DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-093/S-008

AstraZeneca LP
Attention: Paula Clark, Regulatory Affairs Director
1800 Concord Pike
P.O. Box 8355
Wilmington, DE 19803-8355

Dear Ms. Clark:

Please refer to your supplemental new drug application dated January 17, 2008, received January 17, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ATACAND HCT® (candesartan cilexetil and hydrochlorothiazide) Tablets, 16/12.5 mg and 32/12.5 mg.

This "Prior Approval" supplemental new drug application provides for a new tablet strength, 32/25 mg.

We 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 content of labeling [21 CFR 314.50(1) in structured product labeling (SPL) format submitted on January 17, 2008, with the editorial revision listed below.

Please correct a typographical error in the HOW SUPPLIED section under No. 3899. Your label states "No. 3899 – Tablets ATACAND HCT 32-25, are pink, oval, biconvex, non-film-coated tablets scored on both sides and coded with ACD on on side." Please change "on" to "one" in the labeling.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to, except for including the revisions listed above, the enclosed labeling text for the package insert. These revisions are terms of the NDA approval. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission "SPL for approved supplemental NDA 21-093/S-008."

We remind you that you must comply with the reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Teshara G. Bouie, Regulatory Health Project Manager, at (301) 796-1649.

Sincerely,

{See appended electronic signature page}

Eric P. Duffy, Ph.D.
Director
Division of Post-Marketing Evaluation
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

Enclosure – content of labeling submitted on January 17, 2008

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

/s/

Eric Duffy

5/16/2008 03:11:32 PM