DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-198/S-017

Bayer Pharmaceuticals Corporation
Attention: Michael D. Rozycki, Ph.D.
400 Morgan Lane
West Haven, CT 06516-4175

Dear Dr. Rozycki:

Please refer to your supplemental new drug application dated January 22, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ADALAT CC (nifedipine) 30, 60 and 90 mg Extended Release Tablets.

We acknowledge receipt of your submission dated November 16, 2004, which constituted a complete response to our July 22, 2004 action letter.

This supplemental new drug application provides for electronic final printed labeling with revisions to the **PRECAUTIONS/Drug Interactions** section of the labeling as requested by the Division in the July 22, 2004 approvable letter.

We have completed our review of this supplemental new drug application, and it is approved, effective on the date of this letter, for use as recommended in the electronic final printed labeling (FPL) submitted on November 16, 2004.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please call Ms. Denise M. Hinton, Regulatory Project Manager, at (301) 594-5333.

Sincerely,

{See appended electronic signature page}
Norman Stockbridge, M.D., Ph.D.
Acting Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure (FPL)

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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