

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).