NDA 018303/S-040

SUPPLEMENT APPROVAL

Validus Pharmaceuticals LLC
Attention: James Harn
Senior Director of Regulatory Affairs
90 East Halsey Road, Suite 210
Parsippany, NJ 07054

Dear Mr. Harn:

Please refer to your supplemental new drug application (sNDA) dated and received May 7, 2018, and your amendments, submitted of the Federal Food, Drug, and Cosmetic Act (FDCA) for Lopressor HCT (metoprolol tartrate USP and hydrochlorothiazide USP) Tablets.

This Prior Approval sNDA provides for updates to labeling consistent with the Pregnancy and Lactaion Labeling Rule (PLLR) as well as revision to the Physician Labeling Rule (PLR) format of labeling. Revisions have been made throughout labeling, including in Indications and Usage, Dosage and Administration, Contraindications, Warnings and Precautions, Adverse Reactions, Drug Interactions, Use in Specific Populations, Overdosage, Clinical Pharmacology, Nonclinical Toxicology and Patient Counseling Information.

APPROVAL & LABELING

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at FDA.gov.[1] Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*.[2]

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm
[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

If you have any questions, please call Maryam Changi, Regulatory Project Manager, at (240) 402-2725.

Sincerely,

{See appended electronic signature page}

Mary Ross Southworth, PharmD
Deputy Director for Safety
Division of Cardiology and Nephrology
Office of Cardiology, Hemalogy, Endocrinology, and Nephrology
Center for Drug Evaluation and Research

ENCLOSURE(S):
- Content of Labeling
  - Prescribing Information

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

MARY R SOUTHWORTH
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