Annex D
Procedure in the Submission of an Initial HUHS Product Registration Application

I. Procedure Outline

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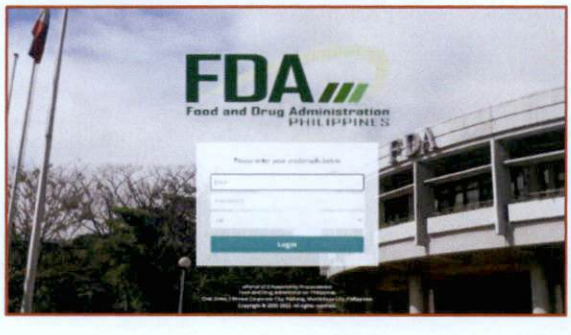
II. Step-by-step Procedure

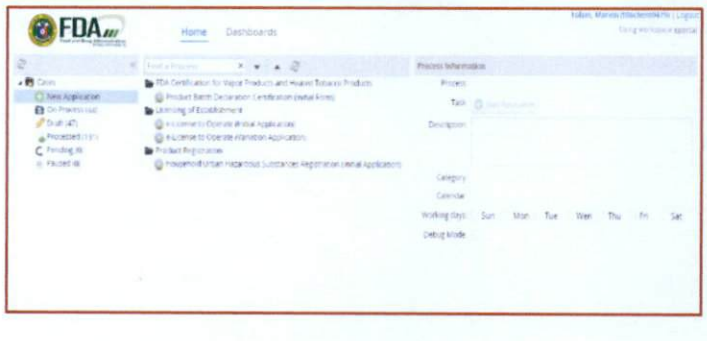
Follow the steps outlined below in order to submit an application for an initial HUHS Product Registration:

A. Logging-in to FDA e-Portal V.2 system

1. Go to the FDA website (https://www.fda.gov.ph/), then click the "Services" and select "ePortal2" or access the FDA e-Portal V.2 (e-Portal2) at https://eportal2.fda.gov.ph (screenshot below).



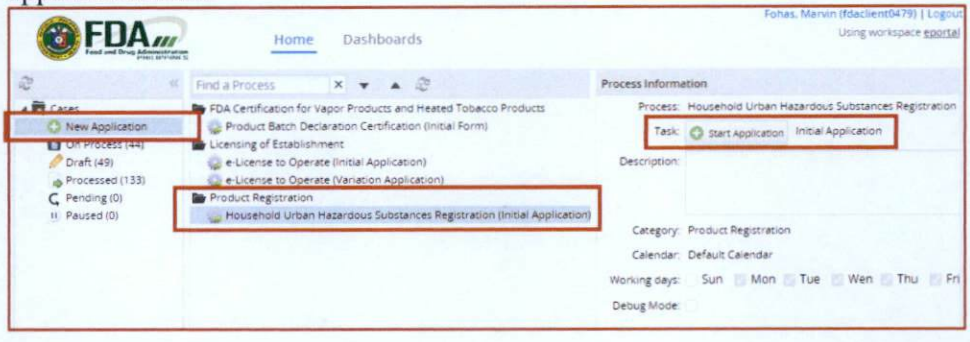
2. Log-in by entering the username and password issued by the FDA. Upon successful log-in, the FDA e-Portal V.2 System Homepage automatically appears in the screen (refer to screenshot below).



B. Preparation and Submission of Initial HUHS CPR Application for Pre-Assessment

1. Creating a new application

In the HOME tab, select "New Application" in the navigation pane and click "Household Urban Hazardous Substances Registration (Initial Application)" then "Start Application" or double click "Household Urban Hazardous Substances Registration (Initial Application)" to proceed to the registration application form.

