DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-838/S-017

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 December 10, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Atacand (candesartan cilexetil) 4, 8, 16, and 32 mg Tablets.

We acknowledge receipt of your submission dated December 19, 2002 that constituted a complete response to our November 15, 2002 approvable letter.

This supplemental new drug application provides for electronic final printed labeling revised to read as follows:

1. Under **WARNINGS**, **Fetal/Neonatal Morbidity and Mortality**, the statement "Post-marketing experience has identified reports of fetal and neonatal toxicity in babies born to women treated with ATACAND during pregnancy" has been added to the first paragraph of this subsection. Due to the insertion of this statement, the first sentence of the sixth paragraph of this subsection that reads "There is no clinical experience with the use of ATACAND in pregnant women" has been deleted.

2. Under **PRECAUTIONS**, **General, Drug Interactions**, new information regarding the administration of lithium and candesartan has been added that reads as follows:

   Lithium- Reversible increases in serum lithium concentrations and toxicity have been reported during concomitant administration of lithium with ACE inhibitors, and with some angiotensin II receptor antagonists. An increase in serum lithium concentration has been reported during concomitant administration of lithium with ATACAND, so careful monitoring of serum lithium levels is recommended during concomitant use.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (package insert included in your submission of December 19, 2002). Accordingly, the supplemental application is approved effective on the date of this letter.

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 contact:

Mr. Edward Fromm
Regulatory Health Project Manager
(301) 594-5332

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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