**FDA ADVISORY**
**No. 20250504**

02 MAY 2025

**TO** : **ALL LICENSED HOUSEHOLD/URBAN HAZARDOUS SUBSTANCES ESTABLISHMENTS AND OTHER CONCERNED STAKEHOLDERS**

**SUBJECT** : **Procedural Guidelines for the Filing and Submission of Applications for Household/Urban Hazardous Substances (HUHS) Certificate of Product Registration (CPR) Automatic Renewal, Variation and Turned Initial through the FDA E-Portal V.2 System**

Pursuant to DOH Administrative Order (AO) No. 2019-0019 and FDA Circular (FC) No. 2020-025, the Center for Cosmetics and Household/Urban Hazardous Substances Regulation and Research (CCHUHSRR) of the Food and Drug Administration (FDA) hereby announces that applications for automatic renewal, variation and turned initial of Household/Urban Hazardous Substances (HUHS) Certificates of Product Registration (CPR) shall be accepted through the FDA Electronic Portal (e-Portal) V.2 System beginning 2 May 2025.

To facilitate the filing of such applications, all concerned stakeholders are requested to be guided by the following:

1. All applications for automatic renewal, variation and turned initial HUHS CPR shall be exclusively filed through the FDA E-Portal V.2 System. From 2 May 2025, the interim procedure for variation applications under Section IV.I of FDA Circular No. 2023-006, respectively, shall no longer be in effect.

   Meanwhile, to assist applicants in the preparation of their renewal applications, the interim procedure to avail of the validity extension and waiver of surcharges under Item No. 3 of FDA Advisory No. 2024-1660 was issued. While the letter of intent for CPR renewal will remain to be accepted until 15 June 2025, all applicants are highly encouraged to file their renewal applications through the system as soon as available

2. The following procedural guidelines for filing and submission of applications are annexed to this Advisory:

   **Annex A** Procedure in the Submission of an HUHS CPR Automatic Renewal Application

   **Annex B** Procedure in the Submission of an HUHS CPR Variation Application

**Annex B.1** Procedure for the Claiming of Re-Issued HUHS Product Registration

**Annex C** Procedure in the Submission of an HUHS CPR Turned Initial Application

3. For previously issued CPRs with Post-Approval Commitment (PAC), the marketing authorization holders (MAHs) shall submit the respective compliance documents through an appropriate variation application in accordance with the prescribed schedule, as annexed.

**Annex D** Types of Variations and Schedule of Submission

For inquiries or clarifications, please email CCHUHSRR at cchuhsrr.lrd.huhs@fda.gov.ph

Dissemination of this Advisory to all concerned is hereby requested.

**DR. SAMUEL A. ZACATE**
Director General

DTN 20250304164039

**Annex A**

**Procedure in the Submission of an HUHS CPR Automatic Renewal Application**

## I. Description

A Certificate of Product Registration (CPR) shall be eligible for automatic renewal when the following conditions are satisfied:

A. The application is filed before the expiration date of the registration.
B. The prescribed renewal fee is paid upon filing of the application; and,
C. A sworn statement indicating no change or variation whatsoever in the product is attached to the application.

All MAHs with CPRs extended until 30 June 2025 based on the interim procedure under FDA Advisory No. 2024-1660 must secure their renewal applications and pay the prescribed fees and charges before this date. Surcharges shall apply to applications filed and paid beyond the validity date of the authorization.

## II. Procedure Outline

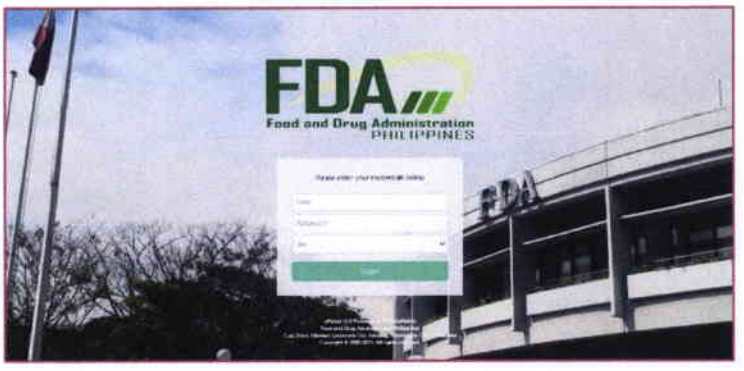
A. Logging-in to FDA e-Portal V. 2 System
B. Preparation and Submission of HUHS CPR Automatic Renewal Application
    1. Creating a new case application
    2. Accomplishing the application form
        a. Declaration of Undertaking
        b. Application Summary and Registration Details
    3. Generating the order of payment and Payment of Fees and Charges
C. Checking of Application Result

## III. Step-by-step Procedure

Follow the steps outlined below in order to submit an HUHS CPR automatic renewal application:

### A. Logging-in to FDA e-Portal V. 2 System

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

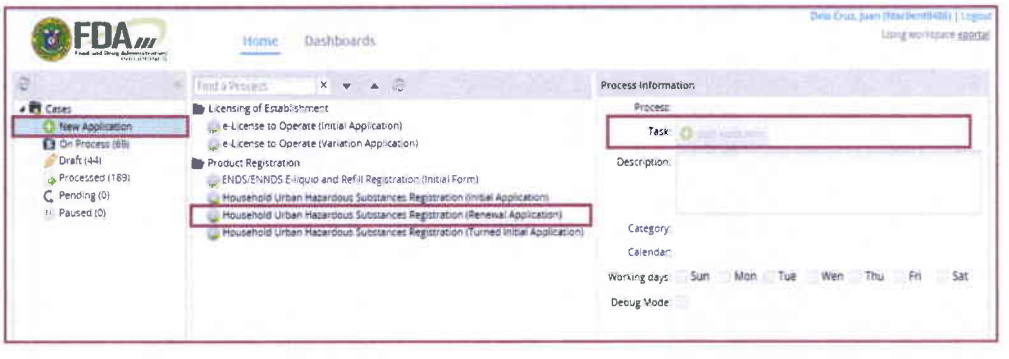



2. Log-in by entering the username and password issued by the FDA. Upon successful log-in, the FDA e-Portal V.2 System Homepage automatically appears on the screen (refer to screenshot below).

