

[FDA CIRCULAR NO. 2014-006, February 24, 2014]

APPLICATION FOR LTO VARIATION

In the interest of delivering a fast and quality service, this Office shall be issuing a Certification for those FDA licensed establishments applying for minor variation during the validity of their Licenses to Operate. This certification shall form an integral part of the LTO attachment issued at the time its LTO is renewed. Consequently, all minor variations shall be incorporated once LTO is re-issued for renewal. Thus, previous LTO and certification related thereto shall be surrendered to this Office.

Minor variations referred hereto shall include the following:

1. Inclusion of product (finished or raw material) and/or product line
2. Inclusion of sources (including toll manufacturer/repacker, trader)
3. Inclusion of activity e.g. from Manufacturer to Toll Manufacturer/ Repacker/ Importer/Exporter or Trader to Trader/Importer/ Exporter (raw materials and bulk products)
4. Change in business name/address of the source
5. Change of key personnel for Quality Assurance, Quality Control, Production Manager, Authorized Person and Pharmacist
6. Deletion of product, source and/or activity

Major variations, as enumerated below, shall require re-issuance of License to Operate as these are reflected in the LTO form itself:

1. Change of business name
2. Change of ownership
3. Transfer of location of the establishment
4. Re-classification of the establishment (e.g. from Distributor/Importer to Distributor/Wholesaler), except for those which were reclassified into another class of establishment (e.g. from Distributor/Importer/ Wholesaler to Trader).

Appropriate fee shall be collected for each variation as provided under A.O. 50 s. 2001 or the Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs, except transfer of location which shall be considered as initial application. Multiple applications for minor variations may be issued under one certification only. However payment shall be made for each minor variation (e.g. Inclusion of source and deletion of source).

For partnership/corporation, change of business name and corporate ownership may be applied under one major variation provided that its incorporators/ shareholders as indicated in previous SEC registration remain the same. A single payment shall be collected for such variations.