FREQUENTLY ASKED QUESTIONS (FAQs)

HUHS REGULATION

1. What is the legal basis for HUHS regulation?

>> Pursuant to Republic Act (RA) No. 9711, otherwise known as the "Food and Drug Administration (FDA) Act of 2009", and consistent with Its Implementing Rules and Regulations, the FDA has issued Administrative Order (AO) No. 2019-0019, and FDA Circular (FC) No. 2020-025, providing for the guidelines on the licensing and registration of household/urban hazardous substances (HUHS).

2. What health products are considered as HUHS?

>>The product listing per category is identified in *Annex A* of FDA Circular No. 2020-025. The product listing is non-exclusive and may be amended as determined by FDA.

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

FDA Circular No. 2020-025 only applies to establishments and products under Categories III and IV.

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.

REGISTRATION OF HUHS PRODUCTS

1. What is a Certificate of Product Registration (CPR)?

>>A CPR is an authorization issued by FDA upon the approval of an application to register a health product prior to engaging in marketing, importation, exportation, sale, offer for sale, distribution, transfer, promotion, advertisement, and/or sponsorship thereof.

2. Which establishments are required to secure a CPR under AO 2019-0019 and FDA Circular No. 2020-025?

>> All FDA-licensed HUHS establishments shall be allowed to apply for a CPR except for Establishments that are Distributor-Wholesalers only.

3. **When is the earliest time to apply for a CPR?**

>> Applicants may access the HUHS product registration application from beginning of 1 February 2020. Reference: *FDA Advisory No. 2020-2035*

4. **How do I apply for a CPR?**

>> Application for CPR shall be submitted through the FDA e-Portal System V.2. using the assigned HUHS user account credentials of the applicant company.

a. Open the link http://eportal2.fda.gov.ph
b. Log-in by entering the issued username and password.
c. Provide all the required information in the Product Registration application form.
d. Accomplish the form by filling in all the field as completely as possible.
**Fields marked with a red asterisk (*) are required to be filled in.*
e. Upload the required documents in PDF format.
f. Save and print the order of payment that will be generated.
g. The application will undergo registration 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.

5. **What are the documentary requirements for a CPR application?**

>> The following documents shall be uploaded through the E-Portal V.2. The acceptable size and format of the file/s is 2MB per attachment (total of 25MB) in .pdf format.

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

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)

**The list and conditions for variations, including documentary requirements for submission are outlined in Annex E of FDA Circular No. 2020-025.*

3.5 Payment of Fees

6. How long is the validity of a CPR?

>> Unless revoked, the LTO shall have the following validity period:

Initial CPR application validity: 2 or 3 years
Renewal CPR application validity: 5 years

7. After submitting my CPR application, what is the next process?

>>An evaluator/assessor from the concerned FDA Center shall conduct pre-assessment on the submitted application if it has complied with the submission of complete set of documentary requirements. Incomplete submission will not be accepted and the application will not proceed to the next step of the process.

8. My application has been tagged as complete after pre-assessment, what is the next process?

>> The applicant will receive an email notification (with attached Order of Payment) notifying to proceed with the payment of the application.

9. What are the prescribed 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.

Product	Initial	Renewal
HUHS Category III and Category IV	1,000.00 (2 year validity) + 200 per variant	2,500.00 (5 year validity) + 500 per variant
	1,500.00 (3 year validity) + 300 per variant	

**A surcharge of 50% renewal fee is collected if renewal registration is submitted within 3 months after the expiration of the CPR. Application for renewal filed beyond the third month after expiration of CPR shall be considered as initial application.*

10. How do I pay for the CPR application?

>> The following steps shall be undertaken:

Step 1: Go to the BancNet Online homepage. https://www.bancnetonline.com). Select the Bank of your choice.

Step 2: A Security Message pop-up window will appear. Click "Continue" to proceed.

Step 3: Read the terms and conditions then click the "I Agree" button to proceed.

Step 4: Click "Payment" and set "FDA Philippines" as the Biller/Institution in the drop down.

Step 5: Take note of the "Account Number" found in the Order of Payment that will be generated right after filling up the FDA online registration form as this will serve as the "Reference Number". Enter the "Account Number" on the "Reference Number" text box and fill up the other information needed then click submit.

