ANNEX A
LTO Requirements for HUHS Establishments

The requirements originally provided under DOH AO No. 2020-0017 and FDA Circular No. 2020-025 as follows must be submitted:

A. Initial Application

1. Accomplished e-Application form with Declaration and Undertaking
    a. Proof of income (Latest Audited Financial Statement with Balance Sheet or Sworn Statement of Capital)
    b. Location Plan;
    c. Global Positioning System (GPS) Coordinates; and,
    d. Credentials of the Qualified Person
        i. PRC ID issued for professions with Board/Licensure Examination, or Diploma for profession without Board/Licensure Examination
        ii. Certificate of Attendance to seminars, training, learning and development activities on HUHS safety, quality and use

2. Proof of Business Name Registration
    a. For Single Proprietorship, Certificate of Business Registration issued by the Department of Trade and Industry (DTI)
    b. For Corporation, Partnership and other Juridical Person, the Certificate of Registration issued by the Security and Exchange Commission (SEC) and Articles of Incorporation
    c. For Government owned and Controlled Corporation, the law creating the establishment, if with original charter, or its Certificate of Registration issued by the SEC and articles of Incorporation, if without original charter
    d. For Cooperatives, proof of Business Name Registration issued by the Cooperative Development Authority

3. Payment of Fees based on the latest FDA issuance

4. Business Permit (e.g., LGU/Mayor's Permit, Barangay Business Clearance/Permit) - if the business establishment address is different from the business name registration address.

5. Additional documents for HUHS establishments that maybe further request shall be presented to FDA specifically to all inspectorate during inspection, including the Risk Management Plan (RMP) and Site Master File (SMF).

B. Renewal Application

1. Accomplished e-Application Form with Declaration of Undertaking; and,
2. Payment of Fees based on the latest FDA issuance

C. Variation Application

1. Accomplished e-Application Form with Declaration of Undertaking;

2. Payment of fees; and,
3. Documentary requirements depending on the variation of circumstances of the establishment or the product:

a. Major Variation

Type of Variation	Document Requirement
Transfer of Location of Manufacturing Plant • Physical transfer of the establishment and may entail changes in the previously approved address	1. Business Permit reflecting the new address 2. Updated Site Master File to be presented upon inspection
Expansion of Manufacturer and/or Additional Product Line; or Change of Manufacturing Activity • Expansion shall refer to expansion made which is adjacent to be existing location of the establishment • Additional product line shall refer to additional type or class of products produced within the same manufacturing site • Change in manufacturing activity shall refer to an additional activity that manufacturer engages in. (e.g. LTO as Repacker to Manufacturer)	Updated Site Master File to be presented upon inspection

b. Minor Variation

Type of Variation	Document Requirement
Transfer of Location of Offices • Physical transfer of the office of the establishment	Proof of business address reflecting the new office location: 1. For Single Proprietorship: Business Permit/Mayor's Permit or Barangay Business Permit/Clearance reflecting the new office location; 2. For Securities and Exchange Commission (SEC)-registered establishments: a. Amended Articles of Incorporation (if transferred from one city/municipality/province; or, b. Updated General Information Sheet (GIS) from SEC (if transferred within the same city/municipality/province) 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
Change of Distributor Activity • Shall refer to an additional/deletion of/change in activity that the distributor engage in	Contract Agreements showing change in activity
Transfer/addition of Warehouse • Physical transfer and addition of warehouse of the establishment	Mayor's Permit or Barangay Business Permit/Clearance reflecting new warehouse location
Expansion of Office Establishments • Shall refer to expansion made which is adjacent to the existing location of the establishment	Expansion floor plan
Change of Ownership • Change in ownership of the licensed establishment	1. Business name registration reflecting new ownership 2. Any proof on the transfer of ownership such as any of the following: a. Deed of sale or assignment or transfer of rights/ownership; b. Memorandum of Agreement; or c. Notarized Affidavit of the owner, proprietor, Chairman or Chief Executive Officer (CEO) of the establishment validating the transfer
Change of Business Name • Change only in the business name of the establishment	Business name registration reflecting new business name
Zonal Change in Address • Change of the name/number of the street/building without physical transfer of the establishment	1. Certificate of Zonal Change 2. Certification from Local Government Unit (LGU) (City/Municipality) stating no physical transfer of the establishment
Change of Qualified Person[1] • Change in the identified qualified person initially registered with the FDA	1. Name of new Qualified Person 2. Valid Professional Regulation Commission (PRC) ID 3. Signed Letter of Resignation duly noted by the former employer, if previously connected with another pharmacy/establishment
Change of Authorized Person • Change of authorized person initially registered with the FDA	1. Name of new Authorized Person 2. Valid Government ID 3. Updated contact details

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[1]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
Any licensed allied health professional	1. PRC ID for professions with Board/Licensure Exam or Diploma for profession without Board/Licensure Exam; and, 2. Certificate of Attendance to seminars, trainings, learning and development activities on HUHS 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