DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-962/S-033

AstraZeneca LP
Attention: Paula Clark
Director, Regulatory Affairs
1800 Concord Pike
P.O. Box 8355
Wilmington, DE 19803-8355

Dear Ms. Clark:

Please refer to your supplemental new drug application dated May 15, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Toprol XL (metoprolol succinate) Extended Release 25, 50, 100, and 200 mg Tablets.

We acknowledge receipt of your submissions dated January 18 and March 28, 2007.

Your submission of January 18, 2007 constituted a complete response to our November 14, 2006 action letter.

This supplemental new drug application provides for revisions to the following sections of the labeling:

- **CLINICAL PHARMACOLOGY**, Pharmacokinetics, Pediatrics
- **PRECAUTIONS**, Pediatric Use
- **DOSAGE AND ADMINISTRATION**, Hypertension, Pediatric Hypertensive Patients ≥6 Years of Age

We have completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We note that you have fulfilled the pediatric study requirement for this application.

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 20852

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

Within 21 days of the date of this letter, submit 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 in content to the enclosed labeling text. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination.

Marketing the product with SPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

If you have any questions, please call Dan Brum, Pharm.D., MBA, Regulatory Health Project Manager, at (301) 796-0578.

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

CC: Enclosed agreed-upon labeling text

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

7/18/2007 03:10:07 PM