DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-058/S-017

AstraZeneca Pharmaceuticals LP
Attention: Ms. Judy W. Firor
1800 Concord Pike
P.O. Box 8355
Wilmington, DE 19803-8355

Dear Ms. Firor:

Please refer to your supplemental new drug application dated December 9, 2004 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Tenormin (atenolol) 5 mg/10 mL Injection.

This supplemental new drug application provides for electronic final printed labeling (FPL) revised as follows:

1. The first sentence of the third paragraph of the **WARNINGS/Pregnancy and Fetal Injury** section has been changed from:

   Neonates born to mothers who are receiving TENORMIN at parturition or breast-feeding may be at risk for hypoglycemia.

   To:

   Neonates born to mothers who are receiving TENORMIN at parturition or breast-feeding may be at risk for hypoglycemia and bradycardia.

2. The first sentence of the second paragraph of the **PRECAUTIONS/Nursing Mothers** section has been changed from:

   Neonates born to mothers who are receiving TENORMIN at parturition or breast-feeding may be at risk for hypoglycemia.

   To:

   Neonates born to mothers who are receiving TENORMIN at parturition or breast-feeding may be at risk for hypoglycemia and bradycardia.

3. The following statement at the end of the label has been changed from:

To:

We have completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the electronic final printed labeling (FPL) submitted on December 9, 2004.

At the time of the next printing, please move the following paragraph from the end of the **WARNINGS/Pregnancy and Fetal Injury** section to follow the first paragraph of the section as noted in the November 6, 2003 approval letter for supplement number 16 to this NDA:

> Neonates born to mothers who are receiving TENORMIN at parturition or breast-feeding may be at risk for hypoglycemia and bradycardia. Caution should be exercised when TENORMIN is administered during pregnancy or to a woman who is breast-feeding (See **PRECAUTIONS, Nursing Mothers**.)

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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