



NDA 21-093/S-006

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 January 17, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Atacand HCT (candesartan cilexetil and hydrochlorothiazide) Tablets, 16-12.5 and 32-12.5 mg.

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

Under “**PRECAUTIONS, General,**” the following was added as the second paragraph to this subsection:

Candesartan

Major Surgery/Anesthesia— Hypotension may occur during major surgery and anesthesia in patients treated with angiotensin II receptor antagonists, including candesartan, due to blockade of the renin-angiotensin system. Very rarely, hypotension may be severe such that it may warrant the use of intravenous fluids and/or vasopressors.

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 labeling submitted on January 17, 2006.

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
Food and Drug Administration
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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:

Quynh Nguyen, Pharm.D.
Regulatory Project Manager
(301) 796-0510

Sincerely,

{See appended electronic signature page}

Norman Stockbridge, M.D., Ph.D.
Director
Division of Cardiovascular and Renal 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
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/s/

Norman Stockbridge
8/17/2006 07:51:47 AM