## B. Preparation and Submission of HUHS CPR Automatic Renewal Application

### 1. Creating a new case application

In the HOME tab, select "New Application" in the navigation pane and click "Household Urban Hazardous Substance Registration (Renewal Application)" then "Start Application" or double click "Household Urban Hazardous Substance Registration (Renewal Application)".



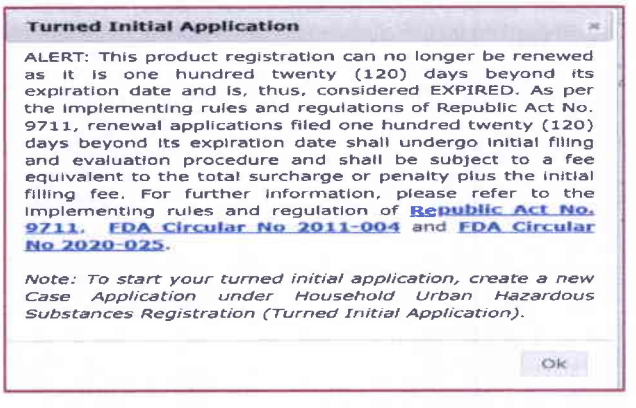
## 2. Accomplishing the application form

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 the start to finish before selecting a response using the dropdown menu. 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 enable the selection of the registration number to be renewed using the dropdown menu and clicking "Next".

- If the selected HUHS product registration number is eligible for renewal, the application shall proceed to the next step. Otherwise, an alert shall appear containing the following prompt:



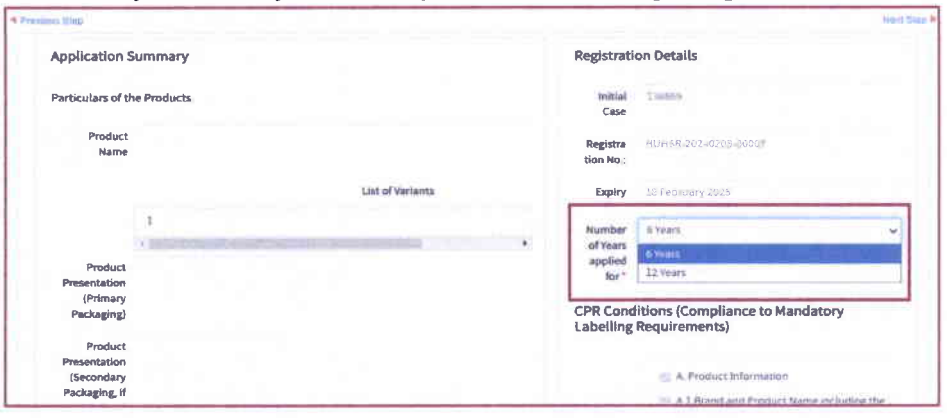

- Note that HUHS product registration that is beyond 120 days after its expiration date shall be considered expired and shall undergo turned initial filing and evaluation with appropriate surcharge or penalty pursuant to the implementing rules and regulations o of

Republic Act No. 9711, FDA Circular No. 2011-004, and FDA Circular 2020-025.

- Click "Ok" to close the automatic renewal application, then proceed to the Turned Initial Application following the procedural guidelines provided under Annex C of this advisory.

**b. Application summary and registration details**

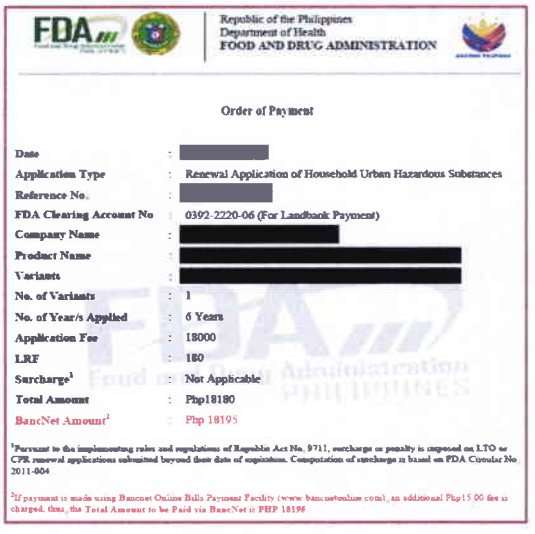
The application summary reflects all the information about the product registered for client verification. The registration details contain the initial case number, registration number and expiration date. Select the number of renewal years to be applied using the dropdown menu and choose from either a 6-year or 12-year validity. Click "Next Step" to proceed.




## 3. Generating the order of payment and payment of fees and charges

a. The Order of Payment shall be generated which contains the fees and charges that must be paid to proceed with the application.

b. It can also be reviewed by searching the application case number under the "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

Order of Payment

| | | |
|---|---|---|
| Date | : | [redacted] |
| Application Type | : | Renewal Application of Household Urban Hazardous Substances |
| Reference No. | : | [redacted] |
| FDA Clearing Account No | : | 0392-2220-06 (For Landbank Payment) |
| Company Name | : | [redacted] |
| Product Name | : | [redacted] |
| Variants | : | [redacted] |
| No. of Variants | : | 1 |
| No. of Year/s Applied | : | 6 Years |
| Application Fee | : | 18000 |
| LRF | : | 180 |
| Surcharge[1] | : | Not Applicable |
| Total Amount | : | Php18180 |
| BancNet Amount[2] | : | Php 18195 |

