DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-303/S-029

Novartis Pharmaceuticals Corporation
Attention: Kristine Tadych, Pharm.D.
One Health Plaza
East Hanover, NJ 07936-1080

Dear Dr. Tadych:

Please refer to your supplemental new drug application dated August 29, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lopressor HCT (metoprolol tartrate and hydrochlorothiazide) 50/25, 100/25, and 100/50 mg Tablets.

We acknowledge receipt of your submissions dated March 8 and June 29, 2006.

Your submission of June 29, 2006 constituted a complete response to our February 28, 2006 action letter.

This supplemental new drug application provides for revisions to the Clinical Pharmacology, Contraindications, Warnings, Precautions, and Adverse Reactions sections of the package insert.

We have completed our review of this supplemental new drug application, as amended. It is approved, effective on the date of this letter, for use as recommended in the electronic final printed labeling (FPL) submitted on June 29, 2006.

At the time of the next printing, please correct the following editorial error in the last sentence of the third paragraph of the CLINICAL PHARMACOLOGY/Lopressor/Pharmacokinetics section. The sentence now reads:

> Approximately 7% of Caucasians and less than 1% Asian are poor metabolizers.

It should be corrected to read:

> Approximately 7% of Caucasians and less than 1% of Asians are poor metabolizers.

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
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20857

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. Melissa Robb, Regulatory Health Project Manager, at (301) 796-1138.

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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