CENTER FOR DRUG REGULATION AND RESEARCH
LIST OF REQUIREMENTS FOR REGISTRATION OF OVER-THE-COUNTER PREPARTIONS AND HOUSEHOLD REMEDIES

A. Initial Application

1) Integrated Application Form
2) Valid agreements between the manufacturer, trader, importer, distributor, where applicable
3) Unit Dose and Batch Formulation
4) Technical Specifications of all Raw Materials
5) Certificate of Analysis of Active Raw Material(s)
   (a) From supplier of API
   (b) From manufacturer of finished product
6) Technical Specifications of Finished Product
7) Certificate of Analysis (CA) of Finished Product (from the same batch of representative sample)
8) Manufacturing Procedure, Production Equipment, Sampling, In-process controls, and Master Packaging Procedure (including specification for container closure system)
9) Assay and Other Test Procedures including Identity, Purity Tests, with Data Analysis, where applicable
10) Stability Studies
11) Labeling Materials (facsimile labels)
12) Representative Sample

Additional Requirements:

1) For products in plastic container:
   (a) Certificate of Analysis for Test of Migratable Substances/ Leachability
2) For imported products:
   (a) Certificate of Pharmaceutical Product
   (b) Foreign GMP Clearance
3) For single component Vitamin A products and drug products containing non-vitamin/non-mineral APIs combined with vitamins nad/or minerals (e.g. Isoniazid + Vitamin B6):
   (a) Proof of interchangeability

B. Regular Renewal Application

1) Integrated Application Form
2) Unit Dose and Batch Formulation
3) Technical Specifications of Finished Product
4) Certificate of Analysis (CA) of Finished Product (from the same batch of representative sample)
5) Assay and Other Test Procedures including Assay with Data Analysis

6) Stability Studies
7) Labeling Materials (actual/commercial labels)
8) Actual commercial sample

Additional Requirements:
1) Post-marketing commitments (if any)

C. Automatic Renewal Application
1) Integrated Application Form
2) Copy of Certifications issued as a result of post-approval change(s)
3) Labeling materials (actual/commercial labels)
4) Actual commercial sample

Additional Requirements:
1) Post-marketing commitments (if any)

Notes:
- All documentary requirements must be in PDF format to be submitted to PAIR
- Image files should be at least 150 dots per inch (dpi)
- A hard copy of the integrated application form is required
- Samples may be submitted at a later date, e.g. when the application has already been decked as indicated in the Document Tracking System