Step 6: Enter the Card Number found in the front of your debit card in the "ATM Card Number" text box. Select "Account type". Enter the "Total Amount Due" in the "Amount to be paid" text box plus the Php 15.00 bank charge.

Step 7: Print the transaction receipt as your payment reference. Payments will be posted in the FDA system after 4-5 calendar days. FDA will issue an Official Receipt (OR) within 5-10 calendar days after posting. Present your printed transaction receipt upon claim of the FDA OR for verification purposes.

Refer to FDA Advisory No. 2015-021 for further information:
https://ww2.fda.gov.ph/attachments/article/241540/FDA%20Advisory%20No.%202015-021.pdf

*For payment through Land Bank of the Philippines:

FDA Clearing Account Name	FDA Clearing Account Number
FDA Cosmetics Clearing Account	0392-2220-06

Refer to FDA Memorandum Circular No.2013-046 for further information:
https://ww2.fda.gov.ph/index.php/issuances-2/others-laws-and-regulations-not-applicable-to-the-above-categories/other-memorandum-circular/125050-fda-memorandum-circular-no-2013-046

11. After paying for the required application fee, what is the next process?

>> The application will undergo the product registration evaluation process to verify the completeness and correctness, quality and veracity of the information and documents provided in the application. Applicant establishments must ensure that all information declared are consistent and substantiated as any inconsistency will be ground for disapproval.

After completion of the evaluation process and upon the recommendation of the Center Director, the application may either be issued an authorization in the form of a CPR (if compliant) or letter of disapproval (if not compliant).

12. How long is the processing of a CPR application?

>> CPR applications shall be processed in accordance with the approved FDA Citizen's Charter.

13. Where can I obtain the result of my application? What should I do next?

>> The authorization (CPR) or letter of disapproval can be downloaded from the User Account of the applicant establishment. Issued CPRs must be printed and displayed in public view within the premises of the establishment.

Re-application for disapproved application may be carried out. The applicant establishment should access its User Account, create a new case, and proceed with the application process as described herein.

14. When is the earliest time to apply for renewal?

>> Application for renewal shall be done within three (3) months prior to the expiration of the validity date of the CPR. Applications filed after the validity date of the CPR shall be subjected to surcharge as prescribed in RA 9711 and it's IRR.

15. Are there specific standards applicable for HUHS products covered under AO 2019-0019 and FC 2020-025?

>> The list of adopted standards for HUHS products are stipulated in Annex 6 of FC 2020-025:

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)

16. Do I need to secure special permit for imported products outside the HUHS' scope (household/institution)? (eg. Paint or adhesives from furniture companies to be consumed/used for their operations)

>> No, there's no need to secure one.

17. What should I do if I need to modify some information in my user account? (eg. email address, company name or in special cases, the owner)

>> The client may lodge their request thru ccrr.lrd.huhs@fda.gov.ph and attach the ff. documentary requirements:

- Cover letter stating a valid reason of changing such information/s
- Valid ID of the Authorized Personnel or Qualified Personnel for verification
- Along with the information listed below to be included in the body of the email:

  Old Email Address:
  Issued Username:
  New Email Address:
  Company Name:
  Company Address:
  Name of Authorized Representative/QP:
  Contact No.:

18. In case I have products in the market that will co-exist with my products covered under the implementation of AO 2019-0019 will I need to file for exhaustion?

>> The client should file for a request for product through the exhaustion, the letter of intent will be received by Food and Drug Action Center (FDAC).

- 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.

19. What are the documents needed upon filing letter of intent for exhaustion?

>> The list of documents are as follows:

1. Request letter stating the valid reason for label exhaustion
2. Initial Inventory of remaining labels

3. Actual Old product label/product and proposed product label/product (submit readable and clear photos of front and back label)
4. Submit valid Certificate of Product Notification of the product/s
5. Notice of Non-Compliance if applicable
6. Reconciliation inventory on the number of labels exhausted and unused for destruction at the end of the label exhaustion period

20. What is the process for additional source?

>> The client should prepare a letter of intent to add an additional source together with the copy of the valid LTO of the source and a copy of agreement between the two companies and submit to FDAC.

