

383 ANNEX A  
384 LTO Requirements for Cosmetic Establishments  
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387 The following requirements originally provided under DOH AO No. 2020-0017 and FDA  
388 Circular No. 2013-002 must be submitted:  
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390 **A. Initial Application**  
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- 392 1. Accomplished e-Application form with Declaration and Undertaking  
393 a. Proof of income (Latest Audited Financial Statement with Balance Sheet or  
394 Sworn Statement of Capital)  
395 b. Location Plan;  
396 c. Global Positioning System (GPS) Coordinates; and,  
397 d. Credentials of the Qualified Person  
398 i. PRC ID issued for professions with Board/Licensure Examination, or  
399 Diploma for profession without Board/Licensure Examination  
400 ii. Certificate of Attendance to seminars, training, learning and  
401 development activities on cosmetic safety, quality and use  
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403 2. Proof of Business Name Registration  
404 a. For Single Proprietorship, Certificate of Business Registration issued by the  
405 Department of Trade and Industry (DTI)  
406 b. For Corporation, Partnership and other Juridical Person, the Certificate of  
407 Registration issued by the Security and Exchange Commission (SEC) and  
408 Articles of Incorporation  
409 c. For Government owned and Controlled Corporation, the law creating the  
410 establishment, if with original charter, or its Certificate of Registration issued  
411 by the SEC and articles of Incorporation, if without original charter  
412 d. For Cooperatives, proof of Business Name Registration issued by the  
413 Cooperative Development Authority  
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415 3. Payment of Fees based on the latest FDA issuance  
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417 4. Business Permit (e.g., LGU/Mayor's Permit, Barangay Business Clearance/Permit) - if  
418 the business establishment address is different from the business name registration  
419 address.  
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421 5. Additional documents for cosmetic establishments that maybe further requested shall  
422 be presented to FDA during inspection, including the Risk Management Plan (RMP)  
423 and Site Master File (SMF).  
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426 **B. Renewal Application**  
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- 428 1. Accomplished e-Application Form with Declaration of Undertaking; and,  
429 2. Payment of Fees based on the latest FDA issuance  
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430 **C. Variation Application**  
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- 432 1. Accomplished e-Application Form with Declaration of Undertaking;  
433 2. Payment of fees; and,  
434 3. Documentary requirements depending on the variation of circumstances of the  
435 establishment or the product:

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**a. Major Variation**

Type of Variation	Document Requirement
Transfer of Location of Manufacturing Plant <ul style="list-style-type: none"> <li>• Physical transfer of the establishment and may entail changes in the previously approved address</li> </ul>	<ol style="list-style-type: none"> <li>1. Business Permit reflecting the new address</li> <li>2. Updated Site Master File to be presented upon inspection</li> </ol>
Expansion of Manufacturer and/or Additional Product Line; or Change of Manufacturing Activity <ul style="list-style-type: none"> <li>• Expansion shall refer to expansion made which is adjacent to be existing location of the establishment</li> <li>• Additional product line shall refer to additional type or class of products produced within the same manufacturing site</li> <li>• Change in manufacturing activity shall refer to an additional activity that manufacturer engage in. (e.g. LTO as Repacker to Manufacturer)</li> </ul>	Updated Site Master File to be presented upon inspection

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**b. Minor Variation**

Type of Variation	Document Requirement
Transfer of Location of Offices <ul style="list-style-type: none"> <li>• Physical transfer of the office of the establishment</li> </ul>	Proof of business address reflecting the new office location: <ol style="list-style-type: none"> <li>1. For Single Proprietorship: Business Permit/Mayor's Permit or Barangay Business Permit/Clearance reflecting the new office location;</li> <li>2. For Securities and Exchange Commission (SEC)-registered establishments:               <ol style="list-style-type: none"> <li>a. Amended Articles of Incorporation (if transferred from one city/municipality/province; or,</li> <li>b. Updated General Information Sheet (GIS) from SEC (if transferred within the same city/municipality/province)</li> </ol> </li> <li>3. If the establishment address is different from the address indicated in the SEC registration, provide LGU/Mayor's Permit or Barangay Business Permit/Clearance reflecting new office location</li> </ol>

<p>Change of Distributor Activity</p> <ul style="list-style-type: none"> <li>• Shall refer to an additional/deletion of/change in activity that the distributor engage in</li> </ul>	Contract Agreements showing change in activity
<p>Transfer/addition of Warehouse</p> <ul style="list-style-type: none"> <li>• Physical transfer and addition of warehouse of the establishment</li> </ul>	Mayor's Permit or Barangay Business Permit/Clearance reflecting new warehouse location
<p>Expansion of Office Establishments</p> <ul style="list-style-type: none"> <li>• Shall refer to expansion made which is adjacent to the existing location of the establishment</li> </ul>	Expansion floor plan
<p>Change of Ownership</p> <ul style="list-style-type: none"> <li>• Change in ownership of the licensed establishment</li> </ul>	<ol style="list-style-type: none"> <li>1. Business name registration reflecting new ownership</li> <li>2. Any proof on the transfer of ownership such as any of the following: <ol style="list-style-type: none"> <li>a. Deed of sale or assignment or transfer of rights/ownership;</li> <li>b. Memorandum of Agreement; or</li> <li>c. Notarized Affidavit of the owner, proprietor, Chairman or Chief Executive Officer (CEO) of the establishment validating the transfer</li> </ol> </li> </ol>
<p>Change of Business Name</p> <ul style="list-style-type: none"> <li>• Change only in the business name of the establishment</li> </ul>	Business name registration reflecting new business name
<p>Zonal Change in Address</p> <ul style="list-style-type: none"> <li>• Change of the name/number of the street/building without physical transfer of the establishment</li> </ul>	<ol style="list-style-type: none"> <li>1. Certificate of Zonal Change</li> <li>2. Certification from Local Government Unit (LGU) (City/Municipality) stating no physical transfer of the establishment</li> </ol>
<p>Change of Qualified Person<sup>1</sup></p> <ul style="list-style-type: none"> <li>• Change in the identified qualified person initially registered with the FDA</li> </ul>	<ol style="list-style-type: none"> <li>1. Name of new Qualified Person</li> <li>2. Valid Professional Regulation Commission (PRC) ID</li> <li>3. Signed Letter of Resignation duly noted by the former employer, if previously connected with another pharmacy/establishment</li> </ol>
<p>Change of Authorized Person</p> <ul style="list-style-type: none"> <li>• Change of authorized person initially registered with the FDA</li> </ul>	<ol style="list-style-type: none"> <li>1. Name of new Authorized Person</li> <li>2. Valid Government ID</li> <li>3. Updated contact details</li> </ol>

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<sup>1</sup>The qualification and training requirements of the Qualified Person shall be in accordance with the existing guidelines under DOH AO No. 2020-0017 as follows:

Qualification	Training Requirements
Registered professional or graduates in the field of allied health profession.	1. PRC ID for professions with Board/Licensure Exam or Diploma for profession without Board/Licensure Exam; and,
For Manufacturer only:	

Resigtered Chemist, Chemical Engineer and pharmacist	2. Certificate of Attendance to seminars, trainings, learning and development activities on cosmetic, HUHS/HUP or TCCA safety, quality and use given by the academe, industry, organization, professional organization, National Regulatory Authorities, international organizations (World Health Organization, International Organization for Standardization), FDA Academy
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