

449  
450  
451  
452  
453  
454  
455  
456  
457  
458  
459  
460  
461  
462  
463  
464  
465  
466  
467  
468  
469  
470  
471  
472  
473  
474  
475  
476  
477  
478  
479  
480  
481  
482  
483  
484  
485  
486  
487  
488  
489  
490  
491  
492  
493  
494  
495  
496  
497  
498  
499

## ANNEX B Procedure in the Submission of an Initial LTO Application

### A. Procedure outline

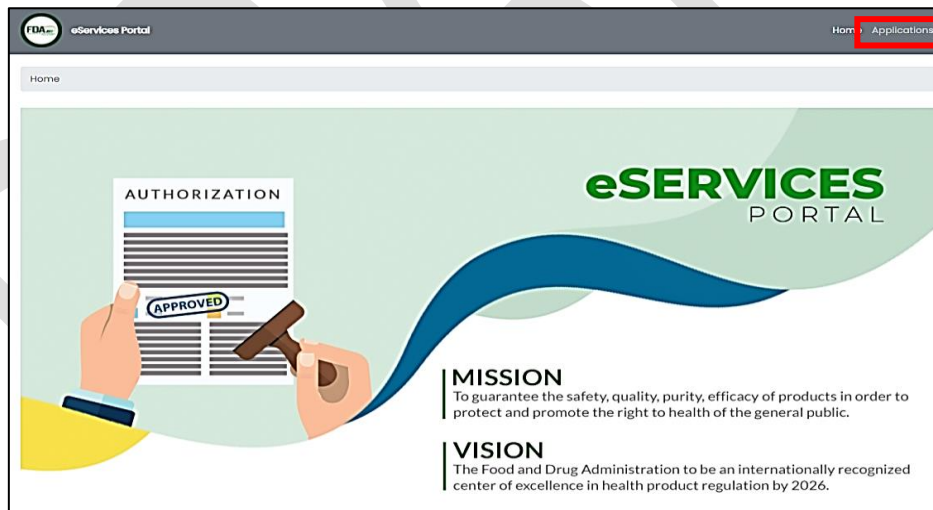
1. Accessing and navigating the FDA eServices Portal System
2. Filing an application
  - a. Page 1: Declaration and Undertaking
  - b. Page 2: General Information
  - c. Page 3: Product Line (*For Manufacturer Only*)
  - d. Page 4: Establishment Information
  - e. Page 5: Office Address
  - f. Page 6: Warehouse Address
  - g. Page 7: Plant Address (*For Manufacturer Only*)
  - h. Page 8: Details of Authorized Person
  - i. Page 9: Details of Qualified Person
  - j. Page 10: Documentary Requirements
  - k. Page 11: Self-assessment Review

### B. Step-by-step procedure

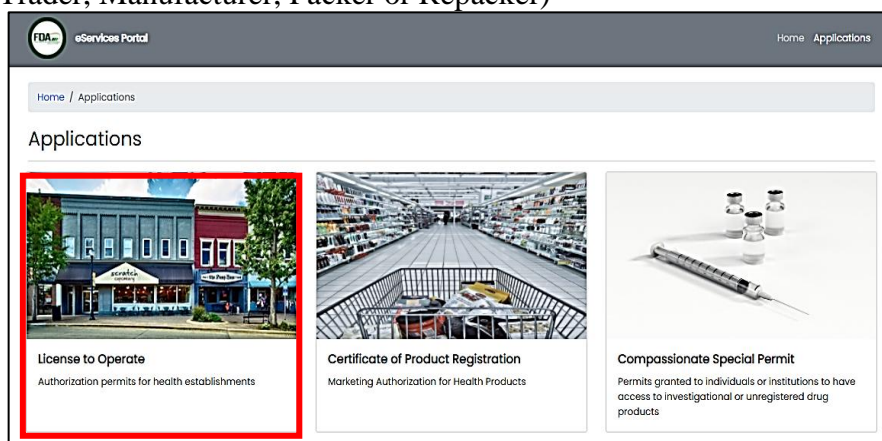
Follow the steps outlined below in order to submit an initial cosmetic LTO application.

#### 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

500  
501  
502  
503  
504  
505  
506  
507  
508  
509  
510  
511  
512  
513  
514  
515  
516  
517  
518

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

519  
520  
521  
522  
523  
524  
525  
526  
527  
528  
529

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.

530  
531  
532  
533  
534  
535  
536  
537  
538  
539  
540  
541  
542  
543  
544  
545  
546  
547  
548  
549  
550  
551  
552  
553  
554  
555  
556  
557  
558  
559  
560  
561  
562  
563  
564  
565  
566  
567  
568  
569  
570  
571  
572  
573  
574  
575  
576  
577  
578  
579  
580

- **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 Initial 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**”.

581  
582  
583  
584  
585  
586  
587  
588  
589  
590  
591  
592  
593  
594  
595  
596  
597  
598  
599  
600  
601  
602  
603  
604  
605  
606  
607  
608  
609  
610  
611  
612  
613  
614  
615  
616  
617  
618  
619  
620  
621  
622  
623  
624  
625  
626  
627  
628  
629  
630  
631

**b. Page 2: General Information**

Fill out the necessary information accurately based on establishment’s activity/ies. Make sure to properly tick the corresponding activity/ies before proceeding onto the next step.