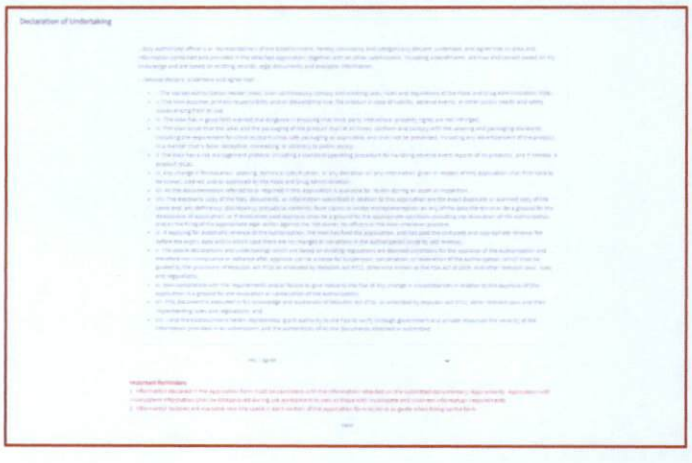


2. Accomplishing the application form

Accomplish the application form as provided in parts by the application wizard. Fill-in the fields as completely as possible following the guide below:

a. Declaration of Undertaking

Carefully read the Declaration of Undertaking from start to finish before selecting a response using the dropdown menu and clicking "Next". Select "Yes, I Agree" if the applicant agrees with the items listed. Otherwise, select "No, I Disagree". Note that selecting "No, I Disagree" will automatically end the application process while choosing "Yes, I agree" will bring the applicant to the next part of the application process.



b. Local Company Responsible for Placing the Product in the Market

i. Select the appropriate LTO number based on the applicant's activity relative to the HUHS product for registration. All relevant information about the applicant establishment will automatically be reflected once a valid LTO has been selected.

ii. Click the 'Next' button to proceed on the next step.

c. Product Source

i. Fill-in the necessary information. The information on product source that must be provided depends on the declared license of the applicant.

(1) For LTO as *HUHS Manufacturer*, the system will automatically fill-up the application form with the recorded information of the manufacturer.

(2) For LTO as *HUHS Trader*, provide the valid LTO number of the toll manufacturer hired to produce the HUHS product. From the indicated LTO number of the toll manufacturer, the system will then automatically provide all other relevant information.

(3) For LTO as *HUHS Distributor-Importer*, declare if the imported products for registration are directly or indirectly sourced and note the following:

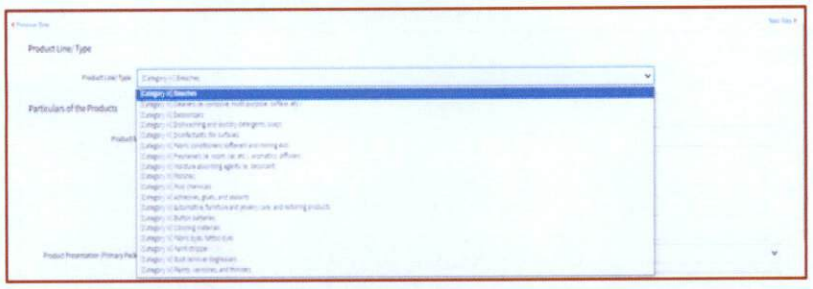
a. Directly sourced. If the HUHS product is procured directly from its (foreign) manufacturer, provide the following information:
   (i) Country of Origin
   (ii) Information on the (Foreign) Manufacturer (i.e. Manufacturer Name, Manufacturer Address)

b. Indirectly sourced. If the HUHS product is procured from a foreign supplier who is not the (foreign) manufacturer, provide the following information:
   (i) Country of Origin
   (ii) Information on the (Foreign) Manufacturer (i.e. Manufacturer Name, Manufacturer Address)
   (iii) Information on the (Foreign) Supplier (i.e. Supplier Name, Supplier Address

ii. Click the 'Next' button to proceed on the next step.

d. Product Line/Type

i. Select from the dropdown menu the product line / type that is most appropriate for the HUHS product for registration.



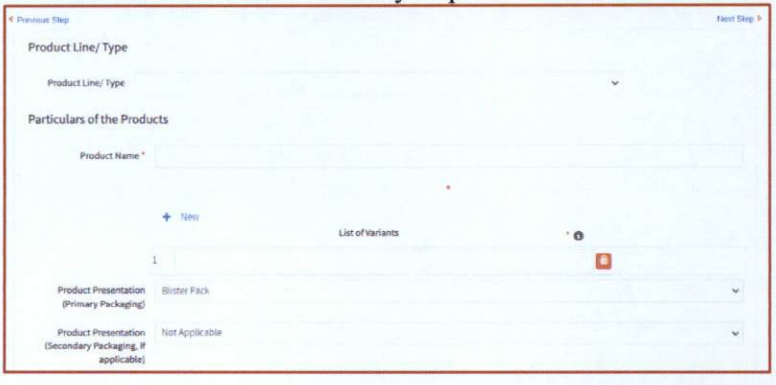
ii. Note that for licensed HUHS manufacturers, only the product line/s that have been declared during their LTO applications are listed in the dropdown menu. In case HUHS manufacturers intends to register a HUHS product that does not fall within the available product lines, it must submit a major LTO variation application first to include the specific product line in its LTO.

