



NDA 20-838/S-019

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 applications dated March 3, 2003, 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 final printed labeling revised as follows:

1. Under **DESCRIPTION**, 2nd paragraph, the chemical name of candesartan cilexetil has been changed to:

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

2. Under **ADVERSE REACTIONS, Post-Marketing Experience**, two new subheadings have been added with the following listing of adverse reactions:

Metabolic and Nutritional Disorders: hyperkalemia, hyponatremia.

Renal: renal impairment, renal failure.

We have completed the review of this supplemental application 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 final printed labeling (package insert included in your submission of March 3, 2003). Accordingly, the supplemental application is approved effective on the date of this letter.

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}

Douglas C. Throckmorton, M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

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/s/

Doug Throckmorton
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