[1]Pursuant to the implementing rules and regulations of Republic Act No. 9711, surcharge or penalty is imposed on LTO or CPR renewal applications submitted beyond their date of expirations. Computation of surcharge is based on FDA Circular No. 2011-004

[2]If payment is made using Bancnet Online Bills Payment Facility (www.bancnetonline.com), an additional Php15.00 fee is charged, thus, the Total Amount to be Paid via BancNet is PHP 18195

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, and its amendments for the process.
    - Link.BizPortal e-payment facility of the Land Bank of the Philippines- refer to FDA Advisory No. 2021-0246, or its amendments for more information.
    - FDA Central Office Over-the-Counter (OTC) Payment System – refer to FDA Advisory No.2024-0320, or its future amendments for more information.


d. After downloading the order of payment, click "Next Step" and then "Continue" to submit the application for payment verification. Once the payment has been made and the FDA Cashier has posted the payment in the FDA e-portal V.2 system, the application shall be forwarded to the Center for processing and final decision.

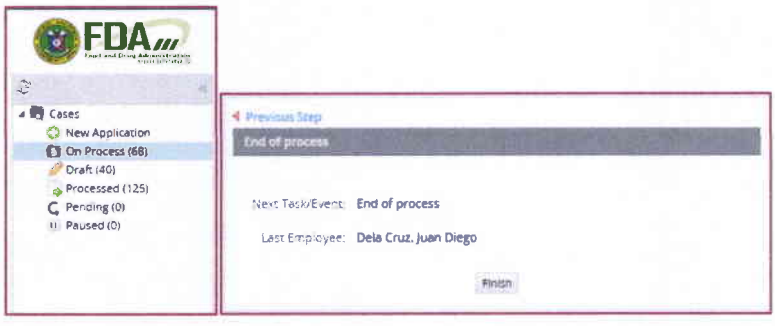
## C. Checking of Application Result

1. Once the application has undergone the automatic renewal process, an email notification will be sent to the registered email address of the HUHS establishment client informing that the application has been processed and providing instructions on how to access the result. The application result may either be approved or disapproved.
2. For approved applications, a Certificate of Product Registration (CPR) reflecting the renewed validity with the same initial registration number shall be generated.
3. For disapproved applications, a Letter of Disapproval (LOD) with the reason/s for disapproval shall be generated. The disapproval of an application is without prejudice to re-application. However, disapproval of application shall mean outright forfeiture of payment.

   In case of re-application, the client is advised to address all noted deficiencies before lodging a new case. Note that a re-application shall mean a new initial CPR application, which shall follow the documentary requirements specified in FDA Circular No. 2020-025, and its future amendments. To retain the same

HUHSR number initially issued to the HUHS product, the client is advised to submit an initial application under Household Urban Hazardous Substances as Turned Initial Application following the guidelines under Annex C of this advisory.

4. The result may be downloaded through the "On Process" folder of the applicant establishment in the FDA e-Portal V. 2 System. Open the application case number, download and print the document (CPR or LOD), and then click "Finish" to end the task.




5. 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.

**Annex B**

**Procedure in the Submission of an HUHS CPR Variation Application**

## I. Description

Changes in the circumstances of a registered HUHS product shall require a variation application, except for a change in manufacturer and formulation which shall require an initial application. The list of variation applications and the corresponding requirements are indicated in Annex E Section II.3 of FDA Circular No. 2020-025.

## II. Procedure Outline

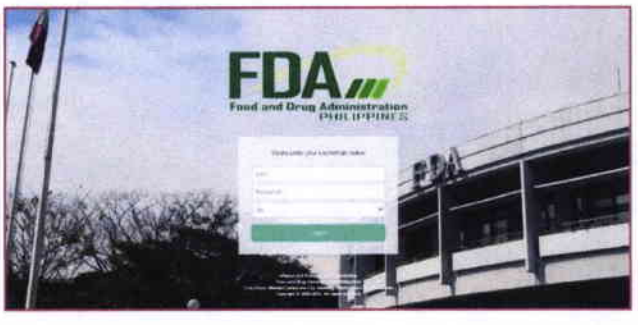
A. Logging-in to FDA e-Portal V. 2 System
B. Preparation and Submission of HUHS CPR Variation Application
   1. Creating a new case application
   2. Accomplishing the application form
      a. Declaration of undertaking
      b. Type of variation
   3. Uploading documentary requirements and product label
   4. Finalizing the application and submission for pre-assessment
C. Checking of Pre-Assessment Result and Payment of Fees and Charges
D. Checking of Application Result

## II. Step-by-step Procedure

Follow the steps outlined below in order to submit a variation application for an HUHS CPR:

### A. Logging-in to FDA e-Portal V. 2 System

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

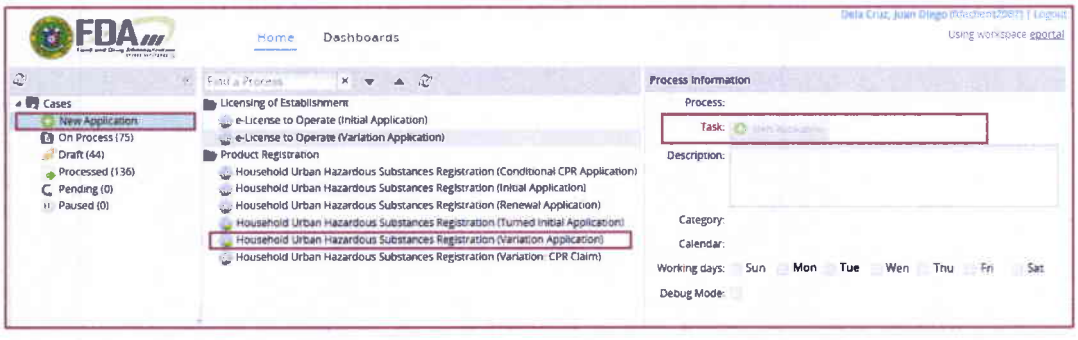



2. Log-in by entering the username and password issued by the FDA. Upon successful log-in, the FDA e-Portal V.2 System Homepage automatically appears on the screen (refer to screenshot below).

