| 799 | | ANNEX C |
|------------|----|--|
| 800 | | Procedure in the Submission of Renewal LTO Application |
| 801 | | |
| 802 | А. | Procedure outline |
| 803 | | |
| 804 | | 1. Accessing and navigating the FDA eServices Portal System |
| 805 | | 2. Filing an application |
| 806 | | a. Page 1: Declaration & Undertaking |
| 807 | | b. Page 2: License to Operate |
| 808 | | c. Page 3: Contact Information |
| 809 | | d. Page 4: Self-Assessment Review |
| 810 | | |
| 811 | B. | Step-by-step procedure |
| 812 | ь. | Follow the steps outlined below in order to submit a renewal cosmetic LTO application |
| 813 | | Tonow the steps outlined below in order to sublint a rene war cosmetic DTO application. |
| 81/ | | 1 Accessing and navigating the FDA eServices Portal System |
| 815 | | a Access the online portal through (https://eservices.fda.gov.ph/) and click |
| 816 | | "Applications" found on the upper right corner of the eServices landing page |
| 817 | | Applications found on the upper right corner of the eservices failding page. |
| 017 Q1Q | | eservices Portal Horn - Applications |
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| 025 | | APPROVED |
| 020 | | |
| 021 | | MISSION To guarantee the safety, quality, purity, efficacy of products in order to |
| 020 920 | | protect and promote the right to health of the general public. |
| 029 920 | | VISION The Food and Drug Administration to be an internationally recognized |
| 030 021 | | center of excellence in health product regulation by 2026. |
| 001 | | b. Click the License to Operate for Cosmetic and Type of Establishment (Distributor |
| 022 | | D. Click the License to Operate for Cosnicile and Type of Establishment (Distributor, |
| 022 | | Trader, Manufacturer, Facker of Repacker) |
| 034 825 | | |
| 022 | | eServices Portal Home Applications |
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| 044 | | License to Operate Certificate of Product Registration Compassionate Special Permit Authorization permits for health establishments Marketing Authorization for Health Products Permits granted to individuals or institutions to have |
| 845 046 | | access to investigational or unregistered drug products |
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 Home / Applications / License to Operate

License to Operate



- 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 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 Renewal Application.

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| eServices Portal | | Home Applications Downloadab |
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| Home / Applications / License | to Operate / Cosmetic | > / Manufacturer / Renewal |
| Cosmetic Manufo | acturer Rene | ewal |
| | | |
| Declaration & Undertaking | License to Op | erate |
| | * License Number | License Number |
| 2 License to Operate | * Date of Validity | Date of Validity |
| 3 Contact Information | * Security Code | Security Code |
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| 4 Self-Assessment Review | | number located at the bottom right corner of the document (e.g. FDA-123456). |
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1003 d. Page 4: Self-Assessment Review

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- i. A Self-Assessment Review summary will appear that reflects all the declared information.
- ii. 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.
- iii. Auto-generated electronic email will be sent containing the Application Summary

| nome / Applications / License | to Operate / Cosmetic / Tro | ader / Renewal | | |
|-------------------------------|--|---|--|--|
| Cosmetic Trader | Renewal | | | |
| Declaration & Undertaking | Self-Assessment | Review | | |
| 2 License to Operate | License to Operate | | | |
| 3 Contact Information | * License Number | | | |
| | * Date of Validity | | | |
| 4 Self-Assessment Review | * 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 | | |
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| | * Mobile Number | 12345678900 | | |
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| EDA | eServices Portal |
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Home / Applications / License to Operate / Cosmetic / Trader / Renewal

Cosmetic Trader Renewal

| Declaration & Undertaking | Self-Assessment | Review | | | |
|---------------------------|-------------------------|---|--|--|--|
| 2 License to Operate | License to Operate | | | | |
| 3 Contact Information | * License Number | | | | |
| Colf Accounted Devices | * Date of Validity | | | | |
| 4 Self-Assessment Review | * 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 Inform | ation | | | |
| | * 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 | 12345678900 | | | |
| | | Update mobile number if necessary | | | |
| | Landline Number | Landline Number | | | |
| | | , | | | |
| | General Inform | ation | | | |
| | * Type of Application | Renewal | | | |
| | * Primary Activity | Trader | | | |
| | * Additional Activities | Exporter of Own Products, Importer of Raw Materials for Own Use, Wh | | | |

Home Applications Downloadables FAQs

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Applications Downloadables FAQs eServices Portal Home / Applications / License to Operate / Cosmetic / Trader / Renewal **Cosmetic Trader Renewal** Self-Assessment Review Declaration & Undertaking 2 License to Operate License to Operate 3 Contact Information * License Number * Date of Validity 4 Self-Assessment Review * 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 12345678900 Update mobile number if necessary Landline Number Landline Number Update landline number if necessary **General Information** * Type of Application Renewal * Primary Activity Trader * Additional Activities Exporter of Own Products, Importer of Raw Materials for Own Use, Wh l'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 commited 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.

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