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ANNEX D Procedure in the Submission of Variation LTO Application

A. Procedure outline

1. Accessing and navigating the FDA eServices Portal System
2. Filing an application
 - a. Page 1: Declaration & Undertaking
 - b. Page 2: License to Operate
 - c. Page 3: Contact Information
 - d. Page 4: Type of Variation
 - e. Page 5: Self-Assessment Review

B. Step-by-step procedure

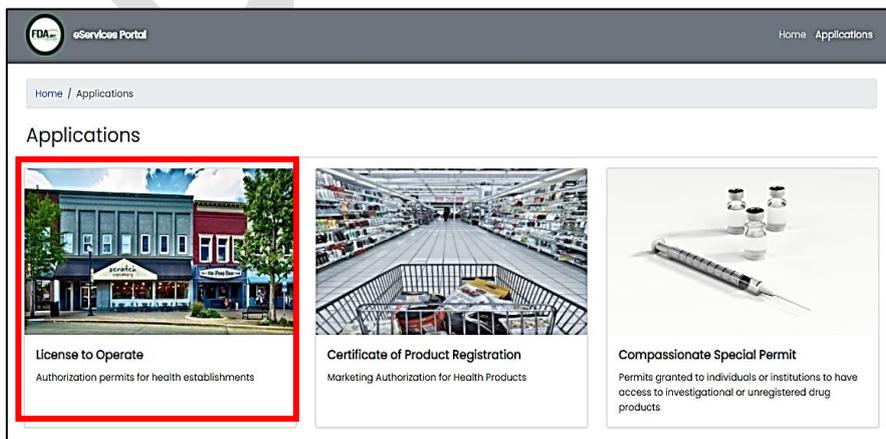
Follow the steps outlined below in order to submit a variation cosmetic LTO application.

1. Accessing and navigating the FDA eServices Portal System

- a. Access the online portal through (<https://eservices.fda.gov.ph/>) and click “Applications” found on the upper right corner of the eServices landing page.



- b. Click the License to Operate for Cosmetic and Type of Establishment (Distributor, Trader, Manufacturer, Packer or Repacker)



License to Operate

 <p>Bottled Water For establishments that handle bottled water products</p>	 <p>Drug For establishments that handle drug products</p>	 <p>Food For establishments that handle food products</p>
 <p>Iodized Salt For establishments that handle salt products</p>	 <p>Device For establishments that handle device products</p>	 <p>Cosmetic For establishments that handle cosmetic products</p>
 <p>Household/Urban Pesticide For establishments that handle Household/Urban pesticide products</p>	 <p>Household/Urban Hazardous Substances For establishments that handle Household/Urban Hazardous Substances products</p>	 <p>Toy and Child Care Article For establishments that handle Toy and Child Care Article products</p>
 <p>Application Status Check the current status of your application</p>	 <p>Distributor License authorization for distributor establishments</p>	 <p>Trader License authorization for trader establishments</p>
 <p>Manufacturer License authorization for manufacturer establishments</p>	 <p>Packer License authorization for packer establishments</p>	 <p>Repacker License authorization for repacker establishments</p>

i. Select the primary activity the applicant intends to engage in which may be one of the following:

