DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 204308/S-006

SUPPLEMENT APPROVAL

Silvergate Pharmaceuticals, Inc
c/o Cardinal Health Regulatory Sciences
Attention: Wayne Vallee, RPh, RAC
Director, Regulatory Affairs and Product Development
7400 W 110th St
Ste 300
Overland Park, KS 66210

Dear Mr. Vallee:

Please refer to your Supplemental New Drug Application (sNDA) dated October 7, 2016, received October 7, 2016, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Epaned (enalapril maleate, USP) Powder for Oral Solution 1 mg/ml.

This Prior Approval supplemental new drug application provides for revisions to labeling to harmonize with the Epaned labeling approved on September 20, 2016 for NDA 208686.

APPROVAL & LABELING

We have completed our review of this supplemental application. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text and with the minor editorial revisions.

1) Removal of the Warnings and Precautions reference in recent major changes in Highlights (as one year has passed) [§ 201.57(a)(5)]
2) Add a vertical line next to the revised text in Section 2.1 [§ 201.57(d)(9)]
3) Update the revision dates in highlights to '3/2017' as this supplement was submitted as a Prior Approval Supplement

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 http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert), 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 titled "SPL Standard for Content of Labeling Technical Qs and As at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf

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 MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, 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).

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, please call Michael Monteleone, Associate Director for Labeling, at (301) 796-1952.

Sincerely,

{See appended electronic signature page}

Mary Ross Southworth, PharmD
Deputy Director for Safety
Division of Cardiovascular and Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE(S):
Content of Labeling

Cc:
Silvergate Pharmaceuticals, Inc.
6251 Greenwood Plaza Blvd
Ste 101

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

MARY R SOUTHWORTH
03/22/2017