## B. Preparation and Submission of HUHS CPR Variation Application

### 1. Creating a new case application

In the HOME tab, select "New Application" in the navigation pane and click "Household Urban Hazardous Substance Registration (Variation Application)" then "Start Application" or double click "Household Urban Hazardous Substance Registration (Variation Application)".




### 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

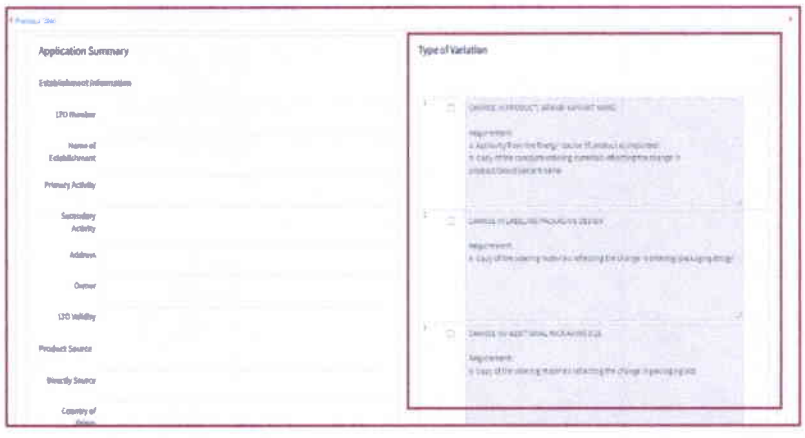
#### a. Declaration of Undertaking

Carefully read the Declaration of Undertaking from the start to finish before selecting a response using the dropdown menu. 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 enable the selection of the registration number subject to variation using the dropdown menu and clicking "Next".

It must be noted that once the MAH has lodged an application for CPR variation and such application remains pending or no decision is given, subsequent submissions of new/additional variation/s and/or simultaneous application for renewal of the registered HUHS product shall not be accepted.

**b. Type of Variation**

The registered product information is displayed on the left side of the application form as reference. The right side of the application shows the type of variation applicable to the registered HUHS product. Choose and tick the box of the type of variation intended to be applied. Proceed to the next step for uploading documentary requirements.




- Note that an HUHS CPR variation application can only accommodate **<u>one type of variation</u>**, with the exemption of the "Change in GHS Hazard Categorization in any of the Physical, Chemical or Environmental Hazard Class" which must be applied simultaneously with the "Change in / Additional Safety Data Sheet Information".

- Specifically for Change in Product Ownership, this variation is a 2-step process:
  (a) Old MAH - Obtain approval from the FDA to change the owner of the product by submitting a CPR variation application (Change in Ownership) following the steps outlined in this Annex; and,
  (b) New MAH - Claim the re-issued HUHS Product Registration in FDA e-Portal V.2 system once the Change in Variation application has been approved, following Annex B.1. "Procedure in the Preparation for HUHS CPR Variation (CPR Claim)" of this advisory.

**3. Uploading documentary requirements and product label**

Upload the document/s and/or product label required for the type of variation being applied for in accordance with FDA Circular No. 2020-025, in PDF and PNG format, respectively, by clicking "Choose Files". Once done uploading, click "Next".

**4. Finalizing the application and submission for pre-assessment**

a. A Variation Summary will appear that reflects all the declared information and uploaded documents.
b. Review and recheck the information and documents uploaded. Assign the applicable document name for the uploaded files using the provided dropdown options. If there are corrections to be made, revisit the pages of the application form by clicking "Previous Step". Attached document/s may also be viewed by clicking its file name.
c. After reviewing the variation application summary, click "Continue" to submit the 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 which may either be approved or disapproved.

### 1. Pre-Assessment Disapproval (tagged as INCOMPLETE)

a. For HUHS CPR variation 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 be accessed in FDA e-Portal V.2 System by proceeding to the "On Process" folder. Click the case number of the CPR variation 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 reason/s for the pre-assessment disapproval on PDF format which can be downloaded/printed.

c. Click "Next" to access the "Application Summary" and verify the result of the pre-assessment.

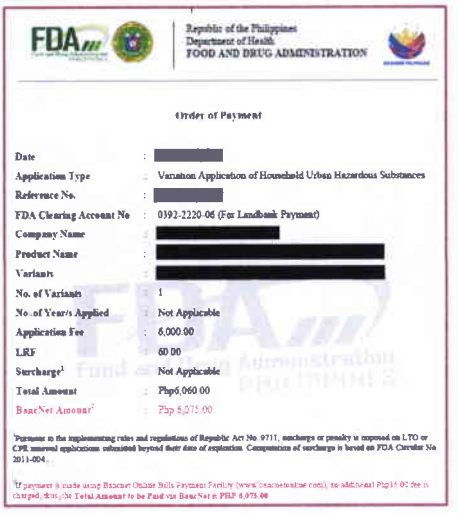
d. Once done, click "Next" and then "Finish" to end the process.

e. The disapproval of HUHS CPR variation application 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 CPR variation applications that have been tagged as complete, the email notification will include the Order of Payment which contains the fees and charges that must be paid.

b. The Order of Payment can also be viewed in the FDA e-Portal V.2 System by searching the 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

Order of Payment

| | | |
|---|---|---|
| Date | : | [redacted] |
| Application Type | : | Variation Application of Household Urban Hazardous Substances |
| Reference No. | : | [redacted] |
| FDA Clearing Account No | : | 0392-2220-06 (For Landbank Payment) |
| Company Name | : | [redacted] |
| Product Name | : | [redacted] |
| Variants | : | [redacted] |
| No. of Variants | : | 1 |
| No. of Year/s Applied | : | Not Applicable |
| Application Fee | : | 6,000.00 |
| LRF | : | 60.00 |
| Surcharge[1] | : | Not Applicable |
| Total Amount | : | Php6,060.00 |
| BancNet Amount[2] | : | Php 6,075.00 |

[1]Pursuant to the implementing rules and regulations of Republic Act No. 9711, surcharge or penalty is imposed on LTO or CPR renewal applications submitted beyond their date of expiration. Computation of surcharge is based on FDA Circular No. 2013-004.

