DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-838/S-015

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 September 27, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Atacand (candesartan cilexetil) Tablets, 4, 8, 16, and 32 mg.

We acknowledge receipt of your submissions dated August 1, 7, and 22, and September 3, 2002. Your submission of September 3, 2002 constituted a complete response to our July 26, 2002 approvable letter.

This supplemental new drug application provides data on the comparison of the antihypertensive effects of Atacand (candesartan cilexetil) Tablets and Cozaar (losartan potassium) Tablets. It also proposes revisions to the **CLINICAL PHARMACOLOGY, (Clinical Trials & Special Populations)**, **PRECAUTIONS**, **OVERDOSAGE**, and **DOSAGE AND ADMINISTRATION** sections of the labeling.

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 electronic final printed labeling (package insert included in your submission of September 3, 2002). Accordingly, the supplemental application is approved effective on the date of this letter.

Please make the following change to the labeling at your next printing:

Under **DESCRIPTION**, 2nd paragraph, please change the chemical name of candesartan cilexetil to:

(±)-1-Hydroxyethyl 2-ethoxy-1-[*p*-(*o*-1*H*-tetrazol-5-ylphenyl)benzyl]-7-benzimidazolecarboxylate, cyclohexyl carbonate (ester).

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please send one copy to the Division of Cardio-Renal Drug Products and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Please submit one market package of the drug product when it is available.

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}

Robert Temple, M.D.
Director
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosed Labeling Text

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

/s/

Robert Temple

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