DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-834/S-022

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 December 11, 2003, submitted electronically under section 505(b) of the Federal Food, Drug, and Cosmetic Act for PLENDIL (felodipine) 2.5, 5, and 10 mg Extended-Release Tablets.

This "Changes Being Effected" supplemental new drug application provides for revisions to the **PRECAUTIONS** section of the labeling. Information has been added to include information regarding a tacrolimus drug interaction. It also includes updates to the **HOW SUPPLIED** section of the labeling, NDC, and revision date.

The proposed changes to the labeling are as follows:

1. Under **PRECAUTIONS/Drug Interactions**, the following was added after the *Anticonvulsants* paragraph:

   Tacrolimus- Felodipine may increase the blood concentration of tacrolimus. When given concomitantly with felodipine, the tacrolimus blood concentration should be followed and the tacrolimus dose may need to be adjusted.

2. Under **HOW SUPPLIED**, the 30 count bottle was deleted for the 2.5, 5, and 10 mg tablets.

3. Updates to the package insert are as follows:

   a. The trademark date, 2003, was added after ©AstraZeneca 2000.
   b. The Package Insert revision date was changed from 01/03 to 11/03.
   c. The NDC number was changed from 9179715 to 9179716 and 630002-15 was changed to 630002-16.

We have completed our review of this supplemental application and it is approved, effective on the date of this letter, for use as recommended in the submitted electronic final printed labeling (package insert included in your submission dated December 11, 2003).

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 M. Hinton
Regulatory Health Project Manager
(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

Enclosure

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

6/7/04 03:14:17 PM