15 March 2010

FDA CIRCULAR
No. 2010-007

TO : ALL MANUFACTURERS OF DRUG, COSMETIC, MEDICAL DEVICE AND HOUSEHOLD HAZARDOUS SUBSTANCES AND TRADERS OF DRUG, COSMETIC AND MEDICAL DEVICE

SUBJECT : 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 systemized 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:

2. An affidavit attesting that the company has no changes in its operation and set-up, in order to avail of the said automatic renewal.

All other establishments not qualified under this memorandum shall be subject to prior inspection before their LTO shall be renewed, subject to Anti-Red Tape Act.

For your information and guidance.

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Acting Director IV