[2]If payment is made using Bancnet Online Bills Payment Facility (www.bancnetonline.com), an additional Php15.00 fee is charged. Thus, the Total Amount to be Paid via BancNet is PHP 6,075.00

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, and its amendments for the process.
   - Link.BizPortal e-payment facility of the Land Bank of the Philippines- refer to FDA Advisory No. 2021-0246, or its amendments for more information.
   - FDA Central Office Over-the-Counter (OTC) Payment System – refer to FDA Advisory No.2024-0320, or its amendments for more information.

d. HUHS CPR variation applications that passed the pre-assessment stage are automatically forwarded to the FDA Cashier for posting of payment. Hence, payments must be made by the client to officially lodge the application with FDA. Note that only paid applications shall be processed.

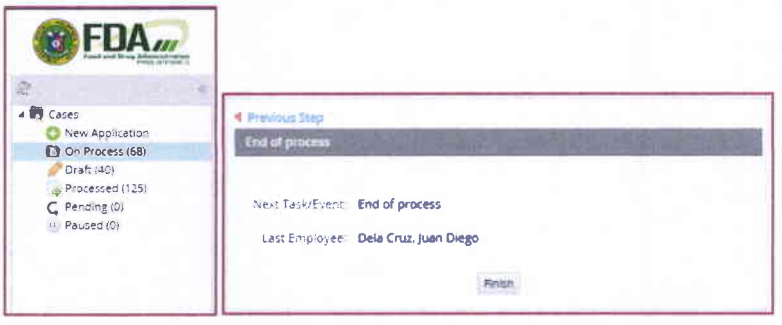
e. Once the payment has been made and the FDA Cashier has posted the payment in the FDA e-portal V.2 system, the application shall be forwarded to the Center for evaluation and final decision.

## D. Checking of Application Result

1. Once the application has undergone the evaluation, an email notification will be sent to the FDA-registered email address of the applicant informing that the application has been processed and providing instructions on how to access the result. The application result may either be approved or disapproved.
2. For approved applications, a CPR and/or Letter of Approval (LOA) reflecting the applied change shall be generated.
3. For disapproved applications, a Letter of Disapproval (LOD) with the reason/s for disapproval shall be generated. The disapproval of an application is without prejudice to re-application. However, disapproval of application shall mean

outright forfeiture of payment. In case of re-application, the client is advised to address all noted deficiencies before lodging a new case. Note that a re-application shall mean new CPR variation application, which shall follow the documentary requirements specified in FDA Circular No. 2020-025.

4. The result may be downloaded through the "On Process" folder of the applicant establishment in the FDA e-Portal V. 2 System. Open the application case number, download and print the document (CPR/LOA/LOD), and then click "Finish" to end the task.




5. 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.

**Annex B.1**

**Procedure for the Claiming of Re-Issued HUHS Certificate of Product Registration (CPR)**

## I. Description

The transfer of an existing product registration is considered as an amendment of the CPR, i.e. Change of Product Ownership. The procedure for the variation entails a two-step process as follows:

(a) Old MAH - Obtain approval from the FDA to change the owner of the product by submitting a CPR variation application (Change in Ownership) following the steps outlined in Annex B "Procedure in the Submission of an HUHS CPR Variation Application"; and,

(b) New MAH - Claim the re-issued HUHS Product Registration in FDA e-Portal V.2 system once the Change in Variation application has been approved, following this Annex.

Claiming of re-issued CPR incorporating the requested change in ownership can only be accessed by the new MAH once the application for CPR variation due to a change in product ownership has been approved.

## II. Procedure Outline

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

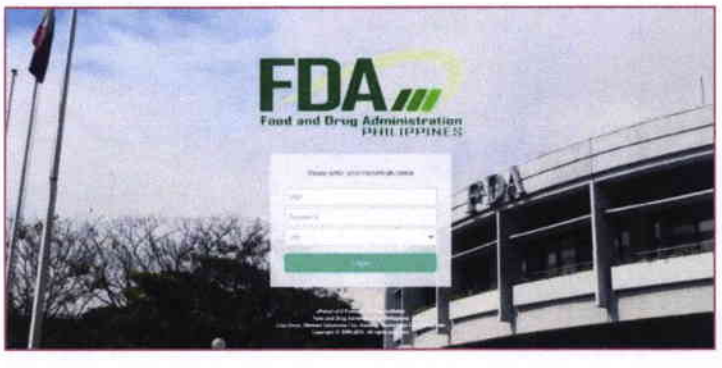
B. Claiming of Re-Issued HUHS Certificate of Product Registration (CPR)
   1. Creating a new case application
   2. Claiming of CPR Document

## II. Step-by-step Procedure

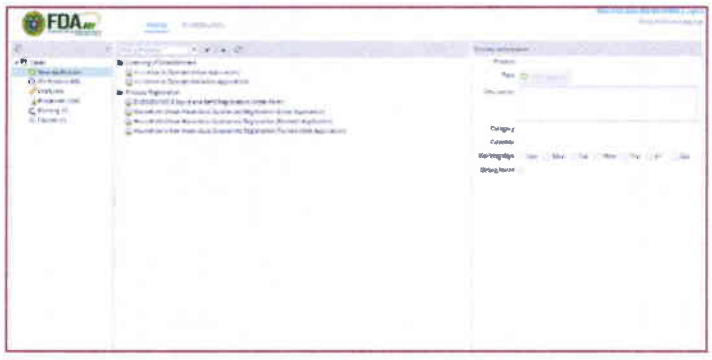
Follow the steps outlined below to claim the re-issued CPR:

