed CoA of the finished HUHS product corresponding to its technical specifications.

4. Part IV – Data on the Safety, Health Risk and Efficacy of the HUHS Product
   4.1 Data on Safety and Health Risk
      4.1.1 Signed safety or health risk assessment report of the HUHS product. This document shall discuss the following parameters pertaining to the finished HUHS product:
         4.1.1.1 Hazard identification
         4.1.1.2 Hazard characterization
         4.1.1.3 Exposure assessment
         4.1.1.4 Risk characterization
      4.1.2 Curriculum vitae of the safety assessor. The safety assessor shall possess qualifications in the fields of toxicology, medicine, chemistry, pharmacy, or other related fields on the conduct of product safety and health risk assessment.

   4.2 Record of Confirmed Adverse Events or Undesirable Effects on Human Health
      4.2.1 Compilation of reports of confirmed adverse events or undesirable effects on human health resulting from the use of the HUHS product, which necessitates the conduct of investigation by the MAH.
      4.2.2 Compilation of adverse effects reports to the FDA, as applicable.
      4.2.3 SOP for handling product complaints.

   4.3 Data on Efficacy of HUHS product, citing applicable references:
      4.3.1 Literature review of published data on the properties of the ingredients contained in the HUHS product
      4.3.2 Literature review of published data on the benefits of HUHS product with similar formulation
      4.3.3 Actual tests performed which can either be in vitro or in vivo.

Annex J
Labeling and Packaging Requirements for HUHS Products

A. Labeling Requirements

1. Minimum Labeling Requirements for HUHS Products
(Under Categories III and IV)

Data Requirements	Remarks
1.1 Product Information	
1.1.1 Brand and Product name	
1.1.2 Full ingredient listing	Indicate the chemical name of the ingredient
1.1.3 Net content	
1.1.4 Batch/Lot/Item/SKU Number	
1.1.5 Manufacturing Date / Expiry Date	Submit stability study to support expiry date claim
1.2 Directions for Use	Include dilution rate, dwell or contact time, etc.
1.3 Precautionary statement or warnings	Refer to description in Item Nos. 2.1.2 & 3.1.2
1.4 Handling, Storage and Disposal	Include PPE requirement, etc.
1.5 Particulars of the Company/MAH: 1.5.1 Name, complete address and contact information 1.5.2 Country of manufacture	Include consumer helplines
1.6 Contact information of the national/regional poison center	

2. Additional Labeling Requirements for HUHS Products
(Under Categories III and IV except Those Intended for Use of Children)

Data Requirements	Remarks
2.1 Product Information	
2.1.1 Product Category	Indicate if for institutional/professional use
2.2 Hazard and Safety Information	
2.2.1 Appropriate hazard information	- Refer to Part V. Item No. 14.3.6.3, Specific Guidelines for appropriate hazard information. - Full compliance to GHS (pictogram, signal word, hazard statement) after three (3) year-transitory period from date of effectivity of this Circular
2.1.2 Precautionary statement or warnings	Indicate the statement, "Keep out of Reach of Children"; include other precautionary statements or warnings in accordance with GHS
2.1.3 Signs/symptoms of poisoning	Indicate as applicable
2.1.4 First aid treatment / Medical advice	

3. Additional Labeling Requirements for HUHS Products Intended for Use of Children

Data Requirements	Remarks
3.1 Hazard and Safety Information	
3.1.1 Age Grading	Submit substantiation to support age grading claim
3.1.2 Precautionary statement or warnings	Include a statement indicating that the use of the product under adult supervision

B. Packaging Requirements for HUHS Products

Data Requirements	Remarks
1. Specification of primary package	Submit whichever is applicable *HUHS products shall be placed in suitable packaging material/s or containers that will ensure protection of children from undue exposure. HUHS labels shall contain information as to storage conditions of the product so as not to be easily accessed by children.
2. Specification of secondary packaging	
3. Specification of bulk package for transport	
4. Specification of child-safety* packaging	