DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-734/S-009

PDL BioPharma
Attention: Robert J. Stagg, Pharm.D.
34801 Campus Drive
Fremont, CA 94555

Dear Dr. Stagg:

Please refer to your supplemental new drug application dated December 21, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cardene® I.V. (nicardipine hydrochloride) 2.5 mg/mL.

This supplemental new drug application provides for information on the use of Cardene® I.V. in patients aged 65 and older and for electronic draft labeling with the following revisions:

Under the **Precautions** section, the subsection after **PEDIATRIC USE** has been changed from:

> **USE IN THE ELDERLY**
> No significant difference has been observed in the antihypertensive effect of Cardene I.V. in elderly patients (≥ 65 years) compared with other adult patients in clinical studies.
>
> To the following:
>
> **GERIATRIC USE**
> The steady-state pharmacokinetics of nicardipine are similar in elderly hypertensive patients (>65 years) and young healthy adults.
>
> Clinical studies of nicardipine did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal or cardiac function, and of concomitant disease or other drug therapy.

We have completed our review of this application and it is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the minor editorial revision listed below:

> Add the following footnote to the **Clinical Pharmacology /ELECTROPHYSIOLOGIC EFFECTS** subsection:
>
> > PA = conduction time from high to low right atrium; AH = conduction time from low right atrium to His bundle deflection, or AV nodal conduction time; HV = conduction time through the His bundle and the bundle branch-Purkinje system.

We also note the following minor editorial revisions:

- Throughout the entire label, the trade name has been changed from “Cardene” to “Cardene®”.

- Under the **How Supplied** section, the room temperature description has been changed From:

  Store at controlled room temperature 20° to 25°C (68° to 77°F). Refer to USP Controlled Room Temperature.

  To:

  Store at controlled room temperature 20° to 25°C (68° to 77°F), refer to USP Controlled Room Temperature.

- The correct spelling of "Hoffmann" in the trademark description.
- The city and zip code for PDL Biopharma, Inc. has been updated to "Redwood City, CA 94063".
- The labeling revision date has been updated to "December 2006".

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, except for the revision indicated, to the submitted labeling (package insert submitted December 21, 2006). These revisions are terms of supplemental NDA approval. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, designate this submission "**SPL for approved supplement NDA 19-734/S-009**."

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 Ms. Denise M. Hinton, Regulatory Project Manager, at (301) 796-1090.

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

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

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