DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDAs 18-704/S-018 and 17-963/S-059

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 applications dated August 29, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lopressor (metoprolol tartrate) 1 mg/mL Injection (NDA 18-704) and 50 and 100 mg Tablets (NDA 17-963).

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

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

These supplemental new drug applications provide for revisions to the Clinical Pharmacology, Contraindications, Warnings, Precautions, and Adverse Reactions sections of the package insert.

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

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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