e. 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.

i. **Product Name.** Indicate the complete Brand and Product Name of the HUHS product for registration and note the following:

- Product name declared in the application form must be consistent with all the submitted documents. In case the product names reflected in the submitted documents are not consistent with the one declared in the application form, submit a declaration/certification stating that the different product names all refer to the HUHS product for registration.
- Brand/Product names must not be identical to those already registered under HUHS and must not be offensive, obscene, scandalous or otherwise contrary to public morals.

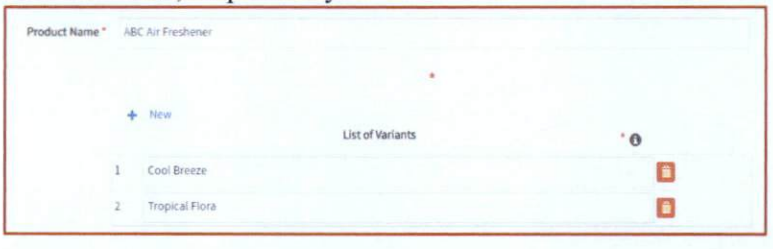


ii. **List of Variants**. A HUHS product for registration with more than one (1) variant can be registered under a single application. A maximum of five (5) variants can be registered in a single application.

(1) Variants of a HUHS product refers to HUHS products with identical base formulation but contains different colorant and/or fragrance.

- The base formulation of the HUHS product variants may either be quantitatively and qualitatively identical, or they may have minor differences in concentration due to adjustments made for the difference in colorants and/or fragrances.
- The concentrations of the colorants and/or fragrance used in the variants of the HUHS product may either be the same or different.
- A change in the concentration of the active ingredient/s is not allowed in variants of HUHS product and shall require a NEW product registration.
- Botanical ingredients (i.e. botanical extracts) are not considered as fragrance material despite its ability to function as such. Hence, in cases where the difference between the formulations of two (2) HUHS product is only the botanical ingredient used, these products will NOT be considered as variants.

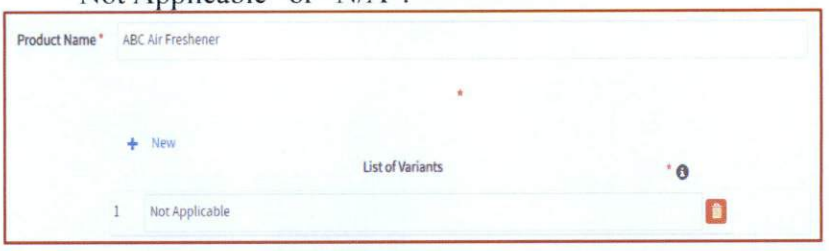
(2) To register more than one (1) variant of a HUHS product in a single application, the brand and product name of the HUHS product must be declared under the "Product Name" while the names of the variants included in the application must be listed under the "List of Variants". Declare one (1) variant name per row. Should there be a need, add or delete rows by clicking + New button on the upper left corner of the field and the button at the end of the row, respectively.



(3) If the applicant intends to register each variant of the HUHS product separately, the following options may be followed:
- Declare the variant name together with the brand and product name of the HUHS product under the "Product Name" and indicate "Not Applicable" or "N/A" in the "List of Variants", OR
- Declare the brand and product name of the HUHS product under the "Product Name" while declaring the variant name in the "List of Variants". Refer to the example below:

Application Form	Multiple Variants in a Single Application	1 Variant per Application (Option 1)	1 Variant per Application (Option 2)
Product Name	ABC Disinfectant Spray	Application #1 ABC Disinfectant Spray – Lavender Application #2 ABC Disinfectant Spray - Lemon	Application #1 ABC Disinfectant Spray Application #2 ABC Disinfectant Spray
List of Variants	Lavender Lemon	N/A	Application #1 Lavender Application #2 Lemon