### A. Logging-in to FDA e-Portal V. 2 System

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



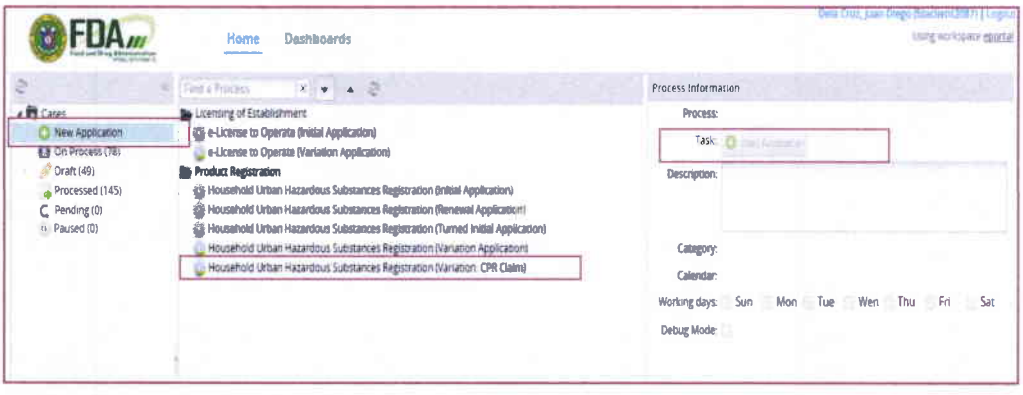
2. Log-in by entering the username and password issued by the FDA. Upon successful log-in, the FDA e-Portal V.2 System Homepage automatically appears on the screen (refer to screenshot below).



## B. Claiming of Re-Issued HUHS Certificate of Product Registration (CPR)

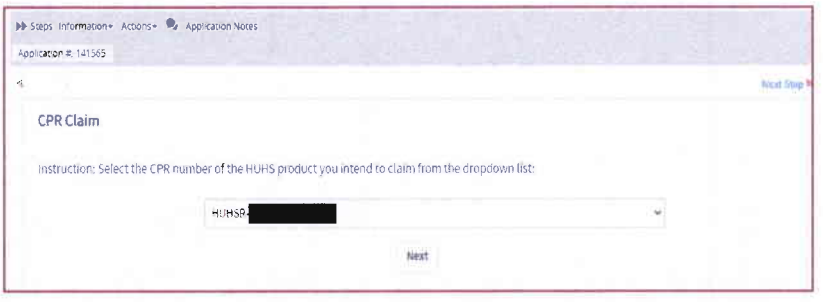
### 1. Creating a new case application

In the HOME tab, select "New Application" in the navigation pane and click "Household Urban Hazardous Substance Registration (Variation: CPR Claim)" then "Start Application" or double click "Household Urban Hazardous Substance Registration (Variation: CPR Claim)".

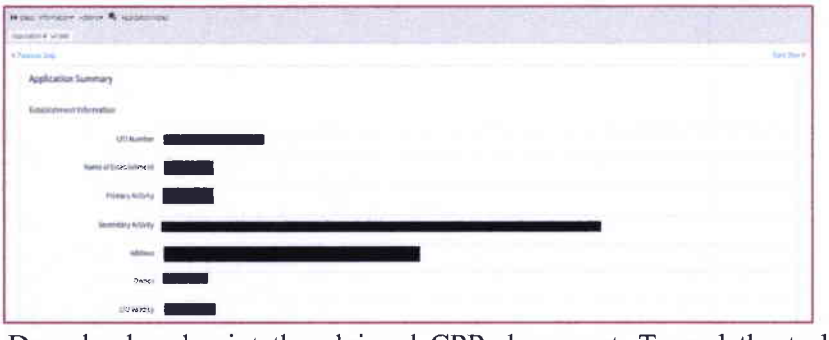


## 2. Claiming of CPR Document

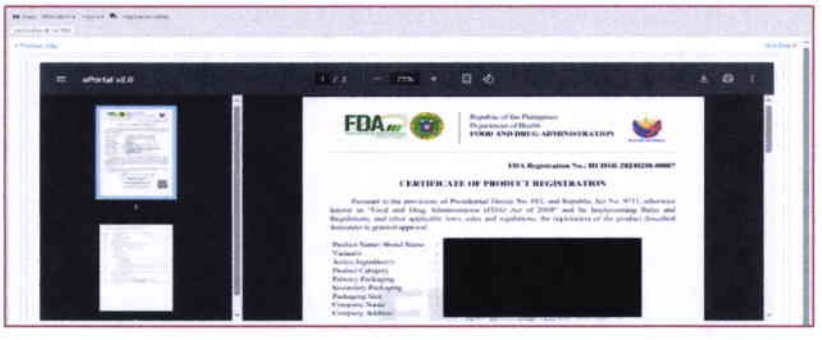
a. Select the CPR number of the HUHS product that is intended to be claimed from the dropdown list. Once selected, click "Next" to proceed.




b. An application summary shall be available for new MAH viewing to verify that the CPR information is correct. Please note that the summary will reflect the information of the new owner/MAH. Click "Next" to proceed.




c. Download and print the claimed CPR document. To end the task, click "Next" and then "Finish". 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.



**Annex C**

**Procedure in the Submission of an HUHS CPR Turned Initial Application**

## I. Description

Any application for renewal of registration filed thereafter shall be considered expired and the application shall be subject to a fee equivalent to the total surcharge or penalty plus the initial filing fee and the application shall undergo the initial filing and evaluation procedure. This application can only be accessed in cases where:

(a) An HUHS product registration for which renewal application was filed for more than 120 days beyond its expiration date therefore deemed ineligible for automatic renewal application; or,

(b) An HUHS product registration for which the automatic renewal application was disapproved.