21. Do I need to declare and submit proof of all my packaging sizes, during CPR application?

>> Yes. The applicant must submit the following:

1. 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. Payment of fees

22. How can I apply for other Authorizations such as Emergency Use Permit (EUP), Certificate of Free Sale (CFS), or Promo permit?

>> Applications for EUP, CFS or Promo permit can be filed thru manual submission at FDAC followed by payment of the corresponding fee.
>>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. Reference: 5 under V of the FC 2020-025.

23. Will my application still proceed/be processed even with minimal incompleteness or inconsistency of information and/or documents?

>> No. Pre-assessment is stringent in technical errors and requires completeness and correctness of the documentary requirements.
>>The file name of the documents to be submitted shall be the content of the document (i.e Certificate of Analysis.pdf, Substantiation (Test Report).pdf, Substantiation (Study).pdf, Safety Data Sheet.pdf).

24. Should I register my multi-purpose and dual use products under HUHS?

>>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. (*4.6 Under V. Specific Guidelines of the FDA Circular No. 2020-025*). However, Multi-purpose products that do not fall within the scope and intended use as HUHS shall not be issued a CPR as HUHS.

25. Can I just declare the trade name for some of my ingredients for the reason of company's trade secret and confidentiality purposes?

>> The use of Trade names to identify the ingredients of the HUHS product for registration is not acceptable.

26. Until when the exhaustion of my products be accepted?

>> 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.

27. How to identify if a product is a variant of the other product?

>> The variants are those considered variation of the primary product in fragrant and colorants.
>> If no other variant except the primary product, kindly input "Not Applicable" in the Variant section of the application form.

28. Will there be a requirement for my substantiations?

>>All proof of substantiation should be scientific and evidence based, supported by known journals and tests should be done by FDA recognized facility.
**for substantiation refer to II, Annex I, of the FDA Circular No. 2020-025*

29. How should I declare the formulation of the ingredients in the full ingredient list in the application form for single product? For variants?

>>All ingredients should be declared as base formulation if the product pertains to one formulation only without variations within applied product e.g. if the declared variants are Variant A and Variant B, the formulation should be base and variant.
>>If the declared variant is Variant A only, the formulation should be considered as base formulation)

30. How do I declare the fragrant and colorants present in the full ingredient list in the application form?

>> For fragrance - if a mixture, declare only the components of fragrance classified as potentially allergenic, when present in concentration greater than 0.001% in leave-on products and 0.01% in rinse-off products in ratio by weight and submit IFRA certificate as part of their substantiation, whenever applicable. The list of potential allergens is found on Annex III of EU Cosmetic Regulation 1223/2009.

If the product does not contain allergen, you may declare the fragrance as a mixture in your re-application and include in the listing that no allergens was found in the fragrance mixture (e.g. CAS No.: Mixture (no allergen)).

If fragrance is not a mixture and is an identified chemical: you need to declare the CAS or CI no, whichever is applicable.

>> For colorants, declare each components of the coloring agents either in their chemical name, CAS Number, or Color Index (CI) Number. The list of acceptable coloring agents is found on Annex IV of the EU Cosmetic Regulation 1223/2009.

31. Do I need to apply a CPR on a per product formulation basis?

>> Yes, the application of CPR will be on a per product formulation and product presentation basis.
>> Different product presentation requires different application. Therefore, you are required to submit a different CPR applications each for bottles, sachets, spray bottles, etc..

32. Do I need to include the test methods used for my product/s in the Certificate of Analysis?

>> Yes, all test methods used shall be reflected in the test report to validate that the methods used followed a specific standard for the test.

33. What is the basis of minimum labelling requirements?

>> The basis for the minimum labelling requirements are Administrative Order No. 311 and Administrative Order No. 7394.

34. Will HUHS include institutional use under their jurisdiction?

>> Institutional use are products intended for industrial and company use only.

35. If I have other questions or concerns regarding CPR application process, where should I lodge my inquiries?

>> For HUHS inquiries and concerns, applicants may call the Center for Cosmetics Regulation and Research (CCHUHSRR) at (02) 8857-1900 loc. 8113 or email ccrr.lrd.huhs@fda.gov.ph