DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-734/S-013

EKR Therapeutics, Inc.
Attention: Mr. Alexander Mironov
1545 Route 206
Bedminster, NJ 07921

Dear Mr. Mironov:

Please refer to your supplemental new drug application dated March 31, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cardene (nicardipine hydrochloride) 2.5 mg/mL Intravenous Solution.

We acknowledge receipt of your submissions dated April 25, May 7, and June 12, 2008.

This supplemental new drug application provides for revisions to support the addition of a new container closure system for Cardene I.V. drug product. The proposed new container closure system is a [redacted]® intravenous (IV) bag which contains a concentration of 0.1 mg/mL nicardipine hydrochloride. This application supports two 0.1 mg/mL nicardipine hydrochloride premixed ready-to-use presentations of the currently marketed Cardene IV ampul after dilution.

We have completed our review of this application, as amended, and it is approved, effective on the date of this letter, for use as recommended in the submissions dated March 25 and May 7, 2008.

The final printed labeling (FPL) must be identical to the package insert submitted on March 25, 2008 and the immediate container and carton labels submitted on May 7, 2008. We highly encourage you to submit revised labeling in Physician Labeling Rule (PLR) format. Please refer to the PLR Resource Page at http://www.fda.gov/cder/regulatory/physLabel/default.htm for guidance.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved **NDA 19-734/S-013**."

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to the enclosed inner carton, vial label, inner carton wafer seal and outer carton label as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005).* Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 19-734/S-013**." Approval of this submission by FDA is not required before the labeling is used.

Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

PROMOTIONAL MATERIALS

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

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:

Alisea Crowley, Pharm.D.
Regulatory Project Manager
(301) 796-1144

Sincerely,

{See appended electronic signature page}

Norman Stockbridge, M.D., Ph.D.
Director
Division of Cardiovascular and Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

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

/s/

Norman Stockbridge

7/31/2008 03:18:36 PM