- In case the HUHS product does not have any variants, indicate "Not Applicable" or "N/A".



iii. **Product Presentation (Primary Packaging).** Select from the dropdown menu the product presentation that best describes the primary packaging presentation of the HUHS product (i.e. Bottle, Canister, Tub, Tube, Blister Pack, etc).
   - In case the primary packaging presentation of the HUHS product is not found in the dropdown menu, select "Others" and indicate the most appropriate description of the primary packaging.
   - If with multiple primary packaging presentations, select "Others" and indicate all available primary packaging presentations. To illustrate, for a HUHS product available in 100mL Bottle and 10mL Sachet, select "Others" and indicate (a) Bottle and (b) Sachet.

iv. **Product Presentation (Secondary Packaging, if applicable).** Select from the dropdown menu the secondary packaging presentation that best corresponds to the HUHS product (i.e. Box, Pouch, Wrapper, etc).
   - In case the secondary packaging presentation of the HUHS product is not found in the dropdown menu, select "Others" and indicate the most appropriate description of the secondary packaging.
   - In case the HUHS product has multiple primary packaging presentations and one or all of them has secondary packaging, select "Others" and indicate the appropriate description of the secondary packaging. To illustrate, for a HUHS product available in 100mL Bottle enclosed in a box and 10mL Sachet sold as is, select "Others" and indicate (a) Box and (b) Sachet.
   - In case the HUHS product does not have a secondary packaging, indicate "Not Applicable" or "N/A".

v. **Net Content.** Indicate the available pack size/s of the HUHS product for registration consistent with those printed on the product label. Use the metric unit in declaring the net content or net weight.
   - In case there are multiple packaging presentation, declare the net content together with their corresponding packaging presentation (i.e. 100mL Bottle, 10mL Sachet).

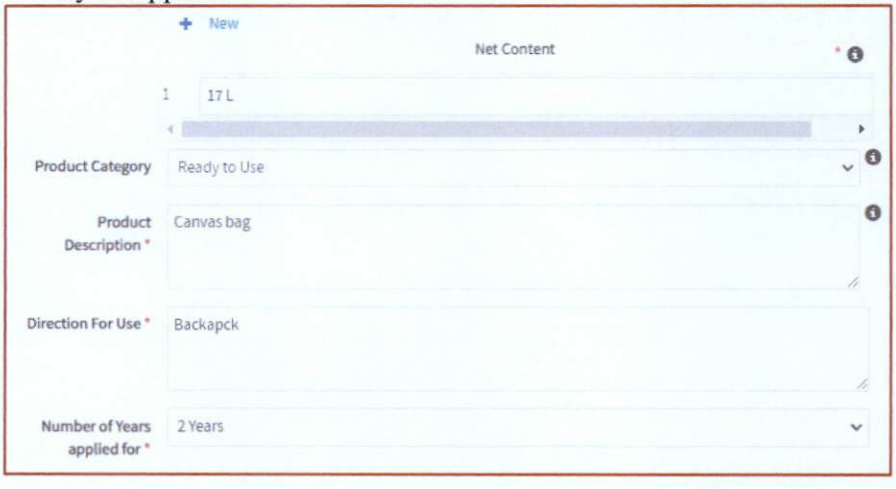
vi. **Product Category.** Select from the dropdown menu the appropriate category of the HUHS product for registration. A HUHS product may either be: "Ready-to-Use" or "For Professional Use".

vii. **Product Description.** Indicate the technical specifications of the HUHS product as reflected in the Certificate of Analysis (COA).

- Results of the tests conducted on the HUHS product as reflected in the COA may also be indicated together with the product specifications, as an option.
- Technical specifications of the HUHS product found in the COA and declared in the application form must be consistent with those reflected in the Safety Data Sheet (SDS) and stability study, if available.

viii. **Direction For Use.** Indicate the instructions for the proper use of the HUHS product for registration as reflected on the submitted product label.

ix. **Number of Years applied for.** Indicate the CPR validity applied for. For initial HUHS product registration, a 2-year or 3-year CPR validity may be applied.



f. Safety Information

Declare the GHS compliance and the safety information for the HUHS product for registration based on the hazard information found in the submitted SDS.

i. GHS Compliance and Hazard Information

(1) **GHS Compliant**

(a) Select "Yes" if the hazard of the HUHS products for registration have already been classified according to GHS.

