**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-838/S-023

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

Dear Ms. Lancaster:

Please refer to your supplemental new drug application dated 7 July 2004, received 8 July 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Atacand® (candesartan cilexetil) 4, 8, 16 and 32 mg Tablets.

This "Changes Being Effected" supplemental new drug application provides for electronic final printed labeling revised as follows:

1. Under **ADVERSE REACTIONS, Post-Marketing Experience**: the following language was added:

   Rare reports of rhabdomyolysis have been reported in patients receiving angiotensin II receptor blockers.

We completed our review of this supplemental new drug application, and it is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on 7 July 2004.

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:

Cheryl Ann Borden, MSN, R.N., CCRN, CCNS
Regulatory Health Project Manager
(301) 594 5312.

Sincerely,

*{See appended electronic signature page}*

Norman Stockbridge
Acting Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**

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/s/

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Norman Stockbridge

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