ANNEX E

Requirements for the Renewal of Notification/Registration of IVD for All Classificatio 3

1. For Automatic Renewal
   1.1 Notarized Application Form
   1.2 Payment
   1.3 A sworn statement indicating no change or variation whatsoever in the product is attached to the application

2. For Regular Renewal
   2.1 Notarized Application Form
   2.2 Payment
   2.3 Copy of Letter of Authorization. For imported IVD, the copy of the Letter of Authorization shall be accompanied by an original copy of a notarized declaration from the legal manufacturer or product owner attesting that the authorization is true and correct.
   2.4 A government - issued certificate attesting to the status of the Manufacturer with regard to the competence and reliability of the personnel and facilities, a Quality Systems Certificate of approval, or a compliance certificate for ISO 13485. For imported IVD, the copy of the certificate shall be accompanied by an original copy of a notarized declaration from the legal manufacturer or product owner attesting that the certificate is true and correct.
   2.5 Colored picture of the IVD from all sides. However, the CDRRHR can require a representative sample or commercial presentation for verification purposes.
   2.6 Clear and complete colored pictures of commercial label from all sides of the packaging.
   2.7 Real-time aging stability test data and results which shall include:
      - shelf life
      - in-use stability
      - shipping stability studies to justify claimed shelf life
      - shall be performed on at least three (3) different product lots manufactured under conditions that are essentially equivalent to routine production conditions.
   2.8 Documents to comply the Post Approval Commitments