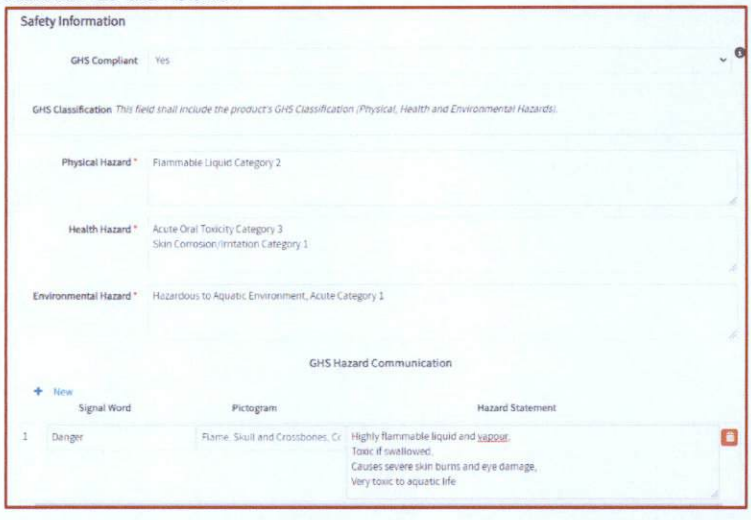
(b) After declaring GHS-compliance by selecting "Yes" in the "GHS Compliant" field, indicate all the GHS hazard classification/s of the HUHS product, as reflected in the SDS, under the appropriate hazard group (i.e. Physical, Health and Environmental). Refer to the GHS guidelines for more information on the different hazard classes under the three (3) hazard groups.

(c) In case the HUHS product does not meet the GHS hazard criteria of any hazard class under the three (3) hazard group, indicate "Not Classified".

(d) For the GHS hazard communication elements, indicate the appropriate:

- Signal Word (i.e. DANGER, WARNING)
- Pictogram/s (i.e. Flame, Gas Cylinder, Skull and Crossbones, Corrosion), and
- Hazard Statement/s (i.e. Flammable liquid and vapour, Harmful if swallowed, Toxic to aquatic life).
- Note that based on GHS, there may only be one (1) signal word assigned to a HUHS product whereas one (1) or more pictograms and hazard statements may be applied depending on its GHS hazard classification/s.

(e) For more information on the precedence rule on the allocation of GHS label elements and permitted combined hazard statements, refer to Chapter 1.4 and Annex 3 of the 8th revised edition of the GHS.



(2) **Non-GHS-Compliant.** For non-GHS compliant HUHS product, declare its hazards in accordance to the following:

(a) Must be compliant to Item 14.3.6.3 under Section V (Specific Guidelines) of FDA Circular No. 2020-025 stating that within the transitory period as 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 described the hazard

(b) Non-GHS compliant hazard information declared in the application form must be consistent with those found in Section 2 of the submitted SDS and on the product label.

(c) Non-GHS compliant HUHS products are only allowed during the transitory period, after which no non-GHS compliant HUHS products will be allowed to be registered with FDA and to be made available in the market.

ii. Precautionary Statements and Warnings

(1) Indicate the precautionary statements and warnings applicable to the HUHS product in accordance with GHS.

(2) For HUHS products not intended for the use of children, the statement "Keep out of reach of children" or its equivalent must also be included

(3) For HUHS products intended for the use of children, the statement indicating that the use of the product requires adult supervision must also be included.

(4) All information on the precautionary statements and warnings declared in the application form should be consistent with those found on the product label and Section 2 of the SDS.

iii. Signs and Symptoms of Poisoning

(1) Indicate the signs and symptoms of poisoning that manifest after accidental or undue exposure to the HUHS product.

(2) Applicants must ensure that the information declared in the application form are consistent with those found on the product label, if indicated, and Sections 4 and/or 11 of the SDS.

iv. First Aid Instructions / Medical Advice

(1) Indicate the information on initial aid or care that should be given in case of accidental or undue exposure to the HUHS product.

(2) Applicants must ensure that the information declared in the application form are consistent with those found on the product label and Section 4 of the SDS.

v. Handling, Storage and Disposal Information

(1) Indicate the information on the proper handling, storage and disposal of the HUHS product.

