



NDA 19-734/S-014

EKR Therapeutics, Inc.
Attention: Alexander Mironov
Director, Regulatory Affairs
1545 US Highway 206, 3rd Floor
Bedminster, NJ 07921

Dear Mr. Mironov:

Please refer to your supplemental new drug application dated May 14, 2008, received May 15, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cardene (nicardipine hydrochloride) 0.2 mg/mL Premixed Injection in 5% Dextrose, and Cardene (nicardipine hydrochloride) 0.2 mg/mL Premixed Injection in 0.83% Sodium Chloride.

We acknowledge receipt of your submissions dated August 12, 2008 and November 3, 2008.

This supplemental new drug application provides for the addition of a new container closure system for the Cardene I.V. drug product and an increase in the concentration of the nicardipine hydrochloride to 0.2 mg/mL.

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 draft labeling submitted on May 14, 2008 and the immediate carton and container labeling submitted on November 3, 2008.

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(1)] in structured product labeling (SPL) format described at <http://www.fda.gov/oc/datacouncil/sp.html> that is identical to the enclosed labeling text (text for the package insert) submitted May 14, 2008. 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 19734/S-014.**"

Please submit final printed carton and container labels that are identical to the November 3, 2008 carton and immediate container labels 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 Application 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-014.**" Approval of this submission by FDA is not required before the labeling is used.

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

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:

Lori Wachter RN, BSN
Regulatory Project Manager
(301) 796 3975.

Sincerely,

{See appended electronic signature page}

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

Enclosure:

Package insert and carton and container labeling

**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
11/7/2008 02:47:19 PM