

## [ FDA CIRCULAR NO. 2010-007, March 15, 2010 ]

### **AUTOMATIC RENEWAL OF LICENSE TO OPERATE (LTO)**

In the exigency of service and to expedite the renewal of License to Operate of all compliant registered drug, cosmetic and medical device traders and registered drug, cosmetic, medical device and household hazardous substance manufacturers under Regulation Division II, please be informed that we shall be issuing an Automatic Renewal to those licenses expiring only within the year 2010 without need of prior inspection.

Application for Automatic Renewal shall be accepted not earlier than three (3) months before the date of validity as reflected on the License to Operate (LTO). A renewed LTO shall be issued only after assessment of complete documentary requirements and should have met the following criteria where the establishment must:

1. **Be operational** for a minimum of 1 year
2. Have **no violative products** reported for the past year
3. Have **latest issuance** of License to Operate not earlier than 2008
4. Have **valid contracts** of the following as required:
  - 4.1 Manufacturing Agreements with toll manufacturer/s (*for traders only*)
  - 4.2 Contract of Lease for plant site/office site
  - 4.3 Warehouse (*if located separately*)
5. Have a pharmacist of good standing (**rendering full time service**) for the past year, if applicable
6. No previous noted deficiencies
7. Have **systematized distribution records** (whether manual or computerized recording)
8. Have compilation of relevant **SOPs**

Additional criteria for manufacturers:

1. Must have been inspected last year – 2009 – with no deficiencies or CAPA has been verified satisfactorily.
2. Must have no changes in its updated Site Information File (SIF).

All concerned establishments are hereby advised to submit the following supporting documents to Regulation Division II and pay the corresponding renewal fees for proper evaluation:

1. An **application** letter for renewal of LTO and photocopy of Official Receipt for renewal payment.