(2) Applicants must ensure that the information declared in the application form are consistent with those found on the product label and Sections 7 and 13 of the SDS.

(3) During transitory period under FDA Circular No. 2021-011-A, special considerations are given to submitted existing product labels which do not reflect the declared hazard information, precautionary statements and warnings, signs and symptoms of poisoning, first aid instructions / medical advice or handling, storage and disposal information consistent with the SDS, as establishments are allowed to submit existing product labels,

regardless of compliance to Annex J of FDA Circular No. 2020-025, provided that all product claims are substantiated. However, it must be noted that the following circumstances shall require the submission of the artwork of the proposed HUHS product label:

- presence of unsubstantiated product claim/s in the existing label, OR
- presence of unallowable safety claim/s in the existing label (In lieu of proposed HUHS product label, a commitment letter stating that the new HUHS product label will no longer reflect the unallowable safety claim may be submitted).

Submitted proposed HUHS product label shall be evaluated to determine compliance with Annex J of FDA Circular No. 2020-025 and to verify consistency of information.

(4) After all required information on the product are declared, click "Next".

g. Ingredient List

i. Provide the qualitative and quantitative formulation of the HUHS product by providing the required ingredient information. One (1) ingredient/raw material per row. To add more rows, click "New".

ii. Based on the number of variants declared in the application, choose "Yes" or "No" in the "With Variant" field.

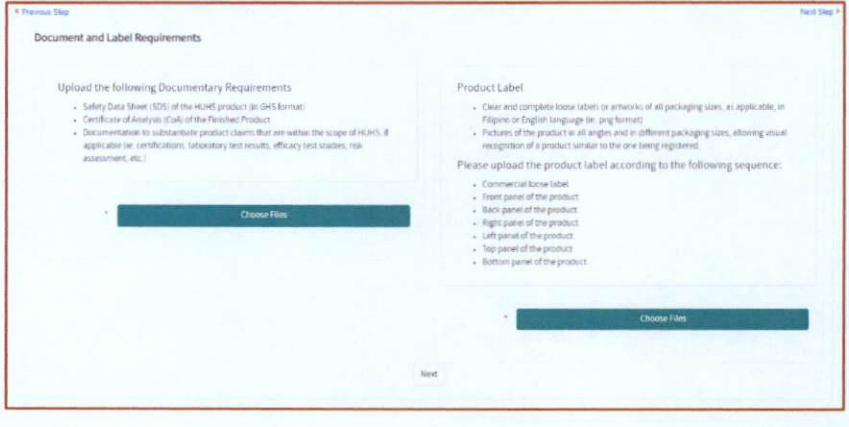
- If more than one (1) variant has been declared, select "Yes" and declare the following ingredient information:
  - Variant Name
  - Ingredient Name
  - CAS No.
  - Function
  - Percentage (%)
  - Formulation (Base or Variant)
  - Active Ingredient/s (Yes or No)
- If there has been up to one (1) variant declared, select "No" and declare the following ingredient information:
  - Ingredient Name
  - CAS No
  - Function
  - Percentage (%)
  - Formulation (Base or Variant)
  - Active Ingredient/s (Yes or No)

iii. Applicants must ensure that the ingredient list provided in the application form is consistent with Section 3 of the SDS. In case the formulation declared in the application form is inconsistent with Section 3 of the SDS, submit a clarification letter explaining the inconsistency.
iv. Once all information is declared, click the 'Next' button.

3. Uploading of Documentary Requirements

a. Upload the required document/s in accordance to FDA Circular No. 2020-025 by clicking "Choose Files":
   - SDS
   - COA
   - Documentation to substantiate product claims
   - Clear and complete loose labels or artworks of all packaging sizes of the existing HUHS product label, including the proposed GHS compliant product label for products falling under the circumstances indicated in Annex D.A.1.b.vi.5); and
   - Picture of the product in all angles and in different packaging sizes. Documents may be uploaded individually or as a set of multiple files.

