



NDA 20-838/S-022

AstraZeneca L.P.
Attention: Ms. Cindy M. Lancaster
Director, Regulatory Affairs
1800 Concord Pike
P.O. Box 8355
Wilmington, DE 19803-8355

Dear Ms. Lancaster:

Please refer to your supplemental new drug application dated 30 June 2004, received 30 June 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Atacand (candesartan cilexetil) 4, 8, 16, and 32 mg Tablets.

We acknowledge receipt of your submissions dated 21 December 2004, 24 January, 8 February, and 17 March 2005.

This supplemental new drug application provides for the use of Atacand (candesartan cilexetil) 4, 8, 16, and 32 mg Tablets for the treatment of heart failure (NYHA class II-IV) in patients with left ventricular systolic dysfunction (ejection fraction $\leq 40\%$) to reduce cardiovascular death and to reduce heart failure hospitalizations. Atacand also has an added effect on these outcomes when used with an ACE inhibitor.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text. We also note changes to the **CLINICAL PHARMACOLOGY, INDICATIONS AND USAGE, and PRECAUTIONS** sections of the labeling.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 20-838/S-022.**" Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We reference our letter dated 26 August 2004 waiving the requirement for pediatric studies for all age groups for this application.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. 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, MD 20857

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 call:

Cheryl Ann Borden, MSN, RN, CCRN, CCNS
Regulatory Health Project Manager
(301) 594 5312.

Sincerely,

{See appended electronic signature page}

Norman Stockbridge, M.D., Ph.D.
Acting Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure: Labeling

**This is a representation of an electronic record that was signed electronically and
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/s/

Norman Stockbridge
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