Annex C
Procedure in the Submission of an HUHS LTO Variation Application

I. Procedure Outline

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B. Preparation and Submission of HUHS LTO Variation Application for Pre-Assessment
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   2. Accomplishing the application form
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D. Checking of Application Result

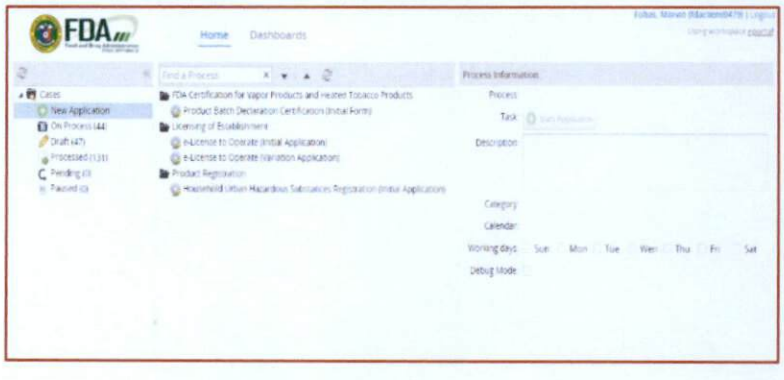
II. Step-by-step Procedure

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

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 System at https://eportal2.fda.gov.ph (refer to screenshot below).

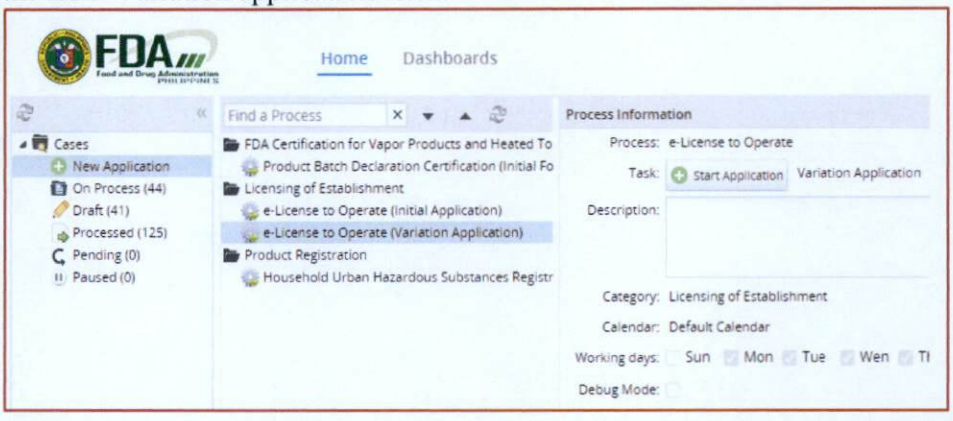
2. Log-in by entering the username and password issued by the FDA. Upon successful log-in, the FDA e-Portal V.2 System Homepage automatically appears in the screen (refer to screenshot below).



B. Preparation and Submission of HUHS LTO Variation Application for Pre-Assessment

1. Creating a new case application

In the HOME tab, select "New Application" in the navigation pane and click "e-License to Operate (Variation Application)" then "Start Application" or double clicking "e-License to Operate (Variation Application)" to proceed to the LTO Variation application form.

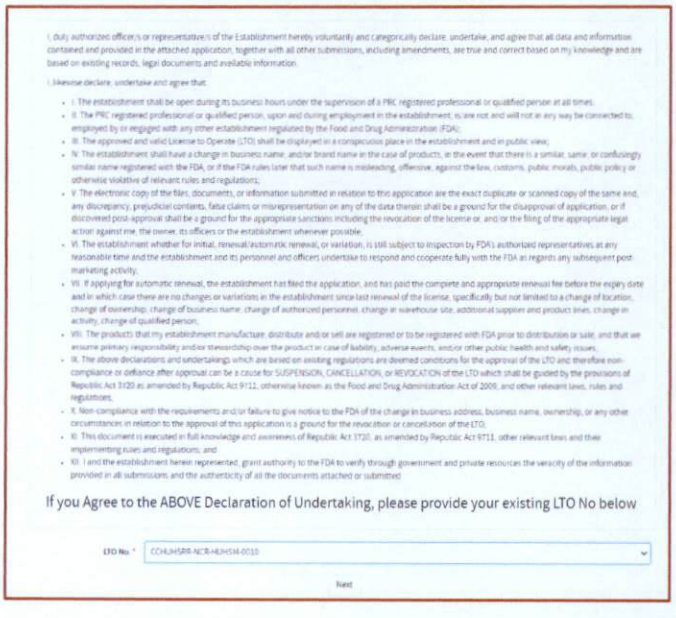


2. Accomplishing the application form

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

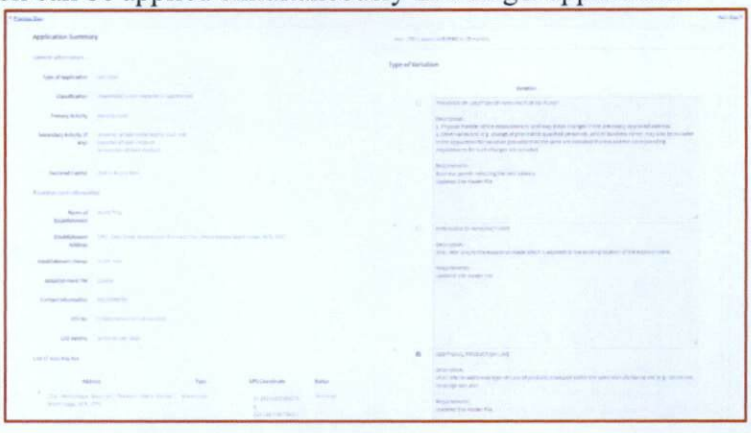
Carefully read the Declaration of Undertaking from start to finish and proceed by selecting the LTO No. for variation and click 'Next'.