## II. Procedure Outline

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

B. Preparation and Submission of HUHS CPR Turned Initial Application

1. Creating a new case application
2. Accomplishing the application form, uploading of the documentary requirements and application submission
3. Checking of Pre-assessment Result and Payment of Fees and Charges

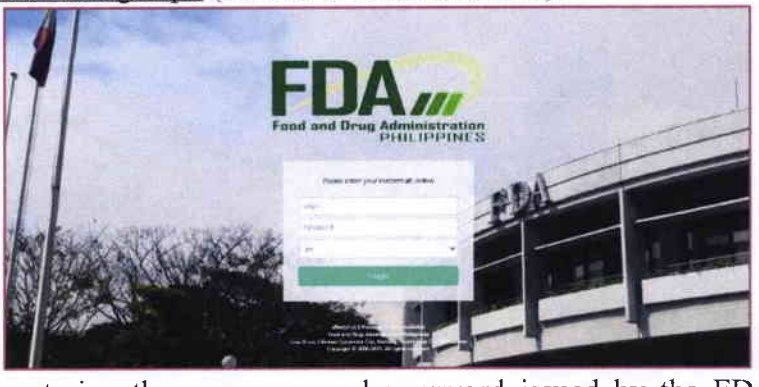
C. Checking of Application Result

## III. Step-by-step Procedure

Follow the steps outlined below in order to submit a HUHS CPR turned initial application.

### A. Logging-in to FDA e-Portal V. 2 System

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

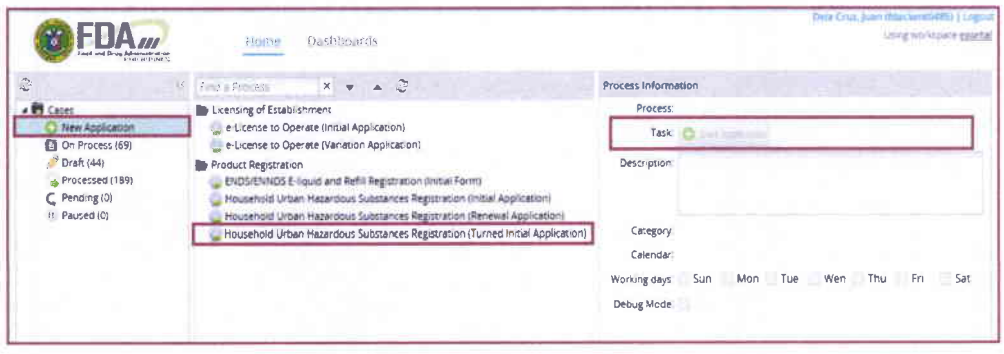



2. Log-in by entering the username and password issued by the FDA. Upon successful log-in, the FDA e-Portal V.2 System Homepage automatically appears on the screen (refer to screenshot below).

## B. Preparation and Submission of HUHS CPR Turned Initial Application

### 1. Creating a new case application

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




### 2. Accomplishing the application form, uploading of the documentary requirements and application submission

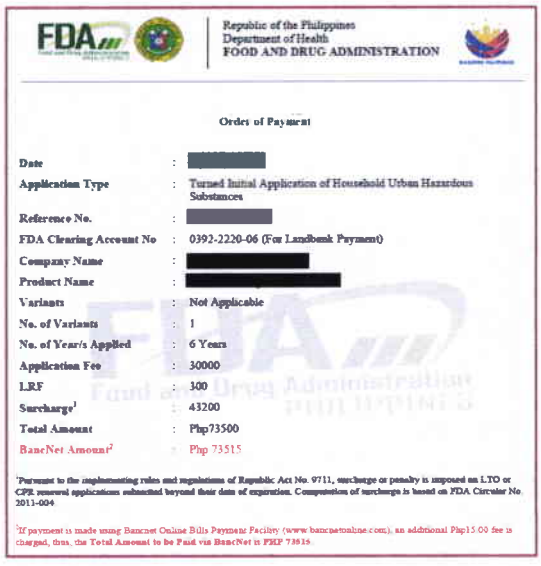
Accomplish the application form, upload the documentary requirements and submit application by following the step-by-step procedure for an initial HUHS product registration application detailed under Annex D of FDA Circular No. 2023-006.

### 3. 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 which may either be approved or disapproved.

1. **Pre-Assessment Disapproval (tagged as INCOMPLETE)**
   a. For HUHS CPR turned initial 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 be accessed in FDA e-Portal V.2 System by proceeding to the "On Process" folder. Click the case number of the CPR turned initial 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 reason/s for the pre-assessment disapproval on 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 CPR turned initial application 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 CPR turned initial applications that have been tagged as complete, the email notification will include the Order of Payment which contains the fees and charges that must be paid to proceed with the application.
   b. The Order of Payment can also be viewed in the FDA e-Portal V.2 System by searching the 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

Order of Payment

| | | |
|---|---|---|
| Date | : | [redacted] |
| Application Type | : | Turned Initial Application of Household Urban Hazardous Substances |
| Reference No. | : | [redacted] |
| FDA Clearing Account No | : | 0392-2220-06 (For Landbank Payment) |
| Company Name | : | [redacted] |
| Product Name | : | [redacted] |
| Variants | : | Not Applicable |
| No. of Variants | : | 1 |
| No. of Year/s Applied | : | 6 Years |
| Application Fee | : | 30000 |
| LRF | : | 300 |
| Surcharge[1] | : | 43200 |
| Total Amount | : | Php73500 |
| BancNet Amount[2] | : | Php 73515 |