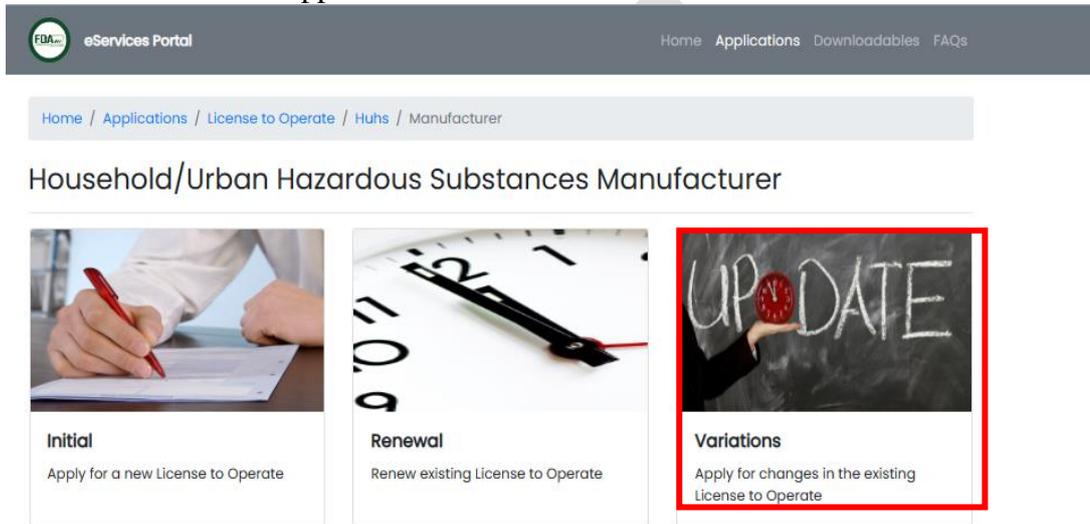
- **Manufacturer-** An establishment that is engaged in any and all operations involved in the production of cosmetic products including preparation, processing, formulating, filling, packaging, repacking, altering, ornamenting, finishing and labeling with the end in view of its storage, sale or distribution.
- **Packer-** An establishment that packages bulk cosmetic product into its immediate container with the end view of storage, distribution, or sale of the product.
- **Repacker-** An establishment that repacks a finished product into smaller quantities in a separate container and/or into secondary packaging, including but

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not limited to relabeling, stickering, and bundling for promo packs with the end view of storage, distribution, or sale of the product.

- **Trader**- An establishment which is a registered owner of a cosmetic product and procures the raw materials and packing components, and provides the production monographs, quality control standards and procedures, but subcontracts the manufacture of such product to a licensed manufacturer.
- **Distributor**- Any establishment that imports/exports raw materials, active ingredients and/or cosmetic products for its own use or for wholesale distribution to other establishments or outlets. If the distributor sell to the general public, it shall be considered a retailer.

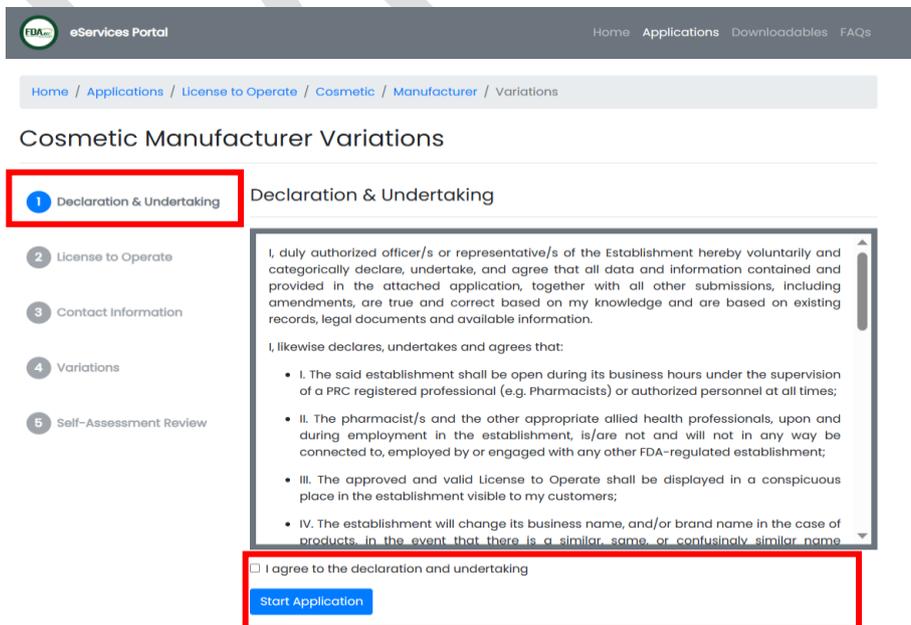
c. Click the Variation Application.



2. Filing an application

a. Page 1: Declaration & Undertaking

To start the application, read carefully and agree to the declaration & undertaking form. Make sure to check the box found below and click on “Start Application”.



