DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDAs 18-240/S-028 & 19-058/S-016

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 applications dated May 21, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Tenormin (atenolol) 25, 50 and 100 mg Tablets (NDA 18-240) and Tenormin (atenolol) 5 mg/10 mL Injection (NDA 19-058).

These supplemental new drug applications provide for electronic final printed labeling (FPL) revised as follows:

1. The following paragraph has been added at the end of the **WARNINGS/Pregnancy and Fetal Injury** section:

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

2. The following paragraph has been added at the end of the **PRECAUTIONS/Nursing Mothers** section:

   Neonates born to mothers who are receiving TENORMIN at parturition or breast-feeding may be at risk for hypoglycemia. Caution should be exercised when TENORMIN is administered during pregnancy or to a woman who is breast-feeding (See WARNINGS, Pregnancy and Fetal Injury.)

3. In NDA 18-240/S-028, the 1000 count presentation for the 50 mg tablet in the **HOW SUPPLIED** section was deleted.

We have completed our review of these supplemental new drug applications. They are approved, effective on the date of this letter, for use as recommended in the electronic final printed labeling (FPL) submitted on May 21, 2003.

At the time of the next printing, move the following paragraph from the end of the **WARNINGS/Pregnancy and Fetal Injury** section to follow the first paragraph of the section:

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

We remind you that you must submit patent information on form FDA 3542, *Patent Information Submitted Upon and After Approval of an NDA or Supplement*, within 30 days of the date of this letter as required by 21 CFR 314.53(c)(2)(ii) and 314.53(d)(2) at the address provided by 21 CFR 314.53(d)(4). The form may be obtained at http://www.fda.gov/opacom/morechoices/fdaforms/cder.html. To expedite review of this patent declaration form, we request you submit an additional copy of the form to these applications and to the Center for Drug Evaluation and Research "Orange Book" staff at:

Food and Drug Administration
Office of Generic Drugs, HFD-610
Orange Book Staff
7500 Standish Place
Metro Park North II
Rockville, MD 20855-2773

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}

Douglas C. Throckmorton, M.D.
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/

Doug Throckmorton

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