[1]Pursuant to the implementing rules and regulations of Republic Act No. 9711, surcharge or penalty is imposed on LTO or CPR renewal applications submitted beyond their date of expiration. Computation of surcharge is based on FDA Circular No. 2013-004

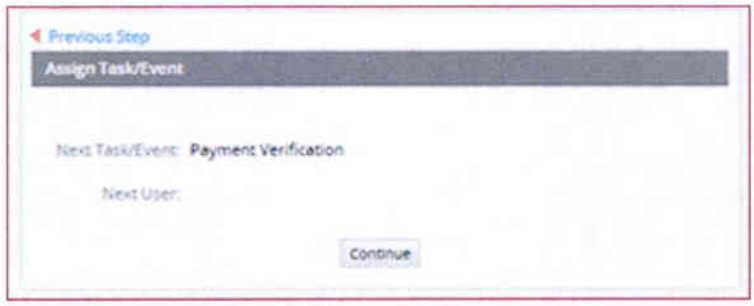
[2]If payment is made using Bancnet Online Bills Payment Facility (www.bancnetonline.com), an additional Php15.00 fee is charged, thus, the Total Amount to be Paid via BancNet is PHP 73515.

c. It can also be reviewed by searching the application case number under the "Processed" folder. Right-click the case number and then choose summary" and go to "Generated Documents"

d. 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, and its amendments for the process.
- Link.BizPortal e-payment facility of the Land Bank of the Philippines- refer to FDA Advisory No. 2021-0246, or its amendments for more information.
- FDA Central Office Over-the-Counter (OTC) Payment System – refer to FDA Advisory No.2024-0320, or its amendments for more information.

e. After downloading the order of payment, click "Next Step" and then "Continue" to submit the application for payment verification. Once the payment has been made and the FDA Cashier has posted the payment in the FDA e-portal V.2 system, the application shall be forwarded to the Center for evaluation and final decision.

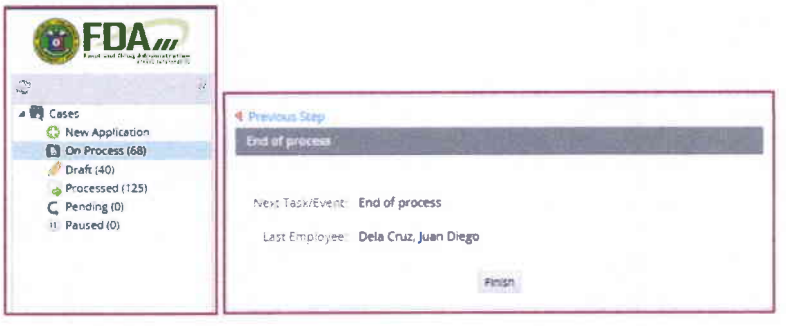


## C. Checking of Application Result

1. Once the application has undergone the HUHS CPR turned initial process, an email notification will be sent to the registered email address of the HUHS establishment client, informing that the application has been processed and providing instructions on how to access the result. The application result may either be approved or disapproved.
2. During the transitory period that is consistent with existing guidelines, 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 registered email address of 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 of whether the applicant has managed to address the noted deficiencies or not, the HUHS product registration application will be automatically reverted to the Center.
    b. To comply with the issued NOD:
        - Access the HUHS product registration application 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.
        - 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.
        - Upload the compliance documents then click "Next" and "Submit" to return the application to the Center for evaluation.
    c. 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 approved applications, the back of the marketing authorization or CPR contains the list of post-approval conditions that must be complied with by the MAH at the end of the transitory period or during the renewal of the CPR.
4. For disapproved applications, a Letter of Disapproval (LOD) with the reason/s for disapproval shall be generated. The disapproval of an application is without

prejudice to re-application. However, disapproval of application shall mean outright forfeiture of payment. In case of re-application, the client is advised to address all noted deficiencies before lodging a new case. Note that a re-application shall mean new initial CPR application, which shall follow the documentary requirements specified in FDA Circular No. 2020-025.

5. The result may be downloaded through the "On Process" folder of the applicant establishment in the FDA e-Portal V. 2 System. Open the application case number, download and print the document (CPR or LOD), 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.

**Annex D**
**Types of Variations and Schedule of Submission**

| Post-Approval Commitment (PAC) Conditions on the Issued HUHS Certificate of Product Registration (CPR) | Type of Variation | Schedule of Submission* |
|---|---|---|
| A. Product Information<br>B. Directions for Use<br>C. Handling, Storage and Disposal<br>D. Particulars of the Company / Marketing Authorization Holder (MAH)<br>E. Contact Information of the National/Regional Poison Center<br>F. Product Category<br>G. Hazard and Safety Information<br>H. Removal of the words "SAFE", "NON-TOXIC", NON-HAZARDOUS" or other equivalent descriptive words, phrases or modifiers from the product label<br>K. Display of the Registration Number (HUHSR-20240208-00009) on the product label | Change of Labeling/Packaging Design | Upon the full implementation of the complete labeling requirement supported by guidelines, and must be within the validity of the renewed authorization |
| I. Use of suitable product packaging | Change in/ Additional Packaging Type or Packaging Material | Must be within the validity of the renewed authorization |
| J. Submission of stability study report (accelerated or real-time) upon renewal of CPR | Change in/ Extension/ Reduction of Shelf-Life | Must be prior to submission of renewal application |
| L. Submission of revised/latest Safety Data Sheet (SDS) in accordance with the adopted version of GHS upon renewal of CPR | Change in/ Additional Safety Data Sheet Information<br>Change in GHS Hazard Categorization in any of the Physical, Chemical or Environmental Hazard Class | In accordance with the timeline prescribed based on the implementing guidelines for Globally Harmonized System of Classification and Labeling of Chemicals (GHS), and must be within the validity of the renewed authorization |

** The schedule does not preclude the MAH from lodging the listed variation application as they deem necessary for their product.*