**1.1. Manufacturer and Trader Activities**

- Importer of Raw Materials for Own Use
- Exporter of Own Products
- Wholesaler of Own Products

**1.2. Distributor Activities**

- Importer
- Exporter
- Wholesaler

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

### Cosmetic Manufacturer Initial

1 Declaration & Undertaking

2 **General Information**

3 Product Line

4 Establishment Information

5 Office Address

6 Warehouse Addresses

7 Plant Address

8 Authorized Person

9 Qualified Personnel

10 Documentary Requirements

11 Self-Assessment Review

#### General Information

\* Type of Application: Initial

\* Product Type: Cosmetic

\* Primary Activity: Manufacturer

Additional Activities

Importer of Raw Materials for Own Use

Exporter of Own Products

Wholesaler of Own Products

Back Next

\* Primary Activity: Trader

Additional Activities

Importer of Raw Materials for Own Use

Exporter of Own Products

Wholesaler of Own Products

Primary Activity: Distributor

Distributor Activities

Importer

Exporter

Wholesaler

**c. Page 3: Product Line (For Manufacturer Only)**

Declare all product lines that the applicant intends to manufacture based on their current production capabilities. Select the applicable product line from the dropdown list. If there is more than one (1) Product Line click “Add Product Line”, then click “Next”.

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

### Cosmetic Manufacturer Initial

1 Declaration & Undertaking

2 General Information

3 **Product Line**

4 Establishment Information

5 Office Address

6 Warehouse Addresses

7 Plant Address

8 Authorized Person

9 Qualified Personnel

10 Documentary Requirements

11 Self-Assessment Review

#### Product Line Details

\* Type: Please Select

- Creams, emulsions, lotions, gels and oils for skin (hands, face, feet, etc.)
- Face masks (with the exception of chemical peeling products)
- Tinted bases (liquids, pastes, powders)
- Make-up powders, after-bath powder, hygienic powders, etc.
- Toilet soaps, deodorant soaps, etc
- Perfumes, toilet waters and eau de Cologne
- Bath or shower preparations (salts, foams, oils, gels, etc.)
- Depilatories
- Deodorants and anti-perspirants
- Hair care products
- Shaving product (creams, foams, lotions, etc.)
- Products for making-up and removing make-up from the face and the mouth
- Products intended for application to the lips
- Products for care of the teeth and the mouth
- Products for nail care and make-up
- Products for external intimate hygiene
- Sunbathing products
- Products for tanning without sun.
- Skin whitening products
- Anti-wrinkle products

Choose Others and specify the Cosmetic product type if not applicable to the product type in the list.

+ Add Product Line

Back Next

632  
633  
634  
635  
636  
637  
638  
639  
640  
641  
642  
643  
644  
645  
646  
647  
648  
649  
650  
651  
652  
653  
654  
655  
656  
657  
658  
659  
660  
661  
662  
663  
664  
665  
666  
667  
668  
669  
670  
671  
672  
673  
674  
675  
676  
677  
678  
679  
680  
681  
682

**d. Page 4: Establishment Information**

Fill-in the necessary information. Field marked with a red asterisk (\*) are required to be filled-in.

**e. Page 5: Office Address**

Utilize the dropdown list when selecting the Region, Province and City or Town. Click the “Get GPS Coordinates” to determine the exact location of the Office Address. Pin accurately the location on the map.

**f. Page 6: Warehouse Address**

Utilize the dropdown list when selecting the Region, Province and City or Town. Click the “Get GPS Coordinates” to determine the exact location of the Warehouse Address. Pin accurately the location on the map.

Cosmetic Manufacturer Initial

g. Page 7: Plant Address (For Manufacturer Only)

For manufacturers, one (1) plant address must be declared. Click the “Get GPS Coordinates” to determine the exact location of the Warehouse Address. Pin accurately the location on the map.

h. Page 8: Details of Authorized Person

**Authorized Person** refers to the owner, President, Chief Executive Officers (CEO) or its equivalent, or any organic or full-time employee representing the establishment in an authorized or official capacity.

734 i. **Page 9: Details of Qualified Personnel**

735 **Qualified Person** refers to an organic or full-time employee of the establishment who  
736 possess technical competence related to the establishment's activities and health  
737 products by virtue of his profession, training or experience. A qualified person has the  
738 responsibility to comply with the technical requirements of the FDA or discuss or  
739 clarify matters with the FDA when submitting technical requirements or engage the  
740 FDA officials when conducting inspection or post-market surveillance activities. The  
741 qualified person may also be the duly Authorized Person of the establishment.

742

762 j. **Page 10: Documentary Requirements**

763 Upload necessary documents in portable document file (PDF), maximum of two (2)  
764 megabytes (MB) file size.

765

785  
786  
787  
788  
789  
790  
791  
792  
793  
794  
795  
796  
797  
798

**k. Page 11: 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

**eServices Portal** Home Applications Downloadables FAQs

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

### Cosmetic Manufacturer Initial

**1** Declaration & Undertaking

**2** General Information

**3** Product Line

**4** Establishment Information

**5** Office Address

**6** Warehouse Addresses

**7** Plant Address

**8** Authorized Person

**9** Qualified Personnel

**10** Documentary Requirements

**11** Self-Assessment Review

#### Self-Assessment Review

##### General Information

\* Type of Application: Initial

\* Product Type: Cosmetic

\* Primary Activity: Manufacturer

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

##### Establishment Information

\* Name of Establishment: ABC Company  
Business Name shall be the same name in the SEC/DTI/CDA permit/Original Charter. Please ensure correctness of the declared Business Name as this will be the same name to be reflected in the License to Operate

\* Owner of Establishment: Juan Dela Cruz  
For SEC/CDA registered establishments, the name of the corporation/cooperative must be used as the owner

\* Tax Identification Number: 12345

\* Declared Capital: 20 Million and below

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