



**CENTER FOR FOOD REGULATION AND RESEARCH**  
**Requirements for Variation Application**  
**(License to Operate for Food Establishments)**

**Reference:** *Administrative Order 2020-017 “Revised Guidelines on the Unified Licensing Requirements and Procedures of the FDA Repealing AO no. 2016-003”*

**Requirements for Specific Variation in the LTO**

**1. Major Variation for Local Manufacturers**

<b>Type of Variation</b>	<b>Requirement</b>
Transfer of Location of Manufacturing Plant - Physical transfer of the establishment (and may entail changes in the previously approved address)	a. Business permit reflecting the new address b. 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 the existing location of the establishment - Additional product line 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 a manufacturer engage in (e.g. LTO as Manufacturer with additional activity as Repacker)	Updated Site Master File to be presented upon inspection

**2. Minor Variation**

<b>Type of Variation</b>	<b>Requirement</b>
Transfer of Location of Offices - Physical transfer of the office of the establishment (which may also entail changes in the previously approved address)	Business permit reflecting new location office
Transfer of Location of Drug Retailers - Physical transfer of the drug retailer (which may also entail changes in the previously approved address)	Business permit reflecting new address



Change of Distributor Activity - Shall refer to an additional/deletion of/change inactivity that the distributor engage in	Contract Agreements showing change in activity
Transfer/Addition of Warehouse - Physical transfer and addition of the warehouse of the establishment (which may also entail changes in the previously approved address)	Business permit reflecting new warehouse
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	a. Business name registration reflecting new ownership b. Any proof on the transfer of ownership such as any of the following: i. Deed of sale or assignment or transfer of rights/ownership; ii. Memorandum of Agreement; or iii. Notarized Affidavit of the owner, proprietor, Chairman or CEO of the establishment validating the transfer
Change of Business Name - Change only in the business name of the establishment	Business permit reflecting the new name
Zonal Change in Address - Change of the name/number of the street/building without physical transfer of the establishment	Certificate of Zonal Change
Change of Qualified Person - Change in the identified qualified person initially registered with the FDA	a. Name of new qualified person b. Applicable requirements as specified in Annex B of AO 2020-017
Change of Authorized Person - Change in the authorized person initially registered with the FDA	a. Name of new qualified person b. Updated contact details

- Food Business Operators shall ensure that food satisfies the requirements of food law and that control systems are in place to prevent, eliminate or reduce risks to consumers (**IRR of RA 10611 “The Food Safety Act of 2013”**)