



NDA 20-668\S-005

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 August 27, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for LEXXEL (enalapril maleate-felodipine ER) 5-5 mg Tablets.

We also acknowledge receipt of your submissions dated July 23, 2001, December 14, 2004 and May 11, 2005. Your submission dated May 11, 2005 constituted a complete response to our March 10, 1999 action letter.

This supplemental new drug application provides for final electronic printed labeling (FPL) with revisions to the **PRECAUTIONS/Geriatric Use** section of the labeling as requested by the Division.

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 enclosed final printed labeling (FPL) submitted on May 11, 2005.

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 Ms. Denise Hinton, Regulatory Health Project Manager, at (301) 594-5333.

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

**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
8/2/05 09:24:04 AM