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b. Page 2: License to Operate

Provide the existing LTO Number, Validity Date, and Security Code (by scanning the QR Code from the given document). Please ensure the correctness of the data given to proceed with the change in licensing authorization. Tick **“I’m not a robot”** then click **“Next”** to proceed.

eServices Portal Home Applications Downloadables FAQs

Home / Applications / License to Operate / Cosmetic / Manufacturer / Variations

Cosmetic Manufacturer Variations

1 Declaration & Undertaking License to Operate

2 License to Operate

3 Contact Information

4 Variations

5 Self-Assessment Review

* License Number License Number

* Date of Validity Date of Validity

* Security Code Security Code

Please scan the QR Code in the document. For previously issued LTO, enter the sequence number located at the bottom right corner of the document (e.g. FDA-123456).

I'm not a robot reCAPTCHA Privacy - Terms

Back Next

c. Page 3: Contact Information

Provide an updated contact information if applicable. Click **“Next”** to proceed.

eServices Portal Home Applications Downloadables FAQs

Home / Applications / License to Operate / Cosmetic / Trader / Variations

Cosmetic Trader Variations

1 Declaration & Undertaking Contact Information

2 License to Operate

3 Contact Information

4 Minor Variations

5 Self-Assessment Review

* Email Address

The owner/authorized representative shall ensure that they have access to the declared email address. The FDA shall not be held responsible or liable in any way for loss of access to the declared email address.

* Mobile Number Update mobile number if necessary

Landline Number Update landline number if necessary

Back Next

d. Page 4: Variations

- i. Choose and tick the box of the type of variation/s applicable for your LTO. More than one type of cosmetic LTO variation can be applied simultaneously in a single application.
- ii. Upload the required document/s for the variation/s in accordance to FDA Circular No. 2013-002, FDA Circular No. 2013-002-A and DOH AO 2020-0017, in pdf format by clicking **“Upload Files”**, then click **“Next”**

Cosmetic Trader Variations

1 Declaration & Undertaking **Minor Variations**

2 License to Operate

3 Contact Information

4 Minor Variations

5 Self-Assessment Review

! If there is also a change in warehouse address, You should also apply it by ticking the Change of Warehouse Variation.

Transfer of Office Location

Expansion of Office Establishment

Transfer/Addition of Warehouse

Change of Ownership

Change of Business Name

Zonal Change in Office Address

Change of Qualified Personnel

Change of Authorized Person

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e. Page 5: Self-Assessment Review

- i. A Self-Assessment Review summary will appear that reflects all the declared information and uploaded documents.
- ii. Review and recheck the information declared and documents uploaded. If there are corrections to be made, the information and documents can directly be updated on the Self-Assessment Review page.
- iii. After the self-assessment review, the applicant shall confirm the correctness of the data and uploaded documents. Tick **“I’m not a robot”**, **Data Privacy Act declaration** and click the **“Confirm”** submit the application.
- iv. Auto-generated electronic email will be sent containing the Application Summary

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Cosmetic Trader Variations

1 Declaration & Undertaking

2 License to Operate

3 Contact Information

4 Minor Variations

5 Self-Assessment Review

Self-Assessment Review

License to Operate

* License Number: CCHUHSRR-NCR-CT-0635

* Date of Validity: []

* Security Code: []

Please scan the QR Code in the document. For previously issued LTO, enter the sequence number located at the bottom right corner of the document (e.g. FDA-123456).

Contact Information

* Email Address: []

The owner/authorized representative shall ensure that they have access to the declared email address. The FDA shall not be held responsible or liable in any way for loss of access to the declared email address.

* Mobile Number: []

Update mobile number if necessary

Landline Number: []

Update landline number if necessary

General Information

* Type of Application: Variation

* Primary Activity: Trader

* Additional Activities: Exporter of Own Products, Importer of Raw Materials for Own Use, Wh

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I'm not a robot 

I hereby confirm that all information I have provided are true and correct to the best of my knowledge.

I understand that any errors that I have committed in this online form may be considered grounds for refusal or cancellation of my application.

In compliance to the Data Privacy Act 2012, I give consent to use any personal information provided herein for Government to conduct the necessary records check and verification of facts in connection with my application.

Back Confirm