CHECKLIST OF REQUIREMENTS FOR VARIATION AND REVALIDATION OF CERTIFICATE OF PRODUCT REGISTRATION OF A MEDICAL DEVICE

1. **CHANGE OF BUSINESS NAME AND ADDRESS OF MANUFACTURER/TRADER/IMPORTER/DISTRIBUTOR**
   a. Letter of request
   b. Valid License to Operate (LTO) reflecting the new business name and address of manufacturer/trader/importer/distributor with the source reflected in the LTO
   c. Original Certificate of Product Registration (CPR)
   d. Complete labeling requirements reflecting the change (Primary, Secondary, and Inserts)

2. **CHANGE IN OWNERSHIP (Inclusion/Deletion or Change in Trader/Importer/Distributor)**
   a. Letter of request
   b. Valid LTO reflecting the source
   c. Termination of Contract/Deed of Assignment
   d. Agreement of Manufacturer and the new Trader/Importer/Distributor
   e. Original CPR
   f. Complete labeling requirements reflecting the change (Primary, Secondary, and Inserts)

3. **REQUEST FOR EXTENSION OF SHELF LIFE**
   a. Letter of request
   b. Stability data supporting the extension
   c. Original CPR
   d. Complete labeling requirements reflecting the change (Primary, Secondary, and Inserts)

4. **CHANGE OF MANUFACTURING SITE (SAME SUBSIDIARY) WITH NO CHANGE IN THE FORMULATION, EQUIPMENT, AND MANUFACTURING PROCEDURE**
   a. Letter of request
   b. Letter from the manufacturer stating that there is no change in the formulation, equipment and manufacturing procedure
   c. Valid LTO reflecting the new site address
   d. Formulation (for solutions) or List of Raw Materials (with the corresponding amount of raw materials used, if applicable)
   e. Finished product specification
   f. For Imported Products – authenticated and valid Certificate of Free Sale and GMP/ISO Certificate
   g. Process Validation Protocol and Data (to be submitted within 1 year)
   h. Original CPR
   i. Complete labeling requirements reflecting the change (Primary, Secondary, and Inserts)

5. **CHANGE OF BRAND NAME (FROM GENERIC TO BRAND, CHANGE OF BRAND TO ANOTHER, DELETION OF BRAND)**
   a. Letter of request
   b. Original CPR
   c. Complete labeling requirements reflecting the change (Primary, Secondary, and Inserts)

6. CHANGE OF STORAGE CONDITION

a. Letter of request
b. Original CPR
c. Stability data to support the change
d. Labeling materials reflecting the change

7. CHANGE/ADDITIONAL INDICATIONS

a. Letter of request
b. Original CPR
c. Studies to support the additional indication
d. Complete labeling requirements reflecting the change (Primary, Secondary, and Inserts)

8. CHANGE OF RE-PACKER/PACKER

a. Letter of request
b. Termination of contract with the previous re-packer/packer
c. Agreement of with the new re-packer/packer
d. Original CPR
e. Complete labeling requirements reflecting the change (Primary, Secondary, and Inserts)

9. CHANGE OF PACKAGING/LABEL DESIGN

a. Letter of request stating the reason for change
b. Original CPR
c. Old label design
d. Proposed label with the new design

10. ADDITIONAL PRESENTATION [e.g. (1) Registered box x 100's, additional presentation of 1 box x 500's; (2) registered 60mL, additional of 120mL]

a. Letter of request
b. Original CPR
c. Complete labeling requirements reflecting the change (Primary, Secondary, and Inserts)

11. RE-CLASSIFICATION

a. Letter of request
b. Original CPR
c. Studies/documents to support the re-classification
d. Complete labeling requirements reflecting the change (Primary, Secondary, and Inserts)

12. RE-VALIDATION

a. Letter of request
b. Original CPR

13. FOR CORRECTION

a. Letter of request
b. Original CPR
c. Complete labeling requirements (where applicable).