DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20-838/S-032

SUPPLEMENT APPROVAL

AstraZeneca LP
Attention: Mr. Ian Wogan
1800 Concord Pike
P.O. Box 8355
Wilmington, DE 19803-8355

Dear Mr. Wogan:

Please refer to your Supplemental New Drug Application (sNDA) dated January 12, 2010, received January 12, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Atacand (candesartan cilexitil) Tablets, 4, 8, 16, and 32 mg.

We acknowledge receipt of your amendments dated August 4, 2011 and January 31, 2012.

The January 31, 2012 submission constituted a complete response to our June 20, 2011 action letter.

This "Prior Approval" supplemental new drug application provides for patient information, i.e, a new Patient Package Insert (PPI). In addition, minor editorial changes have been made.

The following changes have been made (additions are shown as underlined text and deletions are shown as ~~strike-through text~~):

In **HIGHLIGHTS OF PRESCRIBING INFORMATION**

1. The Patient Counseling Information Statement has been changed as follows:

   SEE 17 FOR PATIENT COUNSELING INFORMATION AND FDA-APPROVED PATIENT LABELING

2. White space has been added before the major headings, "**DRUG INTERACTIONS**" and the Patient Counseling Information Statement.

In **FULL PRESCRIBING INFORMATION: CONTENTS***

3. Under **17. PATIENT COUNSELING INFORMATION**, the following was added:

   17.1 Pregnancy

In **FULL PRESCRIBING INFORMATION**

4. Under **2.2 Pediatric Hypertension 1 to < 17 Years of age**, the 9th paragraph was changed as follows:

For children who cannot swallow tablets, an oral suspension may be substituted ~~*[see Preparation of Oral Suspension]*~~as described below:

5. Under **5.2 Morbidity in Infants**, the 2nd sentence was changed as follows:

   ~~The consequences of administering d~~Drugs that act directly on the renin-angiotensin system (RAS) can have effects on the development of immature kidneys.

6. Under **14 CLINICAL STUDIES** in **14.1 Hypertension**, under the Pediatric subsection, the 3rd paragraph was changed as follows:

   The placebo subtracted effect at trough for sitting systolic blood pressure/sitting diastolic blood pressure for the different doses were from 4.9/3.0 to 7.5/~~7~~6.2 mmHg.

7. Under **17 PATIENT COUNSELING INFORMATION**, the following changes were made:

   17 PATIENT COUNSELING INFORMATION
   See FDA-approved patient labeling (Patient Information).

   17.1 Pregnancy
   ~~*Pregnancy*~~Female patients of childbearing age should be told about the consequences of second- and third-trimester exposure to drugs that act on the renin-angiotensin system, and they should also be told that these consequences do not appear to have resulted from intrauterine drug exposure that has been limited to the first trimester. These patients should be asked to report pregnancies to their physicians as soon as possible.

   Post-menarche adolescents should be questioned on a regular basis as to changes in menstrual pattern and the possibility of pregnancy.

8. A new Patient Information section has been added following section 17 (see attached labeling for the Patient Information text.).

9. The revision dates have been updated.

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert, text for the patient package insert, with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at

http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REPORTING REQUIREMENTS

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

If you have any questions, please contact:

Quynh Nguyen, Pharm.D., RAC
Regulatory Health 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

ENCLOSURE:
Content of Labeling

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

/s/

NORMAN L STOCKBRIDGE
04/13/2012