DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-760/S-025

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 June 4, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Tenoretic (atenolol and chlorthalidone) 50/25 and 100/25 mg Tablets.

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

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

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

3. The last sentence of the last paragraph of the **CLINICAL PHARMACOLOGY/Pharmacokinetics and Metabolism** section has been changed from:

   When renal function is impaired, elimination of atenolol is closely related to the glomerular filtration rate; but significant accumulation does not occur until the creatinine clearance falls below 35 mL/min/1.73m^2 (see circular for atenolol [TENORMIN®]).

   To:

   When renal function is impaired, elimination of atenolol is closely related to the glomerular filtration rate; but significant accumulation does not occur until the creatinine clearance falls below 35 mL/min/1.73m^2 (see prescribing information for atenolol [TENORMIN®]).

4. The last sentence of the fifth paragraph of the **PRECAUTIONS/Drug Interactions** section has been changed from:

Read circulars for lithium preparations before use of such preparations with TENORETIC.

To:

Read prescribing information for lithium preparations before use of such preparations with TENORETIC.

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 June 4, 2003.

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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