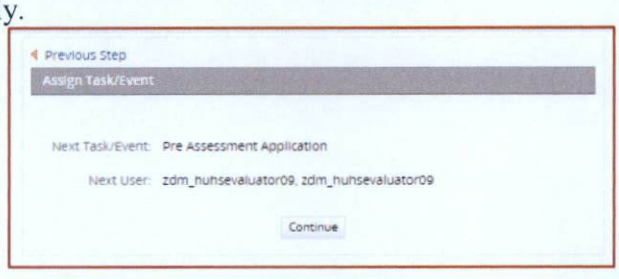
b. Applicants must ensure that the uploaded documents are in the correct format - PDF for documents and PNG for the pictures of the product and sample artwork of the product label (in all angles and if applicable, in different packaging sizes).
c. Click 'Next' to proceed on the next step.



4. Finalizing the application and submission for pre-assessment

a. An application summary will appear that reflects all the declared information and uploaded documents.
b. Review and recheck the information declared and the documents uploaded. If there are corrections to be made, revisit the pages of the application form by clicking 'Previous Steps'. Attached document/s may also be viewed by clicking its file name.
c. Indicate the name of the uploaded document (i.e. SDS, COA, Documentation to Substantiate Product Claims, Other Documents) and the side of the HUHS product in the uploaded photos (i.e. Front, Back, Right, Left, Top Bottom, Commercial Loose).

d. Ensure that the information contained in the HUHS product registration application is CORRECT, CONSISTENT and COMPLETE, and that the application satisfactorily complies with the set FDA standards and requirements.
e. After reviewing the application summary, click "Next" and then "Continue" to submit the HUHS product registration application for pre-assessment. The application will then undergo the Pre-Assessment process accordingly.

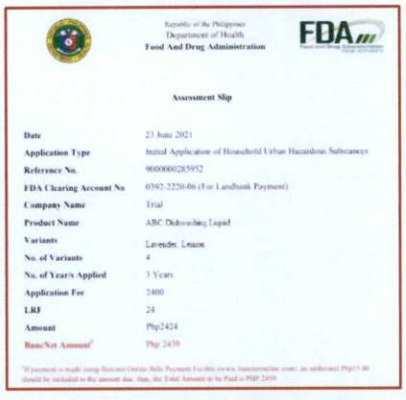


C. Checking of Pre-Assessment Result and Payment of Fees and Charges

After the pre-assessment process, an email notification will be sent to the FDA-registered email address of the applicant containing the result of the pre-assessment which may either be approval or disapproval.

1. **Pre-Assessment Disapproval (tagged as INCOMPLETE).**
   a. For HUHS product registration applications that have been tagged as incomplete, the email notification will contain the reason/s for the pre-assessment disapproval.
   b. The result of the pre-assessment may also be accessed in the FDA e-Portal V.2 System by proceeding to the "On Process" folder. Look for the specific HUHS product registration application and open it by double-clicking on any area within the row of the target application. The system will then show the result of the pre-assessment containing the reasons for the pre-assessment disapproval in PDF format which can be downloaded/printed.
   c. Click "Next" to access the "Application Summary" and verify the result of the pre-assessment.
   d. Once done, click "Next" and then "Finish" to end the process.
   e. The disapproval of HUHS product registration applications during the pre-assessment stage does not preclude the applicant from submitting a new application, provided that the deficiencies noted in the disapproved application have been addressed prior to the submission of the new application

2. **Pre-Assessment Approval (tagged as COMPLETE).**
   a. For HUHS product registration applications that have been tagged as complete, the email notification will include the Order of Payment/Assessment Slip which contains the fees and charges that must be paid to proceed with the application.
   b. The Order of Payment/Assessment Slip can also be viewed in the FDA e-Portal V.2 System by searching the application case number under "Processed" folder. Right-click the case number and then choose "Summary" and go to "Generated Documents".



Republic of the Philippines
Department of Health
Food And Drug Administration

FDA

Assessment Slip

Date	23 June 2021
Application Type	Initial Application of Household Urban Hazardous Substances
Reference No.	900000028592
FDA Clearing Account No	0392-2220-06 (For Landbank Payment)
Company Name	Trial
Product Name	ABC Dishwashing Liquid
Variants	Lavender, Lemon
No. of Variants	4
No. of Year/s Applied	3 Years
Application Fee	2400
LRF	24
Amount	Php2424
BancNet Amount*	Php 2439

*If payment is made using Bancnet Online Bills Payment Facility (www.bancnetonline.com), an additional Php15.00 should be included to the amount due. Thus, the Total Amount to be Paid is PHP 2439.

