**Form No 3**

# Checklist of Requirements for the Re-Registration of Import Traditional Medicine Product

| Item | REQUIREMENTS | Yes | No |
|------|--------------|-----|-----|
| Part I | **ADMINISTATIVE DATA** | | |
| 1 | Letter of Application | | |
| 2 | FDD Application Form No. 3 | | |
| 3 | Letter of Authorization or Application Nomination Agreement between the manufacturer & trader/distributor/exporter <br> - Letter of authorization of product owner <br> - Letter of appointment of contract manufacturer and/ or repacked <br> - Letter of acceptance as contract manufacturer and/ or repacked <br> - Certificate of Pharmaceutical Product (CPP) <br>      Original Certificate of Pharmaceutical Product from the country of manufacture <br>      (Issued at least 1 years from the date the application for registration was filed) <br> - Certificate of Product Registration (Valid original Certificate of Product Registration) | | |
| 4 | Unit Dose and Batch Formulation | | |
| Part II | **TECHNICAL DATA** | | |
| | **QUALITY** | | |
| 5 | Technical Specification of <u>ALL</u> Raw Materials <br> a/ From the supplier of the Active Raw Material (if applicable) <br> b/ From the Manufacturer of the finished product <br> c/Certification of Authenticity of Plant Specimen from the authorized government agency in the country of origin | | |
| 6 | Technical Specifications of Finished Product | | |
| 7 | Certificate of Analaysis of Finish Product(From the same batch or lot of the representative sample submitted) | | |
| 8 | Stability Studies <br> b/ Real time-at least 12 month data, minium of 2 batches at $30°C \pm 2°C/75\%$ RH $\pm 5\%$ RH <br> c/ For products intended to be stored in a refrigerator <br> - Real time-at leaset 12 month data, minium of 2 batches $5°C \pm 3°C$ | | |
| 9 | Labeling Materials <br> a/ Facsimile labels with actual color text(3 copies) <br> b/ Package Insert Lao language/English (3 copies) | | |
| 10 | Representative Sample in market or commercial presentation(at least 1 year before expiry) | | |

**Hear of TMHS Division**                                                     **Evaluators**