It must be noted that HUHS establishments with pending previous application for LTO variation will not be able to submit new LTO variation or renewal application/s. Please wait for the Result before applying for a new application.

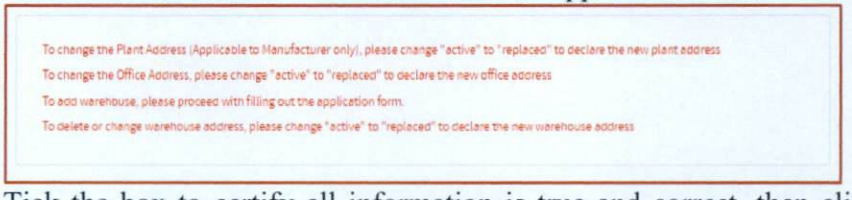
b. Type of Variation

On the next step, choose and tick the box of the type of variation/s applicable for your LTO and click 'Continue'. More than one type of HUHS LTO variation can be applied simultaneously in a single application.



c. Information update

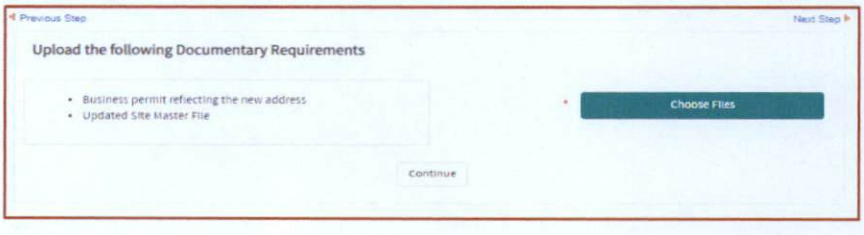
i. Follow the applicable instructions in red text and provide all required information for the chosen variation/s in the application form.



ii. Tick the box to certify all information is true and correct, then click 'Next'.

3. Uploading of Documentary Requirements

Upload the required document/s for the variation/s in accordance to FDA Circular No. 2020-025 and DOH AO 2020-0017, in PDF format by clicking "Choose Files", then click 'Continue'.

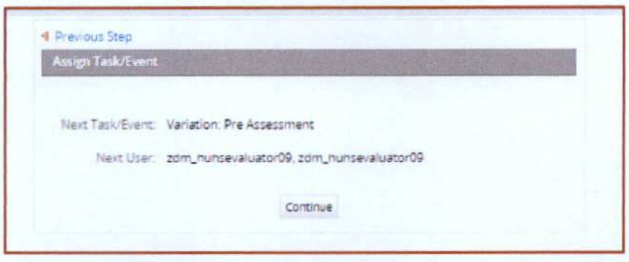


4. Finalizing the application and submission for pre-assessment

a. A Variation Summary will appear that reflects all the declared information and uploaded documents.

b. Review and recheck the information and documents uploaded. 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. 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 LTO 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 LTO 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 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 LTO variation 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 LTO variation 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".

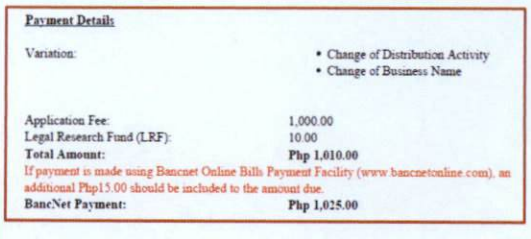

Republic of the Philippines
Department of Health
Food And Drug Administration
FDA

Order of Payment

General Information

Establishment Information

Address	Type
Distributor Trad, Isabela City, Basilan, ARMM, 7300	Office Warehouse
Distributor Trad, Isabela City, Basilan, ARMM, 7300	Warehouse
Distributor Trad 19 January 2022, Caloocan, (Barangay Deguia), Metro Manila-Caloocan, NCR, 1420	Office


Payment Details

Variation:
- Change of Distribution Activity
- Change of Business Name

Application Fee:	1,000.00
Legal Research Fund (LRF):	10.00
Total Amount:	**Php 1,010.00**

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

BancNet Payment: **Php 1,025.00**

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 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. HUHS LTO variation 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 the application 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 no. for the HUHS LTO variation application will then be forwarded to the Center Director of the CCHUHSRR for the final decision.

D. Checking of Application Result

1. Once the application has undergone the evaluation process, 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. 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 (LTO or Letter of Acknowledgement or Letter of Disapproval), and then click "Finish" to end the task.
3. 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.