c. Save and print a copy of the document as reference for payment and settle the appropriate fees and charges via:
   - BancNet - refer to FDA Advisory No. 2015-021 for the process,
   - Over-the-counter in any branch of the Land Bank of the Philippines - refer to Item B.6. (Payment Collection), Section IV (Guidelines) of FDA Memorandum Circular No. 2013-038. For easy reference, the clearing account number for the Center for Cosmetics and Household/Urban Hazardous Substances Regulation and Research is 0392-2220-06, or
   - Link.BizPortal e-payment facility of the Land Bank of the Philippines - refer to FDA Advisory No. 2021-0246 for more information.
   - For transfer or refund of payments made - refer to FDA Circular No. 2021-027.

d. Initial HUHS product registration applications that passed the pre-assessment stage are automatically forwarded to the FDA Cashier for posting of payment. Hence, applicants are advised to make payments as soon as possible to officially lodge their applications with FDA.

e. After the payment has been made and the FDA Cashier has posted the payment in the FDA e-portal V.2 System, the case number for the initial HUHS product registration application will then be forwarded to the assigned evaluator at the CCHUHSRR for the evaluation proper.

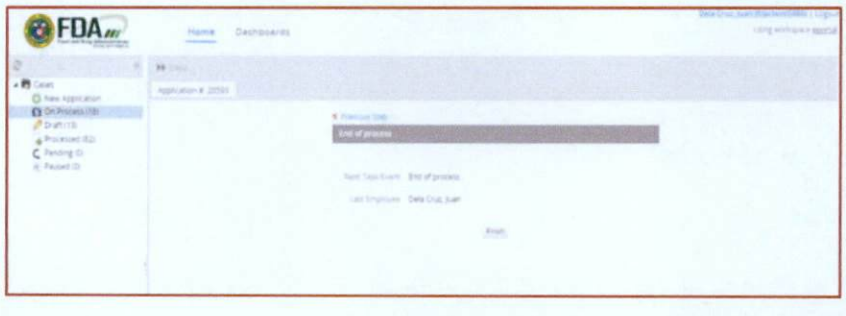
D. Checking of Application Result

1. Once the application has undergone the evaluation process for initial HUHS product registration, an email notification will be sent to the FDA-registered email address of the applicant containing an update on the HUHS product registration application and providing instructions on how to access the result.
2. During the transitory period, as mandated in FDA Circular 2021-011A, HUHS product registration applications that have been found to contain minor deficiencies during the evaluation process are issued with a one-time Notice of Deficiencies (NOD).
   a. The email notification sent to the HUHS Establishment serves as the NOD which contains the deficiency/ies found in the lodged application that must be addressed within fourteen (14) calendar days. Please note that non-submission of compliance within the provided 14-days submission period will render the application disapproved. Thereafter, regardless whether the applicant has managed to address the noted deficiencies or not, the HUHS product registration application will be automatically reverted to the Center. To comply with the issued NOD:

- Access the HUHS product registration application in FDA e-Portal V.2 System by proceeding to the "On Process" folder. Look for the specific HUHS product registration application and open it by double-clicking on any area within the row of the target application.
- Go through the Application Summary, click "Next" to view the evaluation notes from the FDA and then click "Next" to proceed to the part of the application process where the required compliance documents can be uploaded.
- Once done, click "Next" and then "Submit" to return the HUHS product registration application to the evaluator.

b. The submitted compliance documents are evaluated by FDA relative to the original HUHS product registration application. Depending on whether the submitted documents sufficiently address the noted deficiencies, a HUHS product registration application may either be recommended for approval or disapproval.

3. For disapproved applications, the disapproval of HUHS product registration applications does not preclude the applicant from submitting a new application, provided that the deficiencies noted in the disapproved application have been addressed prior to the submission of the new application.
4. For approved applications, the back of the marketing authorization or CPR contains the list of post-approval conditions that must be complied with by the Marketing Authorization Holder at the end of the transitory period or during the renewal of the CPR.
5. The result may be downloaded through the "On-Process" folder in the FDA e-Portal V.2 system. Open the application case number, download and print the document (Certificate of Product Registration or Letter of Disapproval), and then click "Finish" to end the task.



6. To view the result again, under "Processed" folder right-click on the case number and then choose "Summary" and go to "Generated Documents" tab to download and print the result.