DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-668/S-013

AstraZeneca LP
Attention: Ms. Judy W. Firor
1800 Concord Pike
P.O. Box 8355
Wilmington, DE 19803-8355

Dear Ms. Firor:

Please refer to your supplemental new drug application dated April 10, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for LEXXEL (enalapril maleate-felodipine ER) 5-2.5 and 5-5 mg Tablets.

This supplemental new drug application provides for revisions to the **WARNINGS** and **PRECAUTIONS** sections of the labeling based on a recently published article regarding the use of ACE inhibitors during the first trimester of pregnancy.

We have completed our review of this application and 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 April 10, 2007.

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 Denise Hinton, Regulatory Project Manager, at (301) 796-1090.

Sincerely,

{See appended electronic signature page}

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

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

/s/

Norman Stockbridge

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