Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

CENTER FOR DRUG REGULATION AND RESEARCH

CHECKLIST OF REQUIREMENTS FOR AUTOMATIC RENEWAL REGISTRATION

Who May Avail : All Manufacturers, Distributors, Importers, Exporters, Wholesalers, and Traders of Pharmaceutical Products

Fees to be Paid : **AO No. 50 s. 2001**
Branded: PHP 10,000.00 + 1% LRF
Unbranded: PHP 7,500.00 + 1% LRF

CHECKLIST OF REQUIREMENTS

- **RA No. 9711: Food and Drug Administration Act of 2009**
  There shall be automatic renewal of the CPR when the following conditions are satisfied:
  a. The application is filed before the expiration date of the registration;
  b. The prescribed renewal fee is paid upon filing of the application; and
  c. A sworn statement indicating no change or variation whatsoever in the product is attached to the application.

1. Duly signed and notarized Integrated Application Form
2. Proof of Payment
3. Labeling Materials (actual/commercial label) (based on RA No. 6675 and AO No. 2016-0008)
4. Actual commercial samples (with Certificate of Analysis) upon request of FDA
5. Copy of previously-issued CPR and copies of previously approved certificates and/or notifications during the validity of the CPR
6. Valid Certificate of GMP Clearance (and/or initial or renewal application, whichever is applicable)
7. For CLIDP, copy of PCPR or proof of renewal
8. Valid License to Operate (LTO) (importer/manufacturer/distributor/trader) (or proof of renewal)

Note:
Compliance to any post-approval commitments and/or Special Conditions reflected on the back page of the previously-issued CPR shall be checked in addition to the above-listed requirements for AR Registration.

END