DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 019734/S-023

SUPPLEMENT APPROVAL

EKR Therapeutics, Inc.
Attention: Ashlie Adams, M.S., RAC
Sr. Manager, Regulatory Affairs
1255 Crescent Green Drive
Suite 250
Cary, NC 27518

Dear Ms. Adams:

Please refer to your Supplemental New Drug Application (sNDA) dated April 30, 2014, received May 1, 2014, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Cardene (nicardipine hydrochloride) 0.1 mg Injection.

This supplemental new drug application provides for revisions to the **ADVERSE REACTIONS** section of the package insert.

1. Under **ADVERSE REACTIONS**, the following section was added:

   6.2 Post-Marketing and Other Clinical Experience

   Because adverse reactions are reported voluntarily from a population of uncertain size, it is not always possible to estimate reliably their frequency or to establish a causal relationship to drug exposure. The following adverse reaction has been identified during post-approval use of Cardene I.V.: decreased oxygen saturation (possible pulmonary shunting).

2. The revision date was updated.

APPROVAL & LABELING

We have completed our review of this supplemental application, as amended, and 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 listed below and indicated in the enclosed labeling. Please see 21 CFR 201.56(d)(1); 201.57(a)(1); and 201.57(a)(2)].

1. Deletion of the oversized product name from Highlights
2. Properly worded Highlights Limitations statement and Product Title Line
3. Changing Full Prescribing Information to one column (from two columns)
4. Removal of trailing zeroes throughout the label

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 via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications 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 with the revisions listed 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:

Lori Anne Wachter, RN, BSN, RAC
Regulatory Project Manager for Safety
(301) 796-3975

Sincerely,

{See appended electronic signature page}

Mary Ross Southworth, PharmD.
Deputy Director for Safety
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE(S):
Content of Labeling

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
07/23/2014