DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20198/S-022 **SUPPLEMENT APPROVAL**

Bayer HealthCare
Attention: Darshan Patel, Pharm.D.
Global Regulatory Affairs
P.O. Box 1000
Montville, NJ 07045-1000

Dear Dr. Patel:

Please refer to your supplemental new drug application dated May 21, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Adalat (nifedipine) Extended Release Tablets.

We acknowledge receipt of your submission dated May 29, 2009 and January 26, 2010.

Your submission of May 29, 2009 constituted a complete response to our November 20, 2008 action letter.

This "Changes Being Effected" supplemental new drug application provides for revisions to the **CLINICAL PHARMACOLOGY**, **CONTRAINDICATIONS**, and **PRECAUTIONS** sections of the package insert.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed upon labeling text, which is identical to the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format submitted on May 29, 2009.

We also remind you of your agreement to submit a cumulative review and analysis of the use of Adalat in pregnancy.

CONTENT OF LABELING

Please resubmit the enclosed content of labeling in SPL format as soon as possible, but no later than 14 days from the date of this letter. For administrative purposes, please designate this submission, "**SPL for approved NDA 20198/S-022**."

Within 14 days from the date of this letter, please amend all pending supplemental applications for this NDA, including pending "Changes Being Effected" (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 structured product labeling (SPL) format that includes the changes approved in this supplemental application.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert(s) 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

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

LETTERS TO HEALTH CARE PROFESSIONALS

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

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

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:

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

Sincerely,

{See appended electronic signature page}

Mary Ross Southworth, Pharm.D.
Deputy Director for Safety
Division of Cardiovascular and Renal Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure: agreed-upon labeling text

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-20198	SUPPL-22	BAYER HEALTHCARE PHARMACEUTICALS INC	ADALAT CC(NIFEDIPINE)COAT-CORE ORAL TABS

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
03/03/2010