

APPLICATION FOR REVISIONS/UPDATES IN THE PACKAGE INSERT, PATIENT LEAFLET INFORMATION, PRESCRIBING INFORMATION, CORE DATA SHEET AND BASIC SUCCINCT STATEMENT

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Pharmaceutical companies that apply for revisions/updates in the: a) Package insert or labels; b) Patient/leaflet information; c) Prescribing information, d) Core Data Sheet (CCDS)' and e) Basic succinct statement are directed to submit the following requirements:

- Certified True Copy of valid Certificate of Product Registration (CPR)
- Previously approved insert
- Clinical data to justify changes/revisions
- Tabulated list of proposed changes. Sections of the application must be tagged and labeled.

Further, application/s for insert revisions that will include advertently or inadvertently, any indication not previously approved, shall be subject to appropriate FDA sanctions as deemed applicable. This is due to the fact, that in some instances, applications for insert revisions have included indication/s which has not yet been approved by the FDA and not indicated in the CPR.

Further still, indications that were approved shall be stated in the insert/labels, as worded exactly in the application submitted for the indication.

Any application for product insert revision or indication (new, additional or extended indications) shall submit (3) clinical studies that justify the changes made, particularly, those pertaining to new dosages and new routes of administration.

Any changes in the Core Data Sheet or Basic Succinct Statements must be previously approved by the FDA before any product insert revision.

Moreover, it is strictly required that (3) copies of the approved product insert be submitted within 30 days of receipt of approval letter.

All companies are obliged to make sure that their submission and supporting documents are in order.

For strict compliance.

Adopted: 02 June 2011

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