DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-962/S-028

AstraZeneca LP
Attention: Ms. Cindy M. Lancaster
1800 Concord Pike
P.O. Box 8355
Wilmington, DE 19803-8355

Dear Ms. Lancaster:

Please refer to your supplemental new drug application dated January 17, 2005 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Toprol XL (metoprolol succinate) 25, 50, 100, and 200 mg Extended Release Tablets.

We acknowledge receipt of your submission dated March 22, 2005.

This "Changes Being Effected" supplemental new drug application provides for Final Printed Labeling (FPL) revised as follows:

In the ADVERSE REACTIONS/Post-Marketing Experience section, "urticaria" has been added to the list under the heading "Skin".

The following additional changes were noted in the proposed labeling:

1. The title of the package insert was changed from:

   TOPROL-XL
   (metoprolol succinate)
   EXTENDED-RELEASE TABLETS
   TABLETS: 25 MG, 50 MG, 100 MG, AND 200 MG

   To:

   TOPROL-XL®
   (metoprolol succinate)
   extended-release tablets

2. At the end of the HOW SUPPLIED section, the following statement has been changed from:

   All trademarks are the property of the AstraZeneca group

   To:

Toprol –XL is a trademark of the AstraZeneca group of companies.

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 final printed labeling (FPL) submitted on March 22, 2005.

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, HFD-410
FDA
5600 Fishers Lane
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
(301) 594-5313

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

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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